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The work of compounding pharmacies and the possible risks of violating the exclusive rights to original medicines

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The revival of production pharmacies in Russia began in 2022. To effectively use the capabilities of compounding pharmacies, it is necessary to take into account the importance of eliminating the risk of infringement of intellectual property rights.

The aim. The study of the foreign practice of compounding pharmacies in terms of infringement of exclusive rights, as well as the position of foreign patent offices and the World Intellectual Property Organization (WIPO).

Materials and methods. A key aspect of the research was the study of the foreign practice of violating the exclusive rights to original medicines. An information search was conducted for publications related to the activities of compounding pharmacies in the world, as well as issues related to the regulation of the relationship between their activities and legislation in the field of intellectual property.

Results. The article analyzes foreign judicial practices and positions of patent offices, summarized by WIPO, on this issue. The results and discussion are based on the consideration of foreign court cases and legislative norms related to the production of patented drugs in compounding pharmacies. The examples of court cases that raise issues of violations of exclusive rights are given.

Conclusion. In Russia, the possibility of one-time compounding of drugs using the invention in pharmacies according to doctors’ prescriptions is fixed at the legislative level. However, this permission only applies to a “specific recipe”. One possible way to reduce the severity of the problem may be to directly allow pharmacies to use contractors to fulfill a specific request. The concept of “one-time compounding” also requires disclosure, which may expand the capabilities of pharmacies. The results obtained can be used in the framework of legislative regulation of the compounding of medicines in a pharmacy.

Keywords: drugs; compounding pharmacies; patent; invention; intellectual property; exclusive right

Abbreviations: CC RF — Civil Code of the Russian Federation; EAPC — Eurasian Patent Convention; EAPO — Eurasian Patent Office; WIPO — World Intellectual Property Organization; WTO — World Trade Organization; NCBI — National Center for Biotechnological Information; FDA — US Food and Drug Administration; SCP — Standing Committee on the Law of Patents; EPO — European Patent Organization.

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Деятельность производственных аптек и возможные риски нарушения исключительных прав на оригинальные лекарственные средства

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В России с 2022 года началось возрождение производственных аптек. Для эффективного использования возможностей таких аптек требуется учесть важность исключения риска нарушения прав на результаты интеллектуальной деятельности.

Цель. Изучение зарубежной практики производственных аптек с точки зрения нарушения исключительных прав, а также позиции зарубежных патентных ведомств и Всемирной организации интеллектуальной собственности (ВОИС).

Материалы и методы. Ключевым аспектом исследования стало изучение зарубежной практики нарушений исключительных прав на оригинальные лекарственные препараты. Проведён информационный поиск публикаций, касающихся деятельности производственных аптек в мире, а также вопросов регулирования взаимосвязи их деятельности и законодательства в области интеллектуальной собственности.

Результаты. В статье проанализированы зарубежные судебные практики и позиции патентных ведомств, обобщенные ВОИС, относительно данного вопроса. Результаты и обсуждение основаны на рассмотрении зарубежных судебных дел и законодательных норм, касающихся производства запатентованных лекарственных препаратов в производственных аптеках. Представлены примеры судебных дел, поднимающих вопросы нарушений исключительных прав.

Заключение. В России на законодательном уровне закреплена возможность разового изготовления в аптеках по рецептам врачей препаратов с использованием изобретения. Однако это разрешение касается только «конкретного рецепта». Одним из возможных вариантов снижения остроты проблемы может быть прямое разрешение аптекам использовать подрядчиков для выполнения конкретного запроса. Также требует раскрытия понятие «разового изготовления», что может расширить возможности аптек. Полученные результаты могут быть использованы в рамках законодательного регулирования изготовления лекарственных средств в аптечной организации.

Ключевые слова: лекарственные средства; производственные аптеки; патент; изобретение; интеллектуальная собственность; исключительное право

Список сокращений: ЛС — лекарственное средство; ГК РФ — Гражданский Кодекс Российской Федерации; ЕАПК — Евразийская Патентная Конвенция; ЕАПВ — Евразийское патентное ведомство; ВОИС — Всемирная организация интеллектуальной собственности; ВТО — Всемирной торговой организации; NCBI — Национальный центр биотехнологической информации, FDA — Управление по контролю качества пищевых продуктов и лекарственных средств США; ПКПП — Постоянный комитет по патентному праву, EPO — Европейская патентная организация.

