THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

Editor
Daniel A Kracov

THE LAWREVIEWS

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This article was first published in September 2020
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Published in the United Kingdom
by Law Business Research Ltd, London
Meridian House, 34–35 Farringdon Street, London, EC4A 4HL, UK

www.TheLawReviews.co.uk

ISBN 978-1-83862-484-2

Printed in Great Britain by
Encompass Print Solutions, Derbyshire
Tel: 0844 2480 112

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ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following for their assistance throughout the preparation of this book:

ARNOLD & PORTER

AUGUST DEBOUZY

BIRD & BIRD LLP

DANUBIA LEGAL

HERBERT SMITH FREEHILLS

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PREFACE

The pharmaceutical business is truly one of the most global industries, with many companies operating in dozens of countries with differing legal regimes and healthcare systems. In certain respects, the rules governing industry activities have largely become harmonised, such as in drug manufacturing and the conduct of clinical trials. However, in other areas the legal frameworks differ, and those nuances can require significant efforts to both optimise strategies and comply with requirements in local jurisdictions. In the areas of focus of this book – pharmaceutical intellectual property, including patent linkage and exclusivities, and related competition concerns – while general concepts may be shared across jurisdictions, it can be critically important to tailor approaches to the local legal environment.

Maximising the value of intellectual property can make the difference in deciding to pursue the development of an important new treatment, and in determining its sustained success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. This is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability has been a constant source of political scrutiny, as well as patient and physician concern. With the ongoing covid-19 pandemic spurring an intense focus on intellectual property and pricing issues associated with vaccines and other needed treatments, the stakes have grown even higher.

Our objective in framing this volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. I would like to thank the authors for their contributions to this edition of the *Pharmaceutical Intellectual Property and Competition Law Review*. They have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
August 2020

Chapter 11

RUSSIA

Evgeny Yuriev, Evgeny Uporov, Lola Shamirzayeva and Arina Abgaryan[1]

I OVERVIEW

Generally, the Russian pharmaceutical market and respective legislation continue to develop. Both international and local pharmaceutical companies are already established in Russia and have launched various projects related to the production of new drugs and vaccines. Some recent trends have focused on the localisation of the production of pharmaceuticals, introducing innovations, and increasing the quality of and access to healthcare.

Throughout 2019, the pharmaceutical market remained one of the fastest growing non-resource segments of the Russian economy. According to publicly available data, in the first half of 2019, the market volume exceeded 697 billion rubles and the share of Russian-made drugs reached 29.5 per cent in value terms and 60.6 per cent in physical terms.[2]

In March 2019, the government approved changes to the state programme known as 'Development of the Pharmaceutical and Medical Industry' (Pharma 2020). The intended duration of the programme has been extended until 2024, and new targets have been added with respect to ensuring the competitiveness of the pharmaceutical industry.

Recently, the government has updated the list of strategically important drugs, the production of which must be retained within Russia (Order No. 1141-r dated 6 July 2010), which has been expanded from 57 to 215 international non-proprietary names. There are plans to adopt the new strategic document 'Pharma 2030', which will set out new targets for the development of the pharmaceutical industry up to 2030.

Russia intends to create a single pharmaceutical market within the Eurasian Economic Union (EAEU). From 31 December 2020, the authorisation of all new pharmaceuticals in Russia will be conducted solely based on the EAEU Rules. Since the first application was filed in March 2018 in Kazakhstan, only 63 pharmaceutical products have been authorised using the EAEU procedure. By 31 December 2025, it is expected that all pharmaceuticals that had been authorised under the National Regulation[3] will be brought in line with the EAEU Rules.

Due to the covid-19 outbreak, the government has elaborated the new expedited emergency procedure for the authorisation of new drugs in Russia. As a part of this, the

1 Evgeny Yuriev is a partner, Evgeny Uporov and Lola Shamirzayeva are associates, and Arina Abgaryan is a trainee at Herbert Smith Freehills.

2 https://rg.ru/2019/12/01/gosprogramma-farma-2020-prodlena-do-2024-goda.html.

