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Cross-Border IP Enforcement Challenges in Biomedicine E-Commerce

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Abstract

Introduction. Biomedicine has embraced the e-commerce world, where digital markets play a substantial role in distributing life-saving pharmaceuticals, medical devices, and healthcare products. The convergence of biomedicine and e-commerce poses challenges in protecting intellectual property rights across borders due to the global nature of online transactions. E-commerce platforms have enabled global reach for biomedicine companies by breaking geographical boundaries, operating 24/7, facilitating online advertising, easing product distribution, offering personalization, and utilizing data analysis to understand market dynamics. Intellectual property plays a crucial role in safeguarding innovations in biomedicine, encouraging investment, maintaining a competitive edge, allowing licensing agreements, protecting trademarks, and garnering local support. Therefore, the author's objective was to analyze the cross-border protection of intellectual property in e-commerce of biomedical goods with a focus on the differences in the regulatory framework, the problems of counterfeiting and piracy, as well as the identification of jurisdictions requiring cooperation in their solution by stakeholders.

Methods. The methods used in this article involve a comprehensive review of existing international IP enforcement frameworks, with a focus on their application in the biomedicine e-commerce sector. The study applies a multidisciplinary approach, analyzing legal, technological, and regulatory challenges through secondary sources, including international treaties, national laws, and scholarly research. Comparative analysis is conducted to identify gaps in enforcement mechanisms across jurisdictions. Furthermore, case studies and contemporary examples of cross-border IP violations in biomedicine e-commerce are examined to illustrate practical challenges and potential solutions. Policy recommendations are developed by synthesizing insights from legal, technological, and institutional perspectives to propose enhanced enforcement strategies within a globalized context.

Results. Legal and regulatory variations, divergent enforcement procedures, jurisdictional issues, and cultural barriers complicate the enforcement of intellectual property rights in cross-border biomedicine e-commerce. Counterfeit products and piracy endanger consumers, harm reputable manufacturers, and erode stakeholder trust. Addressing these challenges demands coordinated efforts from governments, businesses, and society.

Discussion and Conclusion. Cross-border IP enforcement challenges in biomedicine e-commerce necessitate a comprehensive approach to protect intellectual property rights, combat counterfeiting, and address jurisdictional complexities effectively. Collaborative efforts involving technology, data analytics, legal frameworks, and stakeholder engagement are crucial in mitigating the risks associated with intellectual property infringement in the global digital marketplace. Emphasizing robust enforcement mechanisms and promoting legal harmonization are essential steps towards safeguarding innovation and ensuring a fair and secure environment for biomedicine e-commerce.

Keywords: biomedicine, e-commerce, cross-border IP protection, global market, legal issues

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Научная статья

Проблемы трансграничной защиты прав на объекты интеллектуальной собственности в электронной торговле биомедицинскими товарами

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Аннотация

Введение. Биомедицина стала частью электронной коммерции, где цифровые рынки играют существенную роль в распространении жизненно важных фармацевтических препаратов, медицинских приборов и товаров здравоохранения. Слияние биомедицины и электронной коммерции создает проблемы в защите прав интеллектуальной собственности за пределами границ государств в связи с глобальным характером онлайн-операций. Платформы электронной коммерции позволили биомедицинским компаниям выйти на мировой рынок, преодолев географические границы, работая круглосуточно, облегчая онлайн-рекламу, упрощая распространение продукции, предлагая персонализацию и используя анализ данных для понимания динамики рынка. Интеллектуальная собственность играет решающую роль в защите инноваций в биомедицине, стимулировании инвестиций, сохранении конкурентных преимуществ, разрешении лицензионных соглашений, защите товарных знаков и привлечении местной поддержки. Поэтому автор анализирует трансграничную защиту интеллектуальной собственности в электронной торговле биомедицинскими товарами с

акцентом на различия в нормативной правовой базе, проблемы контрафакции и пиратства, а также определения юрисдикции требующих сотрудничества в их решении заинтересованных сторон.

Методы. Методы, использованные в данной статье, включают всесторонний обзор существующих международных механизмов защиты ИС с акцентом на их применение в секторе электронной торговли биомедицинскими товарами. В исследовании применяется междисциплинарный подход, анализируются правовые, технологические и нормативные проблемы на основе вторичных источников, включая международные договоры, национальные законы и научные исследования. Проводится сравнительный анализ для выявления пробелов в механизмах правоприменения в разных юрисдикциях. Кроме того, для иллюстрации практических проблем и потенциальных решений рассматриваются современные примеры трансграничных нарушений ИС в электронной торговле биомедицинскими товарами. Политические рекомендации разрабатываются на основе синтеза знаний исходя из правовой, технологической и институциональной точек зрения с целью предложить усовершенствованные стратегии защиты прав в условиях глобализации.

Результаты исследования. Различия в нормативном правовом регулировании, несовпадающие процедуры правоприменения, проблемы юрисдикции и культурные барьеры осложняют обеспечение соблюдения прав интеллектуальной собственности в трансграничной электронной торговле биомедицинскими товарами. Контрафактная продукция и пиратство ставят под угрозу потребителей, наносят ущерб авторитетным производителям и подрывают доверие заинтересованных сторон.