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INTRODUCTION

In 2022, Federal Law No. 502-FZ of December 5, 2022, "On Amendments to Article 56 of the Federal Law «On the Circulation of Medicines»[1]," regulating the revival of compounding pharmacies in Russia (RF), was adopted. This initiative is not a novelty introduced exclusively in the Russian Federation. Compounding medicines in a pharmacy is an integral part of providing prompt individual pharmaceutical care to patients when there are no suitable medicines on the market or when a specific dosage form is required [1–3]. Since 2023, pharmacies have been able to produce medicines according to individual prescriptions from doctors, using existing medications in the necessary dosages [4–6]. Due to the lack of a register of compounding pharmacies, it is difficult to reliably assess the dynamics of their opening since the adoption of legislative changes. According to expert estimates[2], there are currently about 460 compounding pharmacies operating in the Russian Federation, and about 2 000 pharmacies have licenses for production activities. A large-scale project within the framework of the revival of compounding pharmacies was the creation of a pilot industrial production facility for the manufacture of "orphan" drugs, announced in 2024. It will operate on the principle of a compounding pharmacy. The project is being implemented on the Federal Territory of Sirius (Russia)[3]. Its opening is scheduled for 2025[4].

The activities of compounding pharmacies, which allow for the prompt replacement of emerging drug shortages, taking into account the individual needs of patients, are closely related to intellectual property, with the turnover of rights to the results of intellectual activity in the area under consideration, namely, with exclusive rights to the original (or reference) drug that is reproduced by pharmacies. In the Russian Federation, compounding pharmacies are only beginning to develop, while similar pharmacies have been operating in European countries [7–9] and the USA [10] for decades. In order to minimize the risks associated with the operation of such pharmacies, the authors of the article decided to study the foreign practice of such pharmacies from the point of view of violations of exclusive rights, as well as the position of foreign patent offices and the World Intellectual Property Organization (WIPO). The importance of understanding this aspect is explained by the fact that the production of medicines is closely related to the existence of exclusive rights to them and their components, granted by a patent. Violation of exclusive rights entails lawsuits from the manufacturer of the original drug against the infringer, which in this case may be a compounding pharmacy.

THE AIM. Analysis of the development of compounding pharmacies in the prism of possible risks of infringement of exclusive rights to original medicines protected by a patent for invention and a trademark certificate.

MATERIALS AND METHODS

An information search of publications was conducted regarding the presence of compounding pharmacies in various countries, as well as issues of regulating the relationship between their activities and legislation in the field of intellectual property. The search was conducted in databases such as: World Intellectual Property Organization (WIPO), National Center for Biotechnology Information (NCBI), ScienceDirect, U.S. Food and Drug Administration (FDA), elibrary.ru. The search results also included publications found through the Google Scholar service. In addition, the scope of the search included regulatory legal bases of the Russian Federation, foreign countries and international communities related to the manufacture and introduction of drugs into civil circulation.

The search was carried out using the following keywords and phrases: "intellectual property", "compounding pharmacy", "law", "patent", "drugs", "extemporaneous compounding", as well as their Russian-language analogues: "интеллектуальная собственность", "производственные аптеки", "закон", "патент", "препарат", "лекарственное средство", "экстемпоральное производство".

The period of studied publications was from November 2024 to January 2025; the search period was 20 years.

A search conducted using keywords in English in the ScienceDirect database revealed 954 thematic works. After screening out publications related to the patenting of pharmaceutical inventions and the activities of compounding pharmacies (*n*=895), as well as articles similar in content (*n*=31), 28 scientific articles were included in the review.

A search conducted using keywords in Russian in the scientific elibrary.ru revealed 213 works; after excluding

[1] Federal Law No. 502-FZ dated 05.12.2022 "On Amendments to Article 56 of the Federal Law "On the Circulation of Medicines". Available from: http://publication.pravo.gov.ru/Document/View/0001202212050043. Russian

[2] Nevinnaya I. The expert explained the importance of manufacturing pharmacies for orphan patients. Projects of Russia. Available from: https://rg.ru/2024/08/17/ekspert-obiasnila-vazhnost-proizvodstvennyh-aptek-dlia-orfannyh-pacientov.html. Russian

[3] An innovative pharmacy for the manufacture of orphan drugs will appear in Sirius in 2024. Available from: https://sirius.gov.ru/tpost/innovatsionnaya-apteka-dlya-izgotovleniya-orfannykh-preparatov-poyavitsya-v-siriuse-v-2024-godu?ysclid=m38lwj36gi311746142

[4] A pharmacy for the creation of rare medicines will be launched in Sirius in 2025. Kommersant. Available from: https://www.kommersant.ru/doc/7283342?ysclid=m38ouy6ksd859117313

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articles similar in content (*n*=191), 22 scientific articles were included in the review.

RESULTS

Problem statement

Pharmacies appeared many centuries ago and have since played an important role in society. The first pharmacy is believed to have opened in the 8th century in Baghdad, and in Russia only in 1581 [11], and since its creation, the state has always paid great attention to them. For a long time, pharmacies were the main institution for the manufacture of medicines, and only with the development of mass industrial pharmaceutical production they began to pay less attention to them. Currently, pharmacy institutions, in addition to retail trade also provide the compounding of drugs for their clients. It is the individual orientation of the production activities of pharmacies that characterizes it in the system of providing society with drugs [12–14]. Until recently this meant that pharmacies were practically not engaged in the compounding of complex modern drugs, today the situation is changing significantly. Pharmacies are able to fill the shortage of certain medicines on the market, ensure the compounding of drugs focused on rare diseases, etc. It is quite clear that the legislator cannot leave this area unattended.