3 Order No. 725-n of the Ministry of Healthcare of Russia, dated 21 September 2016 (in force as of 3 October 2018) on the approval of the administrative regulation of the Ministry of Healthcare of the Russian Federation on providing the state service of state registration of pharmaceutical products for medical use.

government is entitled to grant a temporary registration. Thus, on 1 June 2020 the Ministry of Healthcare of the Russian Federation granted a temporary registration certificate to a covid-19 treatment, Avifavir, produced by the Russian Direct Investment Fund and ChemRar Group.

In the past several years, patent linkage and compulsory licensing have become active legal issues in the wake of an increasing number of disputes initiated by such international pharmaceutical giants as Novartis, Bayer, Pfizer and Boehringer Ingelheim. There have been multiple cases of the authorisation of generic drugs before the expiry of the term of the original patent, which became possible due to legislation peculiarities and contradictory court practice.

The problem of ensuring healthy competition in the Russian pharmaceutical market, as well as in other countries, is of key importance. The Russian competition authority, the Federal Antimonopoly Service (FAS), uses a wide range of its powers (from merger control to suppression of violations connected with unfair advertising), monitors regulatory trends abroad and actively cooperates with foreign competition authorities.

The regulator also focuses on balancing private and public interests in protecting intellectual property rights of drug manufacturers. Often, abuses of such rights by their owners have a negative impact on competition and the availability of mainstream drugs to the public. Although the FAS has limited powers to act against infringers, the regulator is actively seeking ways to prevent such abuses (through the initiative to introduce compulsory licensing or authorise parallel imports).

II LEGISLATIVE AND REGULATORY FRAMEWORK

In Russia, the main legislation providing for the authorisation, pricing, patent duration and public purchasing of pharmaceuticals is based on the Civil Code of the Russian Federation as well as on special laws, including Federal Law No. 61-FZ on the circulation of drugs, dated 12 April 2010 (Federal Law No. 61), Federal Law No. 38-FZ on the advertising of drugs, dated 13 March 2006, and Federal Law No. 135-Ф3 on protection of competition, dated 26 July 2006, and subordinate acts.

Special legislation regarding the development of innovation is also in place in Russia and includes, in particular, regulations related to the activity of the Moscow international medical cluster (Federal Law No. 160-FZ) and Skolkovo Innovation Center (Federal Law No. 244-FZ). These laws contain a set of liberalised rules with respect to companies engaged in the production and use of drugs the territory of the Moscow international medical cluster and Skolkovo Innovation Center.

Such new legal instruments as special investment contracts and offset contracts structured under Federal Law No. 44-FZ,[4] which were introduced relatively recently (2015–2016), have become effective in terms of implementing projects aimed at promoting national industry, including the localisation of the production of drugs in Russia. The legislation provides various incentives and measures of support (including compensation of certain expenses, the possibility to access funding from the Industry Development Fund at special rates, etc.) for investors that meet certain requirements established by law. The investor under a special investment contract must be approved by the government provided that certain

4 Federal Law No. 44-FZ on the contract system in state and municipal procurement of goods, works and services, dated 5 April 2013.

conditions are met (e.g., the investment should equal or exceed 3 billion roubles). Offset contracts can be concluded for up to 10 years with a minimum investment of 1 billion roubles (this type of contract was introduced in 2016).

A number of changes to Russian legislation have been made due to the spread of the covid-19 pandemic and the need to take special state measures in response. These changes include, in particular, the legalisation of the online sale of drugs (which had been discussed since 2017); new rights of the government to introduce simplified procedures for state registration and the circulation of drugs for the prevention of emergency situations or the prevention and treatment of diseases that are dangerous to people; the introduction of special procedures for state registration; and the introduction of a special drugs regime for the circulation of drugs for determining the maximum selling price for vital and essential drugs during emergencies, which will be effective until 1 January 2021, as well as the automatic renewal of registration certificates for certain drugs expiring in 2020.

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHT

i Drugs

The drug registration procedure in Russia is provided by Federal Law No. 61 on the circulation of drugs. To be distributed in Russia, a drug must go through preclinical and clinical trials and receive approval from the Ministry of Healthcare. Clinical trials have been separated from the drug licensing procedures. All drugs, except for orphan drugs, must be subject to clinical trials in Russia. The results of clinical trials conducted outside Russia can be provided when registering an orphan drug under certain circumstances.