Обсуждение и заключение. Задачи трансграничной защиты прав интеллектуальной собственности в электронной торговле биомедицинскими товарами требуют комплексного подхода для защиты прав интеллектуальной собственности, борьбы с контрафактом и эффективного решения юрисдикционных сложностей. Совместные усилия, включающие технологии, аналитику данных, правовую базу и взаимодействие с заинтересованными сторонами, имеют решающее значение для снижения рисков, связанных с нарушением прав интеллектуальной собственности на глобальном цифровом рынке. Упор на надежные механизмы правоприменения и содействие гармонизации законодательства являются важнейшими средствами защиты инноваций и обеспечения справедливой и безопасной среды для электронной торговли биомедициной.

Ключевые слова: биомедицина, электронная коммерция, трансграничная защита интеллектуальной собственности, глобальный рынок, правовые вопросы

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Introduction

Biomedicine has embraced the e-commerce world as the digital market is becoming substantial in the distribution and avail of life-saving pharmaceuticals, medical devices, and healthcare products. The convergence of biomedicine

cine and e-commerce is not only changing the landscape through which people access and purchase healthcare products. It has also elicited the issue of intellectual property protection in a cross-border scenario. Today, the digital era has made it economical for transactions and clients to be conducted and obtained from various locations without the restrictions of geographical boundaries.

Therefore, intellectual property rights (hereinafter – IPR) should be highly protected to save the fruits of innovative technologies, research discoveries, and proprietary information in the biomedicine industry. IPR not only creates a breeding ground for innovation and capital investment, but also provides a barrier that chokes the use, replication, or commercialization of biomedical products and inventions.

This article seeks to bring out the challenges and counter challenges that are associated with the enforcement of IPR in biomedicine e-commerce. We will be addressing the complex issues involved in cross-border IPR enforcement in the active and dynamic e-commerce field from varying angles as possible to offer insight into the issues facing the industry and suggesting a way out.

1. Understanding the Biomedicine E-Commerce Landscape

The biomedicine industry is a super critical sector encompassing the development, production and distribution of medical products and services for the betterment of human health and well-being [1]. It covers: pharmaceuticals, medical devices, biotechnology, diagnostics, and health care services. Because the industry as a whole has recently been subject to major digital transformation opportunities seeking to exploit technological progress, leveraging changes in consumer behavior, and merging of digital tools and platforms to drive rapid growth, particularly in the field of biomedicine in a much broader sense, biomedical e-commerce has given the industry a possibility to open up completely new sales channels, a global market place, and simply overarching opportunities. Biomedicine e-commerce has allowed companies to go beyond traditional selling points in drugstores or medical supply stores and sell directly to patients. Similar solutions apply to any sales channels such as health and dietary supplements stores offering a direct cause-driven approach to reach their target customers. Strengthened by digital e-commerce platforms, these business cases have been completely redefined as drug availability accuracy, promotion, and sales capabilities have all been shuffled out of proportion facilitating both their market value and sales availability. However, digital solutions have also enabled new types of medical care solutions such as telemedicine, digital medicine monitoring tools, personalized medicine approaches, and solutions driven by artificial intelligence. All this further enhances development opportunities and the ability to monetize processed data for companies. Biomedicine's e-commerce development and digitalization has opened completely new opportunities and a much broader and more expansively developing field. On the other hand, however, it also causes many 'evils' in the field of intellectual property law. Business players are forced to protect the law from the development of their numerous innovations, brands, and from vul-

nerability due to diverse regulations and extensive supply chains to the global market.

1.1. Importance of Intellectual Property in Protecting Innovations in Biomedicine

Intellectual property rights are essential in protecting developments in biomedicine. The following are reasons that illustrate the importance of intellectual property in protecting biomedicine innovations: encouraging investment; protection of intellectual property through patents, copyrights, and trademarks gives mineralization organizations and research stakeholders the reason to invest in research and developments; namely, owners have the exclusive rights to their inventions [2]. When investors have such rights, the findings of their research secure them returns, and they can recoup their investment costs. Essentially, for any company to invest in a venture, they must examine how they will benefit from the investment. The exclusive rights maintain the competitive edge, as the original innovators will benefit from their creation and control the market. The third reason is for a competitive edge. As companies protect their research findings and inventions, other organizations cannot directly copy the research or product. Licensing agreements; mineralization organizations can share their research findings with other organizations, research stakeholders, or other institutions while maintaining supremacy. The fourth reason is for a competitive edge. The fifth is protecting one's mark. The article illustrates the importance of having a unique mark because companies producing biomedicine products and services have distinguished products. Local's support is essential for the development of the findings. They sell the patent findings at local markets, hence reducing the prevalence of counterfeit goods. For any biomedicine company, these arguments are valid reasons to own an intellectual property right.

It would also be desirable to separately note and emphasize such objects of copyright, which play an important role in the field of biomedicine, as copyrights. The biomedical field protects various copyrighted items such as scientific research, articles, monographs, software, visualizations of research results, medical graphs, charts, designs of medical equipment and devices, and certain medical techniques, procedures, and algorithms. These objects may be protected by copyright if they represent the result of original creativity. Protection of these objects helps to stimulate innovation, research and development, ensures that authors are entitled to remuneration for their work and encourages further creativity in the field of biomedicine.