The most important arising problem is the need to protect intellectual property while ensuring the interests of society in the production of medicines. The general rule established by intellectual property law is that the use of an object of protection is allowed only with the consent of the copyright holder, except in *cases provided for by law*[5]. Obviously, a pharmacy institution cannot obtain a license from the copyright holder for a one-off production of medicines, therefore, national laws, as a rule, provide for the permission of such actions without the consent of the copyright holder and without payment of remuneration. However, the widespread use of this opportunity by pharmacies (for example, with the development of the concept of compounding pharmacies) can cause certain problems for copyright holders. In this regard, it is important to assess how real these problems are and whether the current legislation needs adjustments.

International aspects of regulation of the drugs' compounding by pharmacy institution

At the 36th session of WIPO, held in Geneva on October 14–18, 2024, within the work of the Standing Committee on Patent Law (SCP), the issue of the attitude of national and regional patent offices to the one-time preparation of medicines in pharmacies, including in judicial practice, was discussed[6].

The legislation of 85 countries (including the Russian Federation, Canada, Brazil, Japan, France, the Republic of Korea, Spain, Sweden, Switzerland, the United Kingdom, etc.) related to the circulation of rights to the results of intellectual activity provides for an exception regarding the one-off (extemporaneous) production of drugs. This complies with international law. Thus, Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) lists the principles that govern exceptions to rights established by members of the World Trade Organization (WTO). In particular, the article states that WTO members may introduce limited exceptions to the rights granted by a patent *if "such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties*."[7]

This formula allows the introduction of new rules on the drugs' compounding by pharmacies into national legislation, expanding their capabilities, but up to a level where copyright holders will be infringed in their commercial plans and cause damage to the possibility of selling their products.

According to the countries positions presented in WIPO regarding the issue, the aims of the exclusion from the list of actions qualifying as a violation of the exclusive rights of the copyright holder are:

1. Ensure a balance of rights, which is necessary when respecting the rights of patients to health protection and free access to medicines while respecting the rights of the patent holder of pharmaceutical innovations (for example, this is the point of view of Brazil)8.
2. Maintenance of public awareness of protecting people's health. Thus, pharmacists should be able to produce prescription drugs, guarantee medical care to patients and being fearless of violating patent rights (these are the positions of the Republic of Korea and the Czech Republic)9.
3. Facilitate the work of doctors and pharmacists. Doctors should prescribe medicines without

[5] Paragraph 1 of Article 1229 of the Civil Code of the Russian Federation. "Exclusive right." Available from: http://pravo.gov.ru/proxy/ips/?docbody=&nd=102110716

[6] WIPO. Standing Committee on the Law of Patents. Available from: https://www.wipo.int/meetings/en/details.jsp?meeting_id=80917

[7] WIPO. World Trade Organization (WTO). Agreement on Trade-Related Aspects of Intellectual Property Rights. Available from: https://www.wipo.int/wipolex/en/text/379915

[8] WIPO. Questionnaire on Exceptions and Limitations to Patent Rights. Available from: https://www.wipo.int/scp/en/exceptions

[9] WIPO. SCP Electronic Forum: Comments and Documents (SCP/36). Available from: https://www.wipo.int/scp/en/meetings/session_36/comments_received.html

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regard to restrictions that may arise due to the exercise of exclusive rights.

The WIPO concept supports objectives encouraging innovation in various fields, including medicine, and does not restrict ways to meet the needs of patients using personalized medicines according to individual prescriptions from doctors.

As part of the work of the Standing Committee on the Law of Patents, issues of interpretation of the exception in question were discussed, namely, which specific pharmacies can use this rule, and who should prepare the drug according to an individual prescription. It is interesting to note that the surveyed states interpret the rule very broadly in terms of the type of place where and by whom the drug will be prepared. In particular, according to the position of the European Patent Office (EPO), the preparation should be carried out in pharmacies, including hospital pharmacies, and not only a pharmacist, but also support personnel can prepare the drug. EPO representatives also believe that this exception also applies to the veterinary field.

In addition, it was mentioned that the exception does not apply to the production of drugs for storage, but only applies to the compounding of a drug for a specific patient.

As mentioned above, the issue of the manufacture of prescription drugs by pharmacists was discussed by representatives of the patent offices of 85 countries, as well as experts from the Eurasian Patent Office (EAPO) and the EPO. They came to the conclusion that in the field of drug manufacturing in pharmacies, there is still no stable judicial practice regarding violations of the exclusive rights of manufacturers of original drug. Only a few court cases were noted.