A preclinical trial of a drug for medical use is carried out by applying scientific assessment methods to obtain evidence of the safety, quality and effectiveness of the drug. Preclinical trials are carried out in accordance with the rules of good laboratory practice, approved by Order No. 199n of the Ministry of Healthcare, dated 1 April 2016.

The practice of conducting clinical trials of drugs for medical use is regulated by Chapter 7 of Federal Law No. 61. Clinical drugs trials are carried out in one or several medical organisations in accordance with the rules of good clinical practice approved by the authorised federal executive body, for the following purposes, in particular: establishing the safety of drugs for healthy volunteers or their tolerance by healthy volunteers, or both, with the exception of such trials of drugs produced outside Russia; and establishing the safety of the drug and its effectiveness for patients with a certain disease and the preventive effectiveness of immunobiological drugs for healthy volunteers.

The organisation of clinical trials of a drug may be carried out by: the developer of the drug or a person authorised by that person; educational organisations of higher education, or organisations of additional professional education; and research organisations.

The list of medical organisations entitled to conduct clinical trials of drugs and the register of issued approvals for clinical trials of drugs are published and posted by the Ministry of Healthcare on its official website.[5]

A clinical trial of the drug is carried out on the basis of a permit to conduct a clinical trial issued by the Ministry of Healthcare, based on the results of an examination of the documents required to obtain a permit and an ethical examination.

5 https://minzdrav.gov.ru/opendata/7707778246-reestrklinicheskihissledovanii/visual.

The following drugs are subject to state registration: all drugs to be put into circulation for the first time in Russia; and medicines registered earlier, but produced in other medical forms in accordance with the list of the names of medical forms, in a new dosage with proof of its clinical significance and effectiveness.

Legislation provides for a number of exceptions when state registration of drugs does not apply. Special rules also relate to drugs used in case of war and other circumstances.

State registration of drugs is carried out according to the results of the examination of drugs. The examination of drugs for medical use includes:

a examination of documents submitted to determine the ability to consider a drug for medical use during state registration as an orphan drug;

b examination of the proposed methods for controlling the quality of the drug and the quality of the submitted samples of the drug using these methods;

c examination of the relationship of the expected benefits to the possible risk of using the drug; and

d examination of the registration dossier for the drug to determine the interchangeability of drugs for medical use.

State registration of a drug is carried out by the Ministry of Healthcare within a period not exceeding 160 business days from the date of acceptance of the relevant application for state registration of the drug.

Having received the registration certificate of the drug from the Ministry of Health, the holder or owner of the registration certificate of the drug submits to the Ministry of Healthcare a report on the results of pharmacovigilance once every six months within the first two years after state registration of the drug in Russia, annually for the next three years and then once every five years.

The rules for registration and examination of drugs for medical use within the framework of the Eurasian Economic Union are regulated by Decision No. 78 of the Council of the Eurasian Economic Commission of 3 November 2016.

The size of the state fee for the state registration of drugs and related procedures is established in the Tax Code and varies from 2,000 to 325,000 roubles. A state fee of 10,000 roubles is charged for the issuance of a registration certificate for a drug.

The state authority has the discretion to refuse to register a drug for medical use on the grounds that the quality or effectiveness of the registered drug, or both, for medical use has not been confirmed by the clinical data obtained or that the risk of harm to human health due to the intake of a drug for medical use exceeds its effectiveness application.

There is no simplified authorisation procedure for a drug already authorised in another jurisdiction or for parallel imports. A simplified registration procedure is available for orphan drugs, the first three generics of the original drug and paediatric drugs, irrespective of whether these medicines have been registered in any other country.

The state register of drugs is available at the special web portal of the Ministry of Health.[6]

Only pharmacies are authorised to distribute prescription drugs to consumers. The pharmacy must hold a licence for pharmaceutical retail activity and only pharmacies are authorised to distribute over-the-counter (OTC) drugs to consumers (retail shops are currently not allowed to sell OTC drugs in Russia).