1.2. E-commerce in Biomedicine: International Experience

In different countries of the world, e-commerce in biomedicine is regulated by a variety of legal acts reflecting the peculiarities of the legal system of each jurisdiction. Let us consider the experience of several countries:

1. USA:

– The U.S. Health Insurance Portability and Accountability Act (HIPAA)¹ sets standards for protecting the privacy and security of medical data in the digital environment.

¹ The Health Insurance Portability and Accountability Act (HIPAA), 1996.

– The Federal Trade Commission (FTC) oversees compliance with e-commerce laws, including advertising and consumer protection regulations.

2. European Union:

– The General Data Protection Regulation (GDPR)² is the primary tool for regulating the processing of personal data in the European Union, including medical data.

– The Medical Device Directive (MDR)³ and the In Vitro Diagnostic Medical Device Directive (IVDR)⁴ set quality and safety standards for medical products and approve certification procedures.

3. Russia:

Russian legal doctrine addresses biomedicine issues through the prism of various legal and political aspects, including protection of patients' rights, ethical norms in medicine, responsibility of medical professionals and regulation of medical activities. The main areas of study of these issues include:

1. Protection of patients' rights: this aspect examines the legal mechanisms of ensuring patients' rights to receive quality medical care, informed consent and confidentiality of medical information [3; 4]. The issues of accessibility of medical care and protection of interests of participants of medical procedures are also considered.

2. Ethical aspects in medicine: within the framework of the study of this direction the questions of ethical norms and principles regulating the behavior of medical workers, as well as the relationship between doctor and patient are considered. Ethical aspects of biomedicine are important to ensure honesty, trust and professionalism in the medical field [5; 6].

3. Medical liability: legal doctrine analyzes the issues of medical professionals' liability for errors, mistakes and violations of patients' rights [7; 8]. The procedure of damages, disciplinary and criminal liability in case of violations of health care legislation is considered.

4. Regulation of medical technologies: in the modern world new technologies in medicine, such as telemedicine, the use of artificial intelligence, genetic engineering and others, are actively developing. Legal doctrine explores the issues of regulation and control over the use of these technologies, considering ethical norms and patients' rights [9; 10].

Thus, Russian legal doctrine considers the problems of biomedicine in various aspects, which contributes to the formation of a balanced and effective legal regulation in the field of health care and biomedicine.

In the Russian Federation, biomedical issues are regulated by a number of federal laws that cover various aspects of health care and medical activities.

² Regulation (EU) 2016/679, General Data Protection Regulation (GDPR).

³ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

⁴ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

The Federal Law “On the Fundamentals of Citizens’ Health Protection in the Russian Federation”⁵ establishes the foundations of state policy in the field of citizens’ health protection, contains provisions on the rights and obligations of citizens in the field of health protection and promotion (Article 33), the basic rights and obligations of medical workers (Article 34) and the rights and obligations of patients (Article 35). It also regulates medical assistance, compulsory and voluntary health insurance, sanitary and epidemiological well-being of the population and other aspects of health care.

In addition, in this context, the Federal Law “On Protection of Citizens’ Health from Exposure to Ambient Tobacco Smoke and Consequences of Tobacco Consumption”⁶ is important; it establishes measures to protect citizens from exposure to tobacco smoke, including restrictions on smoking in public places, places of work, medical institutions and other places. It also regulates the manufacture, labeling, advertising and sale of tobacco products (Article 10).

The Federal Law “On Circulation of Medicines”⁷ establishes the procedure for circulation of medicines on the territory of the Russian Federation. It regulates the issues of clinical trials of medicines (Article 4) and their registration (Article 5). Also, it establishes the procedure for the use of new medical technologies (Article 52), the procedure for control over the quality of medicines and liability for violation of legislation in this area.

The above-mentioned laws and articles play an important role in ensuring an adequate level of healthcare quality, protecting the health of citizens and developing biomedical technologies in Russia. They are based on the principles of responsibility, professionalism and care for the health of citizens, which is a key element in modern medical care and biomedical development.

2. Cross-Border IP Enforcement Challenges

The challenge of cross-border protection of biomedical information systems is critical in today’s world where patient data is stored and transferred across different countries and jurisdictions. Here are some specific challenges and practical examples of IP protection in biomedicine from different jurisdictions:

1. Protecting patients’ personal medical data is a major challenge. For example, the European Union has the General Data Protection Regulation (GDPR)⁸, which sets high privacy standards and requirements for the processing of personal data in healthcare.

⁵ Federal Law of 21 November 2011 No. 323-FZ “On the Fundamentals of Health Protection of Citizens in the Russian Federation”. Access from the legal reference system “ConsultantPlus”.

⁶ Federal Law of 23 February 2013 No. 15-FZ “On Protection of Citizens’ Health from Exposure to Ambient Tobacco Smoke and Consequences of Tobacco Consumption”. Access from the legal reference system “ConsultantPlus”.

⁷ Federal Law of 12 April 2010 No. 61-FZ “On Circulation of Medicines”. Access from the legal reference system “ConsultantPlus”.

⁸ Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR).

2. Cross-border transfers of healthcare data require security measures. For example, U.S. laws such as HIPAA (Health Insurance Portability and Accountability Act)⁹ establish requirements to protect sensitive medical information when data is transferred outside the country.