Thus, one of such cases was a dispute between the corporations Sanofi-Aventis Farmaceutica Ltda and Farma Ltda. It concerned the patented active substance “rimonabant”, used for the treatment of obesity and cardiovascular diseases (Sanofi-Aventis Farmaceutica Ltda v. Sp Farma Ltda, Court of the State of São Paulo, April 18, 2013, case No. 0158190-77.2008.8.26.0100, Brazil). A representative of Sanofi-Aventis Farmaceutica Ltda argued that the defendant was violating the company’s rights to the patented invention by importing and selling rimonabant in Brazil. According to the plaintiff, the defendant’s actions do not fall under the exceptions, since Farma Ltda does not manufacture medicines according to individual prescriptions, but only supplies the substance to pharmacies. In turn, compounding pharmacies without having the appropriate permission to do so, which violates the plaintiff’s rights. As a result, on April 18, 2013, the court in São Paulo decided that the supply of rimonabant to pharmacies that manufacture medicines based on it falls under paragraph III of Art. 43 of the Law on Industrial Property of Brazil[10]. The document states: «43. The provisions of the previous article do not apply: [...] III. to the preparation of a drug according to a doctor’s prescription for individual cases, performed by a qualified specialist, as well as to a drug prepared by this way». Thus, the court considered that the defendant acted in the interests of specific patients, importing rimonabant for pharmacies, which is used for the preparation of individual prescription drugs. In this regard, the court did not see a patent infringement. It also concluded that the defendant’s advertising aimed at attracting new customers is not a violation of patent rights. This case is important because it showed the need for a broad interpretation of the usual restriction of the exclusive right provided for pharmaceutical institutions.

It is important to note that the document published by the Secretariat of the Standing Committee on the Law of Patents (WIPO, Geneva) following the discussion on October 14–18, 2024 of exceptions — does not contain the position of the United States. Though it is in the United States that compounding pharmacies (in the United States they are called compounding pharmacies) have been developing in recent decades and there is extensive judicial practice.

Attitude of drug manufacturers to the activities of compounding pharmacies in the USA and the position of the FDA

According to the FDA[11], doctors in hospitals and other medical facilities have the right to give a prescription for a compounded drug that has not been approved by the FDA [15]. It is possible in two cases:

1. An FDA-approved drug cannot be used for a specific patient in case of possible allergic reaction to certain components or due to the unavailability of the required form of the drug, as in the case when a patient cannot swallow a tablet or capsule due to age and needs to take the drug in another form, for example, as a suspension.
2. The drug is on the shortage list at the time of prescription to the patient.

The fact that a compounded drug is not FDA-approved, meaning it has not been tested for safety and efficacy, is the most common primary argument used by

[10] Article 43 (III) of Law No. 9.279 of May 14, 1996, Industrial Property Law as amended by Law No. 14.200 of September 2, 2021, Brazil. Available from: https://www.wipo.int/wipolex/ru/legislation/details/515

[11] U.S. Food and Drug Administration. Compounding and the FDA: Questions and Answers. Available from: https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers#:~:text=What%20is%20compounding%3F,drugs%20are%20not%20FDA%2Dapproved

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pharmaceutical manufacturers of original drugs against the activities of compounding pharmacies. In their opinion, prescription drugs compounded in a pharmacy put patients at risk of health loss [16–18], as the lack of control over the compounding process of such a drug can lead, for example, to a low or, conversely, excessively high dose of the active substance [8, 19, 20].

However, in the United States, the FDA regulatory document contains rules governing the compounding of drugs in compounding pharmacies[12] (in Russian legislation, the analogue of the concept of "compounding pharmacies" is manufacturing pharmacies). Thus, sections 503A and 503B of the FDA mainly concern the compounding of drugs. Section 503A[13] applies to the compounding of drugs for humans by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician who is not registered with the FDA as an outsourcing facility[14]. Section 503B applies to the compounding of drugs for patients in an outsourcing facility. Outsourcing institutions are a category of drug manufacturers created in 2013 by the Drug Quality and Security Act. Outsourcing facilities are inspected by the FDA[15].

Thus, the activities of both licensed pharmacies and outsourcing facilities are regularly monitored and inspected.

It is worth noting that biologicals cannot be compounded according to sections 503A and 503B of the Drug Act[16]. The term "biologicals" is explained in section 351(i)(1) of the Public Health Service Act (PHS). The definition of this term includes a vaccine, virus, toxin and antitoxin, therapeutic serum, blood and its components, allergenics, as well as a protein (excluding a chemically synthesized polypeptide) or similar product, or arsphenamine, or arsphenamine derivative (any other trivalent organic arsenic compound) used for the prevention and treatment of a patient's disease or condition. Section 351(a)(1) of the PHS Act prohibits the introduction into commerce of any biologicals unless "a license... is not valid for the biologicals." In order that the FDA approve such a product, it must contain data demonstrating safety, purity and efficacy, as well as data that the facility in which the biologicals will be manufactured, processed, packaged or stored meets standards developed to ensure that the biological product continues to be safe, pure and effective (section 351(a)(2)(C) of the PHS Act). All this is quite difficult to comply with in the context of compounding drugs [21–23].