6 https://grls.rosminzdrav.ru/GRLS.aspx.

Online sale of drugs is possible if conducted by a pharmacy, provided compliance with certain rules that were introduced in May 2020. According to new regulation, the online sale of OTC medicines (except narcotic drugs, psychedelic drugs and drugs containing over 25 per cent of ethyl alcohol) is now permitted. Online selling of prescribed drugs (except narcotic drugs, psychedelic drugs and drugs containing over 25 per cent of ethyl alcohol) is now also allowed in cases of emergency or where there is an occurrence of a threat of transmission of a disease constituting a danger to the public. The specific rules for selling prescribed drugs must be temporarily determined by the Russian government on a case-by-case basis. Such rules have not yet been developed.

Thus, online trade may be carried out by pharmacies that have a licence to carry out pharmaceutical activities, which they have held for at least one year, and provided that the pharmacy meets the established criteria, including, in particular:

a the operation of pharmaceutical activities in at least 10 places in Russia;

b the availability of premises equipped in accordance with the legislative requirements for the storage of drug orders; and

c the availability of an own courier service that has the necessary equipment to maintain the appropriate temperature for the delivery of thermolabile medicines, or a contract with a courier service that has such equipment.

However, despite the adoption of the new law and subordinate legal acts, some problem areas remain unresolved or insufficiently regulated (e.g., how an employee of a pharmacy should inform the buyer of instructions relating to the proper consumption of the relevant drug and other issues).

ii Generic and follow-on pharmaceuticals

There are two ways that original and generic drugs may be authorised for sale and distribution.

International authorisation

Russia has been a member of the EAEU since its creation on 29 May 2019, along with countries such as Armenia, Belarus, Kazakhstan and Kyrgyzstan. By Decision No. 78 of the Council of the EAEU, dated 3 November 2016,[7] the EAEU passed rules for the registration and authorisation of medicinal products for medical use (the EAEU Rules), which establish a registration process and compliance with certain requirements to authorise generic and follow-on drugs within the territories of the member states of the EAEU.

National authorisation

The procedure for national registration of all medical products is regulated by the National Regulation.

7 The EAEU Rules were implemented in Russia by Order No. 23-n of the Ministry of Healthcare of Russia, dated 25 January 2019 on the approval of the administrative regulation of the Ministry of Healthcare of the Russian Federation on providing the state service of state registration of medicinal products destined for circulation on the common market of medicinal products in the framework of the Eurasian Economic Union, in accordance with the rules for registration and expertise of medicinal products for medical use, approved by Decision No. 78 of the Council of the Eurasian Economic Commission dated, 3 November 2016.

After 31 December 2020, the authorisation of drugs will be conducted solely on the basis of the EAEU Rules. Therefore, pharmaceuticals authorised under the National Regulation must be brought in line with the EAEU Rules before 31 December 2025.

The purpose of the intended harmonisation of the National Regulation with the registration procedure contained in the EAEU Rules is to establish a single market for pharmaceuticals within the EAEU. However, pharmaceuticals registered in one Member State will not be automatically recognised in the territory of another Member State.

To facilitate effective registration across all EAEU Member States, the following procedures have been established:

a mutual recognition (which requires successive authorisation in each Member State where the drug will circulate); and

b decentralised registration (which requires registration in all relevant Member States at once, and the designation of one of those Member States as a reference).

The National Regulation stipulates a six-year period[8] during which preclinical and clinical studies are forbidden without permission of the manufacturer of the reference drug.

However, at both the EAEU and national level, the authorisation (registration) of generic drugs may be processed expeditiously without filing the results of preclinical and clinical trials, provided that the manufacturer of the relevant generic pharmaceutical undertakes a bioequivalence evaluation. The first three registration applications are eligible to be processed through the expedited procedure.

Rather than carrying out preclinical trials, the manufacturer of the generic drug may instead apply for authorisation by providing a summary of scientific publications that have reviewed existing preclinical studies of the reference drug. The right of the manufacturer of the generic drug to use public data of this kind, including scientific publications, for the purpose of applying for authorisation was confirmed in the precedential case of *Novartis v. the Ministry of Healthcare of Russia and BioIntegrator*.