3. Another challenge is managing risk and compliance with different legal requirements in different jurisdictions. For example, healthcare organizations must comply with different standards and certifications depending on the country in which they operate.

4. It is equally important to provide technical security measures to protect IP from cyberattacks and data breaches. Examples include the use of data encryption, multi-factor authentication, and regular security updates.

5. Adherence to international standards, such as ISO/IEC 27001¹⁰, helps to ensure a high level of data protection in cross-border health information systems.

These challenges and examples of protecting biomedical information systems emphasize the importance of international cooperation and compliance with data security legislation to ensure an appropriate level of protection and privacy of patients medical information.

2.1. Legal and Regulatory Variations

One of the challenges when it comes to enforcing IP rights across borders is legal and regulatory variations among jurisdictions [11].

They can largely influence the effectiveness of IP enforcement in the biomedicine industry e-commerce. Among the concerns are:

Every country or a region has its own body of laws, regulation, and special judicial system that governs IP rights. Legal divergences are manifested in varied legal standards applicable for IP protection enforcement. For example, the definition of IP infringement, its scope, and available remedies.

Enforcement of IP rights also greatly differs from one jurisdiction to another. Across-border procedural differences include dissimilar court proceedings and requirements for evidence, availability of interim measures – injunctions. It is a challenge for biomedicine companies to protect their IP assets when they enter a foreign market.

It is often a challenge to decide on which court to appeal when filing an IP infringement claim. Among the difficult questions are where the infringement took place, where the infringement is located and which courts can have jurisdiction. It is a task to know that often requires a deep analysis of legal principles such as territoriality.

Even though international treaties and agreements aim at harmonizing IP law, it is still a challenge. The harmonization of treaties can be flawed because of its poor implementation and interpretations. Such harmonization variations create legal uncertainties that make it complicated for companies that operate in multi-jurisdictions.

⁹ The Health Insurance Portability and Accountability Act of 1996 (HIPAA).

¹⁰ ISO/IEC 27001:2022, Information security, cybersecurity and privacy protection – Information security management systems.

Cross-border IP enforcement is also influenced by cultural differences and language barriers. The most pronounced element in cross-border e-commerce that will impact IP enforcement is a language. Different nationalities speak different languages and the perception of one language by one could be really hard on another.

Also in connection with the discussion of the cross-border nature of intellectual property, and its peculiarity, which is its “territorial” character, we should elaborate on this aspect. “Territorial character” of intellectual property refers to the principle that intellectual property rights (copyright, patent rights, trademark rights and others) are protected within a certain territory exclusively in accordance with the law of that territory [12]. This principle implies that in order to ensure the protection of one’s intellectual property rights, it is necessary to comply with the laws of the particular country or region where the legislation establishes the rules governing the use, protection and enforcement of intellectual property rights.

One of the key aspects of the discussion of the territorial nature of intellectual property is related to the need to register intellectual property rights. Registration makes it possible to clearly define the legal status of authors, inventors and right holders, and to establish their exclusive rights to works, inventions or trademarks. This process also ensures that the rights of right holders can be effectively protected in the event of disputes or infringements [13].

Intellectual property registration provides owners with legal protection and exclusive rights for a specified period of time. Owners are able to control the use of their creative products and innovations, protect their interests from competitors and fraudsters, and benefit financially from the complex commercialization of their intellectual assets.

However, in case of insufficient or absent registration of intellectual property rights in certain states, serious problems arise in ensuring effective protection of these rights. Unregistered trademarks, works of authorship or patents are vulnerable to infringement, copying or unlawful use without the ability to hold infringers accountable.

2.2. Challenges in Intellectual Property Infringement Detection and Prevention

In the case of biomedicine, detecting and preventing IPR infringement in cross-border e-commerce is extraordinarily challenging. The problem is based on counterfeiters’ anonymity, quick adaptation, the distribution of many sources of counterfeits, and the extent of digital border sales [14]. Identifying fake items and the unapproved use of intellectual property requires technology for detection, data analytics, communication among all homeowners, and industry-related organizations, customs employees, and maybe law enforcement agencies. Additionally, sometimes actions must obey laws of several states, making it even tougher to tackle the piracy in biomedicine e-commerce. A robust response built on high-tech enforcement, detection, and stakeholder collaboration.

Counterfeiting and Piracy

Counterfeit products and piracy have devastating consequences for the biomedicine sector that, in turn, impacts e-commerce on multiple fronts [15].

Counterfeit pharmaceuticals, medical equipment, and health products endanger consumers' lives and health; in addition, they tarnish the name of reputable biomedicine manufacturers. Furthermore, piracy of original or confidential research, investments, and inventions harms the competitiveness of companies. The availability of fakes and illegally traded products on the web undermines customers' and stakeholders' loyalty and results in financial harm and legal actions against biomedicine businesses.

Jurisdictional Issues

Regarding jurisdictional problems in cross-border IP disputes in biomedicine e-commerce, the challenges are due to the interdependence of international trade and digital commerce. In this sense, the following can be said:

- 1) complexity determining jurisdiction in cross-border IP disputes, and
- 2) challenges enforcing IP rights across multiple jurisdictions in biomedicine e-commerce.