Although American law regulates attentively the activities of institutions entitled to dispense drugs by prescription, there are many publications about litigation concerning the dispensing of drugs compounded this way.

In particular, the increase of lawsuits[17] is noted, which is due to the prevalence of the practice of compounding drugs by prescription. Lawsuits are filed by pharmaceutical companies and related to the area of violation of exclusive rights. Lawsuits mainly contain claims based on:

1. Violation of laws on fraudulent and unfair trade practices, violation of patent rights, violation of the Lanham Act (US Federal Trademark Act[18]) due to false statements in product advertising, as well as violation of trademark rights.
2. Violation of the principles of patient safety due to the fact that compounded drugs do not undergo pre-sale testing for safety, efficacy or quality. Drugs compounded in pharmacies are not evaluated by the FDA for safety or efficacy, do not have standard labelling or information on use, and are not required to report side effects to the FDA, unlike FDA-approved drugs. Product quality is assessed inconsistently, and testing is carried out inconsistently.
3. Patent violation, as they confirm exclusive rights to manufacture, use, and sell a patented product. According to pharmaceutical manufacturers[19], only pharmacies engaged in compounding drugs by prescription, and not their suppliers (i.e., manufacturers of substances), are exempt from patent infringement.

According to the analysed articles, patent infringement may be recognized if the compounded

[12] U.S. Food and Drug Administration. FD&C Act Provisions that Apply to Human Drug Compounding. Available from: https://www.fda.gov/drugs/human-drug-compounding/fdc-act-provisions-apply-human-drug-compounding

[13] U.S. Food and Drug Administration. Section 503A of the Federal Food, Drug, and Cosmetic Act. Available from: https://www.fda.gov/drugs/human-drug-compounding/section-503a-federal-food-drug-and-cosmetic-act

[14] U.S. Food and Drug Administration. Text of Compounding Quality Act. Available from: https://www.fda.gov/drugs/human-drug-compounding/text-compounding-quality-act

[15] U.S. Food and Drug Administration. Compounding and the FDA: Questions and Answers.

[16] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License. Application Guidance for Industry. Available from: https://www.fda.gov/media/90986/download?attachment

[17] Compounding Pharmacies in the US — Market Research Report (2014-2029). Available from: https://www.ibisworld.com/united-states/industry/compounding-pharmacies/5706/

[18] Intellectual Property Challenges for 503A Pharmacy Compounding. Available from: https://www.frierlevitt.com/articles/intellectual-property-challenges-for-503a-pharmacy-compounding/

[19] U.S. Food and Drug Administration. Compounding and the FDA: Questions and Answers.

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drug is “essentially a copy” of a commercially available drug at the time it is prescribed to the patient[20].

Regarding trademark infringement, most cases against pharmacies are initiated due to the compounding of semaglutide[21]. Pharmacies are accused of trademark infringement and unfair competition, as well as false and misleading advertising. The main argument in lawsuits is that pharmacies “substitute” their unapproved compounded drugs, containing semaglutide, as “Ozempic” or “Wegovy,” or in some cases promote their products under the guise of these branded products (Novo Nordisk v. A/S v. Effinger Health PA Tallahassee Clinic, Case No. 4:23-cv-00265 (D.C. N. D. June 21, 2023). Specifically, the allegations are that compounding manufacturers use the brand name drug in their advertising and promotion on their website, and that when viewing it, patients wishing to obtain the original drug are misled by the use of the trademark on such a site. Another accusation against pharmacies compounding semaglutide is the production of unsafe counterfeit “Ozempic”[22] [20]. Bloomberg[23] describes cases where in Louisiana, one pharmacy produced nearly 300 vials of injectable weight loss drug without proper testing for ontaminants, and in Arizona, a pharmacy mixed drugs in non-sterile conditions. It led to the development of side effects in patients.

The problems outlined here show that granting pharmacies the right to compound drugs entails very diverse, though very related, issues.

Despite the existence of litigation in foreign jurisdictions regarding the activities of compounding pharmacies, numerous articles of foreign authors, it is noted that dispensing drugs according to doctors’ prescriptions is one of the effective ways to address the acute drugs shortages[24]. Licensed pharmacists can create drugs that are not commercially available due to production shutdowns, shortages, or other supply chain issues. Compounding pharmacies serve small local groups of patients and doctors, locally addressing shortage issues. Another advantage of compounding drugs prescription is a personalized approach to patient treatment[25] — compounding an individual dose of the drug, an individual compounding of the drug, an individual dose form of the drug [24, 25].