Both the international and national routes to authorisation are briefly described below.

The EAEU authorisation (registration) procedure

The period of registration and expertise of a pharmaceutical product may not exceed 210 calendar days for the decentralised procedure; 210 calendar days for the procedure for mutual recognition (registration in a reference state); and 100 calendar days for the registration in the country of recognition.

There are no specifics for follow-on pharmaceuticals.

Points 48–74 (reference state) of the EAEU Rules are applicable to generic pharmaceuticals. A brief description of the stages of registration are provided below. We have not considered the impact on timing where the Ministry of Healthcare requires additional documents. All days mentioned below are working days, unless otherwise noted:

a step 1: registration of the application and set of accompanying documents (14 days);

b step 2: expertise (90 calendar days); and

c step 3: opinion and registration (20 days plus 30 calendar days).

8 Para 18, Article 18 of Federal Law on circulation of medicines (drugs).

The national authorisation (registration) procedure

Points 38–64 of the National Regulation are applicable to generic pharmaceuticals. Below is a brief description of the stages of registration.

We have not considered the impact on timing where the Ministry of Healthcare requires additional documents (another 90 days are provided for their submission, which are not included within the 160-days period):

a step 1: registration of the application and set of accompanying documents (two days). The set of documents includes, inter alia, the necessary licences of manufacturers, and pharmacological and toxicological documentation;

b step 2: verification that the application and annexes thereto are accurate and complete (seven days);

c step 3: expertise (90 days (not included in the expertise period) plus 60–110 days); and

d step 4: issue of the opinion and registration (10 days).

From the effective date of registration of the pharmaceutical, there are four years during which a generic pharmaceutical may not be registered. No exclusivity is granted to the successful generic drug applicant.

iii Biologics and biosimilars

The regulation of biologics and biosimilars is based on Federal Law No. 61 on the circulation of drugs, dated 12 April 2010. As such, Russian legislation defines biological drugs (biologics) as drugs whose active substance is produced or separated from a biological source and whose properties and quality can be determined using a combination of biological and physical-chemical methods. Biological medicinal products include immunobiological drugs, drugs made of blood, blood plasma of humans or animals (except for whole blood), biotechnological drugs and gene therapy drugs. A bioanalogue drug (biosimilar) is defined as a biological drug that is similar in terms of quality, efficacy and safety to a reference biological medicinal product in the same pharmaceutical form with an identical mode of administration.

With regard to biologicals for medical use, the applicant must also submit the results of measures provided for by the risk management plan approved by the authorised federal executive body during state registration of the medicinal product for medical use. Within the framework of the Eurasian Economic Union, special rules for conducting trials have been adopted with regard to biologics.[9]

The registration of biologics and biosimilars (and expert procedures) is subject to special rules established by Federal Law No. 61, Decree of the Ministry of Healthcare No. 558n, dated 24 August 2017, and other legislative acts.

Thus, during the state registration procedure of biosimilars (in particular, during the examination of the correlation between expected benefits and possible risks of a drug) the authorised state institution must establish the biosimilar drug's interchangeability. Determination of the interchangeability of a biosimilar is carried out taking into account the data obtained from the results of clinical trials that it does not have clinically significant differences in safety, efficacy, and immunogenicity compared to the reference drug. Moreover,

9 See the Decision of the Council of the Eurasian Economic Commission of 3 November 2016 No. 89 on the adoption of the rules for the investigation of biological medicinal products of the Eurasian Economic Union.

when determining the interchangeability of a biosimilar as a drug, instead of the 'equivalence' criterion, the 'comparability' criterion is applied. The Ministry of Healthcare plans to modernise and specify the rules on drug interchangeability.

There are no specific requirements defining the procedure for prescribing biosimilar drugs. If a biologic drug (or biosimilar drug) meets the criteria established by the Russian Civil Code with respect to patent procedure for inventions (including novelty criterion), it can be patented. A biosimilar may be registered upon the expiration of the three-year period of registration of its reference biologics drug.

The accelerated procedure for the examination of drugs is not applicable to biosimilars.