As for the first problem, it is necessary to consider the combination of several factors that make the jurisdictional issue complex due to the multiformity of these factors. When an infringement occurs online, the determination of jurisdiction is even worse because the internet has no borders, and e-commerce platforms are often multinational. Therefore, it results in the fact that it is difficult for the parties to ascertain the period and the court where they can file the claim. This problem leads to an infringement in searching for a court (forum shopping), which delays prosecution and causes uncertainty over the outcome [16]. If the second problem is considered, it is appropriate to mention that IP enforcement differs among nations. It is a material and procedural matter. Multilateral cooperation, clear legislation, and conflict resolution mechanisms can help solve such difficulties.

3. Solutions for Effective Cross-Border IP Enforcement

3.1. International Cooperation

International cooperation is essential for pushing back against cross-border IP infringement in the biomedicine e-commerce sector. Without the ability to share information, expertise, and resources, doing so effectively becomes almost impossible. This is because most intellectual property crimes will have already transcended one or more national borders [17]. In collaboration, countries will be able to better enforce their laws against IP infringement in other countries, expedite the legal process, and ensure that cross-border infringers can't take advantage of judicial red tape.

Several successful international instruments show that international collaboration is beneficial in enforcing IP across the border. The World Intellectual Property Organization provides a stage on which States Members cooperate on IP matters, develop shared guidelines and best practices [18]. The WIPO Arbitration and Mediation Center provide IP-specific alternative dispute resolution procedures to address international disputes more quickly. Among other commercial agreements that affect IP is the Trade-Related Aspects of Intellectual Property Rights agreement within the World Trade Organization. TRIPS provisions set the minimum standards for IP protection and enforcement and push the cooperating countries to adopt and adhere to similar laws [19].

As with other aspects of international cooperation, there are also bilateral and regional agreements promoting cross-border IP enforcement. One of the examples is the European Union Intellectual Property Office, which cooperates with each of its IP counterparts across the European Union. Agencies combine their efforts in fighting counterfeiting and piracy, form joint enforcement teams and coordinate data sharing.

Several successful international instruments demonstrate that collaboration and international friendship contribute to cross-border enforcement of IP. The World Intellectual Property Organization serves as a platform for cooperating States Members to develop shared IP protections and guidelines and even provides for shared best practices [20]. The WIPO Arbitration and Mediation Center provides alternative dispute resolution specifically adapted to IP issues and allows for quicker solving of international disputes. The phenomenon is also described by various commercial agreements that impact IP, which includes the Trade-Related Aspects of Intellectual Property Rights within the World Trade Organization.

3.2. Technology and Tools

Additionally, technology is a critical contributor to increased enforcement of intellectual property rights in the sector of biomedicine e-commerce [21]. Due to the massive increase in online commerce, technology has been crucial in the monitoring, detection, and fighting against various forms of IP infringements. Notably, the various aspects of technology that are considered here include data analysis and monitoring technologies used to check and track the online platforms and marketplaces where IP infringements arise. Similar technologies are also used to analyze and identify counterfeit products and the unauthorized distribution of trademarks. Secondly is the digital rights management which is solutions designed to fasten the reaction of the rights holders through tracing digital work ownership distribution. Blockchain technology, as discussed earlier, is an IT tool used to improved traceability and verification of products to reinforce IP ownership security [22]. Artificial technology also plays a role in the sense of AI and Machine Learning automation capabilities, which help the companies to detect the patterns and anomalies in IP infringements and respond promptly. In the platform aspect, online monitoring and enforcement also provide the status of IP infringement information in real time to allow timely respond.

As mentioned earlier, IP provides a significant aspect in biomedicine e-commerce, as it promotes innovation and guarantees patient safety [23]. For this reason, thus, it is essential that specialized technology tools and solutions are used.

4. Future Trends and Recommendations

4.1. Biomedicine E-Commerce Emerging Trends and Implications for IP Enforcement

The biomedicine e-commerce landscape is rapidly changing opportunities are driven by technology development, consumer tendencies, and market regulation modifications. In view of these changes, we need to outline and analyze current trends that underpin the dimensions in which biomedicine products

are purchased, sold, and distributed. This will help to outline the most likely challenges and opportunities concerning all aspects of enforcing intellectual property in our sector.

1. Digital health platforms

The online platforms and marketplaces specifically dedicated to solutions of digital health, telemedicine, and wearable healthcare devices are changing the world's way of providing and accessing health services. Due to their convenience factor for consumers, one of the main problems for IP enforcement consists of their universality, being open to customers and suppliers from all over the world.

2. Personalized medicine

Genomics sequencing and personalized therapy advance demands for biomedicine products tailored for each individual. Moreover, this trend becomes a suitable offer for diagnostics, which drives many practitioners to implement personalized solutions of products. These circumstances require stronger intellectual protection because biomedicine firms and computers more and more rely on the data-based algorithms of AI permitting personalized treatments.

3. The power of blockchain

Blockchain integration is transforming the most critical sectors of the biomedicine industry, including supply chains and authentication, as well as data transferring. They provide opportunities to keep up with IP enforcement by recording transactions and supply and dissemination history.