Development of compounding pharmacies in Russia as of 2024 in the context of patent law

The legal status of pharmacies in our country is defined by Federal Law No. 61-FZ of April 12, 2010 “On the Circulation of Medicines,” which establishes that a pharmacy organization (pharmacy) is “an organization, a structural subdivision of a medical organization, engaged in retail trade of medicines, including remote sale, storage, transportation, compounding and selling of medicines for medical use in accordance with the requirements of this Federal Law[26].” Thus, the possibility of pharmacies compounding drugs initially stems from the functional characteristics of this organization. However, carrying out their functions, pharmacies must act in compliance with intellectual property law.

The general principle established by the Civil Code of the Russian Federation is that persons other than the right holder may not use the relevant result of intellectual activity or means of individualization without the consent of the right holder, except in cases provided for by this law[27].

It is worth noting that a drug consists of pharmaceutical substances, which may be separately protected by a patent. According to Article 1358 of the Civil Code of the Russian Federation, the patent holder has the exclusive right to use the invention any way that does not contradict the law. Use of the invention means — importation into the territory of Russia, manufacture, further use, including offering for sale, the sale itself and other introduction into civil circulation or storage of the product in the creation of which the invention, utility model or industrial design was used. Accordingly, to manufacture a drug, it is necessary either to obtain the consent of the right holder or to take advantage of one of the exceptions established by the Civil Code of the Russian Federation.

In Russia, the possibility of one-time compounding of drugs in pharmacies according to doctors’ prescriptions using an invention is enshrined at the legislative level

[20] Ibid.

[21] Why millions are trying FDA-authorized alternatives to Big Pharma’s weight loss drugs // Popular Science. Available from: https://www.popsci.com/health/glp1-compounding-pharmacies-wegovy-zepbound-copycat-drugs-shortages/

[22] Unsafe Ozempic Knockoffs Are Flooding the Market // Bloomberg. Available from: https://www.bloomberg.com/news/articles/2024-07-22/ozempic-wegovy-knockoffs-for-weight-loss-are-flooding-market

[23] Unsafe Ozempic knockoffs are flooding the market // BNN Bloomberg. Available from: https://www.bnnbloomberg.ca/business/2024/07/22/unsafe-ozempic-knockoffs-are-flooding-the-market/

[24] Kumar S. Compounding Inequities Through Drug IP and Unfair Competition (February 26, 2024). Shweta K., Compounding Inequities Through Drug IP and Unfair Competition, 102 Wash. U. L. Rev. (forthcoming 2024), Available from: https://ssrn.com/abstract=4739356

[25] Health Dimensions Clinical Pharmacy. Compounding pharmacy vs retail pharmacy: Top 5 ways they’re different. Available from: https://www.hdrx.com/general/compounding-pharmacy-vs-retail-pharmacy-top-five-ways-theyre-different/

[26] Clause 35 of Article 4 of Federal Law No. 61-FZ dated April 12, 2010 “On the Circulation of Medicines”. Available from: http://pravo.gov.ru/proxy/ips/?docbody=&nd=102137440&ysclid=m720ikunte627102595

[27] Paragraph 1 of Article 1229 of the Civil Code of the Russian Federation. “Exclusive right.” Russian

(subparagraph 5, paragraph 1, Article 1359 of the Civil Code of the Russian Federation[28]). Such action is not considered a violation of patent rights. It is worth noting that the resurgence of compounding pharmacies in Russia began in 2022. Since 2023, pharmacies have again begun to compound drugs according to doctor's prescriptions with individual dosages. However, to date, the practice of litigation concerning violations of the exclusive rights of substance or drug owners has not yet been developed.

There are very few articles on the objective, interpretations of the specified norm of the Civil Code of the Russian Federation. At the same time, it is worth mentioning the following comment of Russian specialists in the field of patent law[29]: "...5. Subparagraph 4 of paragraph 1 of the commented article further limits the scope of the exclusive right of the patent holder, preventing its extension to personal, family, household or other needs not related to entrepreneurial activity, if the purpose of such use is not to obtain profit (income). *On the one hand, this approach reflects the legislator's desire to establish a balance of interests between both the patent holder and society. On the other hand, we are talking about a sphere in which the number of persons using an invention, utility model, industrial design can be so large, and the scale of use by each of them is so small that the realization of the patent holder's rights and the protection of his interests by the state become practically impossible.* 6. The provision contained in subparagraph 5 of paragraph 1 of Article 1359 is due to reasons similar to those listed in the commentary to subparagraph 4.".

Thus, one of the reasons for the existence of this rights' limitation is the practical impossibility of prohibiting such a variant of using the relevant objects of patent law.