4. Artificial intelligence and machine learning

The demand for AI and machine learning algorithms and inventions includes pharmaceutical sciences, diagnostics, and individual therapy and diagnostics. AI more often migrates up to e-commerce articulating IP enforcement

The use of new tools, such as blockchain and artificial intelligence, to protect infringed rights, including intellectual property, represents a significant opportunity to increase the effectiveness of control mechanisms and ensure reliable protection of rights holders' rights. Let's take a closer look at the challenges they can address:

1. Blockchain:

- Immutable record of information: Blockchain technology enables the creation of immutable records of data, helping to protect rights and prevent tampering.

- Access and rights management: Blockchain can be used to implement smart contracts that control access to intellectual property and automate compliance with legal agreements.

- Tracking the chain of title: Blockchain provides transparency and integrity of the chain of title documents, which facilitates proof of ownership and authorship.

2. Artificial intelligence:

- Big Data Analytics: AI is capable of processing large amounts of data, identifying patterns of infringement and predicting possible threats to intellectual property.

- Image Recognition: Machine vision and image processing technologies help identify and protect copyrights in graphic works.

– Process automation: Artificial intelligence can automate processes for monitoring infringement, managing rights and protecting intellectual property data.

The effective application of blockchain and artificial intelligence in intellectual property protection improves transparency, reduces the risks of infringement and conflict, and automates protection processes. These tools not only provide increased security for the legal interests of right holders, but also contribute to the overall development of the intellectual property protection system.

4.2. Recommendations on the Algorithm of Actions to Protect Intellectual Property Objects in Foreign Countries in the Field of Biomedical Technologies

In the modern world, the protection of intellectual property rights in cross-border electronic commerce is a complex and urgent problem that requires a comprehensive approach and concerted action at the international level. With the diversity of legal and regulatory systems in different countries, there are some complexities and challenges that may make it difficult to effectively protect intellectual property rights abroad. In this context, it is particularly important to develop and apply strategies and measures aimed at preventing infringements and ensuring effective protection of intellectual property owners' rights. In order to ensure such protection, it is necessary to take into account the specificities of each jurisdiction and to act jointly at the international level. The following recommendations on the algorithm of actions for protection in foreign countries in the absence of a unified protection mechanism are presented, which can serve as a basis for the development of effective strategies to combat infringement of intellectual property rights in the international context.

In the context of protecting intellectual rights in the field of biomedical technologies, the following specific measures can be proposed:

1. Registration of patents: One of the key ways to protect intellectual rights in the field of biomedical technologies is to register patents for new inventions. This will eliminate the possibility of illegal copying and use of developments by others.

2. Confidentiality and non-disclosure of information: Confidential agreements in the exchange of information and materials between partners, specialists and researchers will help to prevent leakage of intellectual content and unfair use of research results.

3. Adherence to international standards: It is important to follow international intellectual property standards and regulations to ensure that biomedical developments are legally and safely protected.

4. Licensing of rights: In case it is necessary to use the intellectual developments of third parties, it is beneficial to enter into licensing agreements that define the terms and conditions of the permitted use and compensation for it.

5. State support and control: Interaction with state authorities to ensure control over the observance of intellectual property rights and support of innovative developments in the field of biomedicine.

The application of these measures will create a more favorable environment for the development of biomedical technologies, ensuring their protection and promoting innovative development of this important field of science.

Conclusion

Intellectual property and its protection play a key role in today's digital world, especially in the field of biomedicine and e-commerce. As the research analysis shows, the problems of cross-border protection of intellectual property rights in e-commerce of biomedical goods have many aspects that require attention and solutions.

In the context of Russia, it is important to note that the existing differences in legal regulation, enforcement procedures, problems of counterfeiting and piracy, as well as jurisdictional complexities create additional challenges for the effective protection of intellectual property rights in cross-border e-commerce. The need for coordinated efforts on the part of government, business and society becomes even more acute in light of such complex problems.

Consequently, high technology, stakeholder cooperation and enforcement of various legal frameworks are necessary to successfully overcome the challenges of intellectual property infringement. Only collaborative efforts involving technological innovation, data analytics, legislative development and active stakeholder engagement will effectively mitigate the risks associated with intellectual property infringement in the global digital marketplace.

By emphasizing the importance of robust enforcement mechanisms and encouraging legislative harmonization, a significant step can be taken towards protecting innovation and ensuring a fair and safe environment for biomedical e-commerce. The implementation of comprehensive measures and joint efforts will be a crucial factor in successfully combating the challenges facing the biomedical e-commerce industry in today's world.

References

1. Benis, A., Tamburis, O., Chronaki, C., Moen, A. One digital health: a unified framework for future health ecosystems. *Journal of Medical Internet Research*. 2021;23(2):e22189. DOI: 10.2196/22189.
2. Kieff, F. S. Property rights and property rules for commercializing inventions. *Minnesota Law Review*. 2000;(85):697. DOI: 10.2139/ssrn.229981.
3. Bogdanova, E. E., Maleina, M. N., Ksenofontova, D. S. Separate problems of protection of citizens' rights in the use of genomic technologies. *Lex Russica*. 2020;5(162):129-142. (In Russ.) DOI: 10.17803/1729-5920.2020.162.5.129-142.
4. Donetsky, D. V., Kravchenko, N. V. [Current problems of patient rights protection in the Russian Federation]. *[Research of innovative potential of society and formation of directions of its strategic development]*. Collection of scientific articles of the 13th All-Russian Scientific and Practical Conference with international participation. In 2 vols. Kursk: Universitet-skaya kniga; 2023. Pp. 175–177. (In Russ.)
5. Gridneva, L. G., Barabanova, L. V., Gridnev, Yu. V. [Ethical aspects in medicine]. *[Actual Directions of Scientific Research of the XXI Century: Theory and Practice]*. 2016;4(3):144-146. (In Russ.)