At the same time, it is very important that there is no introduction of the obtained products into civil circulation in this case: "Contrary to popular belief, in this case there is no need for a special indication that for the free use of medicines it is not enough to manufacture it, it is also necessary to sell it, i.e. put it into circulation. There is no "sale" here: the medicine is made for a fee, but at the request of the person presenting the prescription, i.e. there is a contract. So, the mentioned process does not allow the introduction of the compounded drug into circulation (the sale of the manufactured drug by the customer will be a violation of the exclusive right)[30]."

Thus, the danger of such actions is minimal for the interests of the right holder, and the social significance is very high. It should be noted that this norm of the Civil Code of the Russian Federation concerns only the direct compounding of drugs, but not preparatory actions. This means that the pharmacy must purchase pharmaceutical substances that have been put into civil circulation.

At the same time, the storage of drugs compounded in accordance with this norm of the Civil Code of the Russian Federation does not require the author's permission. This general rule, which operates in the field of intellectual property [26], was clearly expressed by the Supreme Court of the Russian Federation in relation to copyright objects: "The storage of a material carrier in which a copyright object is expressed, without the purpose of introducing it into civil circulation, is not an independent way of using the work, and therefore such storage does not require special consent of the copyright holder[31]."

It is obvious that a drug compounded on the basis of a prescription can be used repeatedly by one patient. Or a doctor can use the same prescription for several patients. But it is important to note that "it is not the production of drug by the pharmacy in advance for sale, but the compounding of drugs in each individual case — upon receipt of a doctor's prescription from the buyer. At the same time, the indication "one-off production" refers only to the actions of the pharmacy; the doctor's prescriptions are not limited in their number." Therefore, the pharmacy cannot produce the drug in advance - in anticipation of a request from potential customers, it must always respond to a specific prescription.

It is obvious that pharmacists should have possibility to compound specific drugs according to doctors' prescriptions without risking being accused of infringing the rights of patent holders. This will facilitate access of the population to drugs, especially in critical situations (for example, temporary absence of a certain form or dosage of the medicine on the market) [27–29].

Russian legislation generally allows pharmacies to carry out their functions, but limiting the permit to only a "specific prescription" makes it difficult to compound drugs that require a long and complex process. Since "make-to-stock" is not allowed for pharmacies, the

[28] Paragraph 1 of Article 1229 of the Civil Code of the Russian Federation. "Exclusive right." Russian

[29] Gorlenko SA, Kalyatin VO, Kiriy LL, Kozyr OM, Korchagin AD, Orlova VV, Pavlova EA, Sinelnikova VN, Stepanov PV, Trakhtenherts LA, Shilokhvost OYu. "Commentary to the Civil Code of the Russian Federation (Part four) (article-by-article)". Moscow: Infra-M Publishing House, 2016. Russian

[30] Article-by-article commentary to the Civil Code of the Russian Federation, Part Four; Valeeva NG, Vsevolozhsky KV, Gongalo BM, et al.; edited by Krasheninnikov PV; Moscow: Statute; 2011. Russian

[31] Paragraph 92 of the Resolution of the Plenum of the Supreme Court of the Russian Federation dated 04/23/2019 No. 10 "On the application of Part Four of the Civil Code of the Russian Federation". Available from: https://www.consultant.ru/document/cons_doc_LAW_323470/?ysclid=m72140z5gy36622264. Russian

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production process must begin only after receiving a prescription from the client, which means that the client may receive the required drug very soon. One possible way to reduce the severity of this problem could be to allow pharmacies directly use contractors to fulfill a specific request (and not just produce drugs themselves). However, this will not completely eliminate the issue; it is clear that it requires discussion in order to find a mutually acceptable option for regulating the activities of pharmacies. It also requires disclosure (for example, at the level of documents of the Supreme Court of the Russian Federation) of the concept of one-time manufacturing, which may expand the capabilities of pharmacies. Perhaps some completely new solution is also needed.

DISCUSSION

The article provides an overview of modern approaches to the operation of compounding pharmacies and the connection of their activities with the violation of the exclusive rights of manufacturers of original drugs. This analysis examines the advantages of compounding pharmacies for doctors, patients, and the state. The current trend regarding the development of compounding pharmacies in Russia is highlighted. The key aspect of pharmaceutical compounding is the possibility of an individualized approach to treatment, as well as a quick response to drug shortages [29–31].