6. Shcherbakov, A. A., Pavlova, M. V. [Ethical aspects of the “Hippocratic Oath” in modern medicine]. *Zdravookhranenie Chuvashii* = [Healthcare in Chuvashia]. 2008;(4):35-38. (In Russ.)
7. Kichenina, V. S. [Liability of a medical worker due to improper provision of medical care resulting in harm to the life and health of a citizen]. *Uchenye zapiski Sankt-Peterburgskogo imeni V. B. Bobkova filiala Rossijskoj tamozhennoj akademii* = [Scientific Notes of the Bobkov St. Petersburg Branch of the Russian Customs Academy]. 2018;(4):75-77. (In Russ.)
8. Khodusev, A. A. [Features of criminal liability of medical workers for improper fulfilment of professional duties in the sphere of medical services]. *Aktual'nye problemy meditsiny i biologii* = [Actual Problems of Medicine and Biology]. 2022;(2):39-44. (In Russ.)
9. Orlova, N. V., Suvorov, G. N., Gorbunov, K. S. Ethics and legal regulation of the use of large databases in medicine. *Medical Ethics*. 2022;3(10):4-9. (In Russ.) DOI: 10.24075/medet.2022.056.
10. Salimov, R. R., Zaripova, R. S. [Ethical and legal aspects of the use of artificial intelligence in medicine]. *[Digital systems and models: theory and practice of design, development and application]*. Proceedings of the All-Russian (with international participation) Scientific-Practical Conference. Kazan, 10–11 April 2024. Kazan: Kazan State Power Engineering University; 2024. Pp.1060–1063. (In Russ.)
11. Fawcett, J. J., Torremans, P., eds. *Intellectual property and private international law*. Oxford University Press; 2011. 560 p. ISBN: 9780198853312.
12. Borodaenko, N. V., Maksimenko, A. V. The territoriality of intellectual property rights on the Internet and private international law. *International Journal of Humanities and Natural Sciences*. 2021;(11-3):82-84. (In Russ.)
13. Shchetinin, V. A. International protection of intellectual property rights. *Economics. Business. Banks*. 2017;(S8):71-76. (In Russ.)
14. Farrand, B. Combatting physical threats posed via digital means: the European Commission’s developing approach to the sale of counterfeit goods on the Internet. *European Politics and Society*. 2018;19(3):338-354. DOI: 10.1080/23745118.2018.1430721.
15. Ekeledo, I., Sivakumar, K. The impact of e-commerce on entry-mode strategies of service firms: a conceptual framework and research propositions. *Journal of International Marketing*. 2004;12(4):46-70. DOI: 10.1509/jimk.12.4.46.5321.
16. Maloy, R. Forum shopping: what’s wrong with that? *QLR*. 2005;(24):25.
17. Kar, D., Spanjers, J. Transnational crime and the developing world. *Global Financial Integrity*. 2017:53-59. URL: <https://globalinitiative.net/analysis/transnational-crime-and-the-developing-world/>.
18. May, C. The world intellectual property organization. *New Political Economy*. 2006;11(3):435-445. DOI: 10.4324/9780203004067.
19. Reichman, J. H. The TRIPS Agreement comes of age: conflict or cooperation with the developing countries. *Case Western Reserve Journal of Inter-*

- national Law*. 2000;(32):441. URL: <https://scholarlycommons.law.case.edu/jil/vol32/iss3/3>.
20. George, A. Transcending territoriality: international cooperation and harmonization in intellectual property enforcement and dispute resolution. *Tsinghua China Law Review*. 2017;(10):225. URL: <https://www.tsinghuaachinalawreview.law.tsinghua.edu.cn/issues/info/10217>.
21. Ezell, S., Cory, N. The way forward for intellectual property internationally. *Information Technology and Innovation Foundation*. 2019. April. URL: https://www.researchgate.net/publication/333292534_The_Way_Forward_for_Intellectual_Property_Internationally.
22. Zhu, P., Hu, J., Li, X., Zhu, Q. Using blockchain technology to enhance the traceability of original achievements. *IEEE Transactions on Engineering Management*. 2021;70(5):1693-1707. DOI: 10.1109/TEM.2021.3066090.
23. Mackey, T. K., Nayyar, G. Digital danger: a review of the global public health, patient safety and cybersecurity threats posed by illicit online pharmacies. *British Medical Bulletin*. 2016;118(1):110-126. DOI: 10.1093/bmb/ldw016.