The review of foreign practices, on one hand, demonstrates a neutral attitude towards the activities of compounding pharmacies in most countries (according to the position described in the WIPO final document), and, on the other hand, shows that the active development of such institutions, for example, in the USA, correlates with the growth of litigation related both to violation of patent rights and trademarks [29, 32, 33]. Due to the fact that the stage of formation of compounding pharmacies is currently taking place in the Russian Federation, it is advisable to take into account in detail the judicial practice of foreign countries in which such pharmacies are widespread when forming Russian legislation [34–36]. This will allow to neutralize the risks of violating both patient rights and the exclusive rights of copyright holders of original drugs [37]. In the context of discussing the risks of drug shortages, the experience of Dutch scientists [38] is of interest, who in 2022, in the context of a shortage of pilocarpine solution on the market (used to diagnose such an orphan disease as cystic fibrosis), conducted a comparative study of the prepared solution in a compounding pharmacy and the original drug. Thus, the study showed similar levels in the concentrations of chloride obtained in the two pilocarpine solutions. This allowed the authors of the article to conclude that the use of compounding pharmacies for the rapid replacement of drugs unavailable on the market is promising and effective. The issue of manufacturing specifically orphan drugs within the framework of compounding pharmacies and hospital pharmacies is increasingly being raised in various countries [39–41]. The need for the availability of such drugs for patients, the number of which is very small, is being discussed. Compounding pharmacies can meet this demand. However, this issue is closely related to the interests of developers of original drugs, whose exclusive rights, on one hand, should not be a barrier to saving patients with orphan diseases, and, on the other hand, should not prevent the creation of new drugs as a result of the loss of a stimulating factor for manufacturers [42, 43]. The last aspect is related to the fact that the development of new drugs is a long research process requiring financial costs. Often the result of such research can be unpredictable. Granting exclusive rights to manufacturers of original drugs is an important incentive, allowing developers to be motivated and, thanks to a temporary monopoly, to compensate for their costs[32] [44–46].

It should be noted that issues related to the activities of compounding pharmacies in other countries [47, 48] do not differ significantly from those arising in Russia. In this regard, it is advisable to take into account the above problems.

The rise of compounding pharmacies in the Russia may lead to an increase in litigation relating, inter alia, to infringement of the exclusive rights of copyright holders. In this regard, it is advisable to pay attention to the formation of regulatory legal acts governing the activities of such pharmacies. On the one hand, they should regulate the procedure for the activities of such pharmacies that are permissible in terms of the production of drugs according to a doctor's prescription, and, on the other hand, in the event of a legal dispute, clarify the legal aspects of such activities.

CONCLUSION

In conclusion of this article, it can be noted that due to the adoption of legislative changes in Russia, which became an important step in the development of drug compounding in pharmacies, it became necessary to study foreign practice in this area, especially judicial practice. The study of the development of compounding pharmacies and possible risks of violation of exclusive rights to drugs made it possible to better understand

[32] The Role of Patents and Regulatory Exclusivities in Drug Pricing (R46679). Available from: https://crsreports.congress.gov/search/#/?termsToSearch=The%20Role%20of%20Patents%20and%20Regulatory%20Exclusivities%20in%20Drug%20Pricing&orderBy=Relevance

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the positions of foreign patent offices, courts of various jurisdictions, as well as WIPO.

The study also showed that the concept of WIPO and most countries supports objectives aimed to encourage innovation and does not limit ways to meet the needs of patients through the use of personalized drugs according to individual prescriptions. Conceptually, in most countries, the law regarding intellectual property in terms of the possibility of compounding a patented drug in a pharmacy according to a doctor's prescription is formulated the same way — this is not a violation of the exclusive rights of the patent holder of the original drug. At the same time, according to practice, for example, in the USA there is a number of legislative norms regulating the control over the activities of such pharmacies. However, the study revealed the existence of lawsuits in this country regarding violations of the exclusive rights of manufacturers of original drugs in the field of their manufacture.

The resurgence of the practice of drugs manufacturing in compounding pharmacies is a very promising area, especially in the context of a constantly emerging shortage. However, taking into account foreign experience, in particular the experience of the United States, it is advisable to work out in detail the issue of legislative regulation of the activities of such pharmacies and mechanisms for monitoring their activities, as well as to work out the issue of measures to prevent pharmacies from violating the exclusive rights of manufacturers of original drugs. It is important to maintain a balance — on the one hand, pharmaceutical patents should not restrict the doctor's freedom to prescribe drugs in the interests of the patient's health. On the other hand, thanks to intellectual property, namely exclusive rights, which are granted to developers, the creation of the very drugs that support or restore the health of the population is stimulated, subject to temporary compensation to developers for costs.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

AUTHORS' CONTRIBUTION

Alexey V. Alekhin — problem statement, concept, making comments of intellectual content, final approval of the manuscript; Tatiana N. Erivantseva — collection of material, critical analysis of literary sources, writing the text of the manuscript; Vitaly O. Kalyatin — scientific editing of the text, interpretation of materials; Natalya A. Alekhina — critical analysis of literary sources, editing and formatting the text of the manuscript; Roman A. Ivanov — critical analysis of literary sources, editing the text of the manuscript. All authors confirm that their authorship meets the international ICMJE criteria (all authors made a significant contribution to the development of the concept, conducting research and preparing the article, read and approved the final version before publication).

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