Список источников

1. Benis A., Tamburis O., Chronaki C., Moen A. One digital health: a unified framework for future health ecosystems // *Journal of Medical Internet Research*. 2021. Vol. 23, no. 2. Art. e22189. DOI: 10.2196/22189.
2. Kieff F. S. Property rights and property rules for commercializing inventions // *Minnesota Law Review*. 2000. Vol. 85. P. 697. DOI: <http://dx.doi.org/10.2139/ssrn.229981>.
3. Богданова Е. Е., Малеина М. Н., Ксенофонтова Д. С. Отдельные проблемы защиты прав граждан при использовании геномных технологий // *Lex russica*. 2020. № 5 (162). С. 129–142. DOI: 10.17803/1729-5920.2020.162.5.129-142.
4. Донецкий Д. В., Кравченко Н. В. Актуальные проблемы защиты прав пациентов в Российской Федерации // *Исследование инновационного потенциала общества и формирование направлений его стратегического развития : сб. науч. ст. 13-й Всерос. науч.-практ. конф. с междунар. участием : в 2 т. Курск : Университет. кн., 2023. С. 175–177.*
5. Гриднева Л. Г., Барабанова Л. В., Гриднев Ю. В. Этические аспекты в медицине // *Актуальные направления научных исследований XXI века: теория и практика*. 2016. Т. 4, № 3. С. 144–146.
6. Щербаков А. А., Павлова М. В. Этические аспекты «Клятвы Гиппократ» в современной медицине // *Здравоохранение Чувашии*. 2008. № 4. С. 35–38.
7. Киченина В. С. Ответственность медицинского работника вследствие ненадлежащего оказания медицинской помощи, повлекшей причинение вреда жизни и здоровью гражданина // *Ученые записки*

- Санкт-Петербургского имени В. Б. Бобкова филиала Российской таможенной академии. 2018. № 4 (68). С. 75–77.
8. Ходусов А. А. Особенности уголовной ответственности медицинских работников за ненадлежащее исполнение профессиональных обязанностей в сфере оказания медицинских услуг // *Актуальные проблемы медицины и биологии*. 2022. № 2. С. 39–44.
 9. Орлова Н. В., Суворов Г. Н., Горбунов К. С. Этика и правовое регулирование использования больших баз данных в медицине // *Медицинская этика*. 2022. № 3. С. 4–9. DOI: 10.24075/medet.2022.056.
 10. Салимов Р. Р., Зарипова Р. С. Этические и правовые аспекты использования искусственного интеллекта в медицине // *Цифровые системы и модели: теория и практика проектирования, разработки и применения : материалы Всерос. (с междунар. участием) науч.-практ. конф., Казань, 10–11 апреля 2024 г. Казань : Казан. гос. энергет. ун-т, 2024. С. 1060–1063.*
 11. Intellectual property and private international law / eds. J. J. Fawcett, P. Torremans. Oxford : Oxford University Press, 2011. 560 p. ISBN: 9780198853312.
 12. Бородаенко Н. В., Максименко А. В. Территориальность прав интеллектуальной собственности в Интернете и международное частное право // *Международный журнал гуманитарных и естественных наук*. 2021. № 11-3 (62). С. 82–84.
 13. Щетинин В. А. Международная защита прав интеллектуальной собственности // *Экономика. Бизнес. Банки*. 2017. № S8. С. 71–76.
 14. Farrand B. Combatting physical threats posed via digital means: the European Commission's developing approach to the sale of counterfeit goods on the Internet // *European Politics and Society*. 2018. Vol. 19, no. 3. P. 338–354. DOI: 10.1080/23745118.2018.1430721.
 15. Ekeledo I., Sivakumar K. The impact of e-commerce on entry-mode strategies of service firms: a conceptual framework and research propositions // *Journal of International Marketing*. 2004. Vol. 12, no. 4. P. 46–70. DOI: 10.1509/jimk.12.4.46.5321.
 16. Maloy R. Forum shopping – what's wrong with that // *QLR*. 2005. Vol. 24. P. 25.
 17. Kar D., Spanjers J. Transnational crime and the developing world // *Global Financial Integrity*. 2017. P. 53–59. URL: <https://globalinitiative.net/analysis/transnational-crime-and-the-developing-world/>.
 18. May C. The world intellectual property organization // *New Political Economy*. 2006. Vol. 11, no. 3. P. 435–445. DOI: 10.4324/9780203004067.
 19. Reichman J. H. The TRIPS Agreement comes of age: conflict or cooperation with the developing countries // *Case Western Reserve Journal of International Law*. 2000. Vol. 32. P. 441. URL: <https://scholarlycommons.law.case.edu/jil/vol32/iss3/3>.

20. George A. Transcending territoriality: international cooperation and harmonization in intellectual property enforcement and dispute resolution // *Tsinghua China Law Review*. 2017. Vol. 10. P. 225. URL: <https://www.tsinghuachinalawreview.law.tsinghua.edu.cn/issues/info/10217>.
21. Ezell S., Cory N. The way forward for intellectual property internationally // *Information Technology and Innovation Foundation*. 2019. April. URL: https://www.researchgate.net/publication/333292534_The_Way_Forward_for_Intellectual_Property_Internationally.
22. Zhu P., Hu J., Li X., Zhu Q. Using blockchain technology to enhance the traceability of original achievements // *IEEE Transactions on Engineering Management*. 2021. Vol. 70, no. 5. P. 1693–1707. DOI: 10.1109/TEM.2021.3066090.
23. Mackey T. K., Nayyar G. Digital danger: a review of the global public health, patient safety and cybersecurity threats posed by illicit online pharmacies // *British Medical Bulletin*. 2016. Vol. 118, no. 1. P. 110–126. DOI: 10.1093/bmb/ldw016.

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