Companies such as Biokad and Gerofarm are among the Russian companies engaged in the production of biosimilars in Russia.

Overall, the regulation of biologics and biosimilars in Russia requires developments and needs to be improved in terms of best international practices.

IV PATENT LINKAGE

i The early authorisation procedure for generic drugs

In Russia, the manufacturer's right to authorise a generic drug before the expiration of the term of the original patent, known as early authorisation, is a controversial topic.

The term of a pharmaceutical patent is 20 years from the filing date of the application (with an option to extend up to five years).

Legislation explicitly forbids the early authorisation of pharmaceuticals during the period of market exclusivity, which is four years for generic drugs from the date of authorisation of the reference drug in Russia.

In the case *Technologia Lekarstv LLC v. the Ministry of Healthcare of Russia*, the court stated that the generic drug 'Emtricitabine-TL' cannot be registered during a period of market exclusivity. The court also stated that bioequivalence evaluations cannot be carried out during this period. A similar position was taken in the case of *Pharmasyntes JSC v. the Ministry of Healthcare of Russia* in 2017.

Save for early authorisation during a period of market exclusivity, courts have mainly supported the position of generic drug manufacturers, having repeatedly refused to determine the early authorisation of generic drugs as a violation of original patent rights. In a number of cases, courts have stated that only the early trade of generic drugs (a trade before the expiry of patent term), but not early authorisation itself, shall constitute a violation of patent rights.

However, in the 2019 case of *Astrazeneca UK v. Jodas Expoim*, the Supreme Court considered that the early authorisation of a generic drug containing the patented reactant 'gefitinib' constituted a threat to the claimant's patent rights. It was stated that the authorisation of a generic drug was done in preparation to trade.

The same year, the Ministry of Public Health and Social Development of the Russian Federation proposed amendments to the Federal Law on circulation of medicines (drugs). According to these amendments, early authorisation of generic pharmaceuticals must be suspended until the expiry of patent rights. The amendments have provoked wide discussion among market players on both sides. Early authorisation enables the manufacturers of generic drugs to start trading immediately after the expiry of the relevant patent, which is critical for manufacturers of generic drugs. At present, the amendments remain under consideration by the government and have not yet been sent to the floor of the state Duma.

ii The early authorisation procedure for generic drugs in the EAEU

Corresponding regulation that defends patentees from early authorisation of generic drugs already exists in the EAEU Rules. According to the EAEU Rules, a manufacturer of generic pharmaceuticals must provide information in its application as to the existence of a patent in EAEU territory. If such a patent exists, an applicant should provide a copy of the patent or a copy of the licence agreement entered into with the patentee. Moreover, applicants must provide a letter indicating that the intellectual property rights of any third persons protected by a patent or transferred under a licence will not be violated by the authorisation of the particular generic drug.

Registration in accordance with the EAEU Rules is currently used in Russia alongside the authorisation procedure that is governed by the National Regulation. However, starting from 2021, the EAEU Rules will be applied solely (see Section III 'National authorisation').

Compulsory licensing

Another way to avoid patent exclusivity for the manufacturer of a generic drug is to obtain a compulsory licence during the trial procedure.

Currently, it is only possible to obtain a compulsory licence in a limited number of situations, as follows:

a when the patent is insufficiently used by the rights holder within four years of the registration (which leads to insufficient supply of goods on the market); or

b when the holder of the original patent for the invention refuses to enter into an agreement with the owner of a patent for a supplementary invention, which results in the latter's paralysis such that it cannot be used.

Compulsory licences to the drug producers in the above-mentioned situations were granted in a very few cases (e.g., *Celgene Corporation v. LLC Nativa* (for the drug Lenalidomide) and *Pfizer v. LLC Nativa* (for the drug Sunitinib)).

The manufacturer of the generic drug must prove that it possesses the necessary production capacity and that it had attempted to obtain the patentee's permission.

When objecting to the grant of a compulsory licence, the patentee is entitled to prove that the patent is in use or that there is a justifiable reason for its non-use.

In the case of *Sugen LLC, Pharmacia & Upjohn Company LLC v. Nativa LLC*, the claim of Nativa LLC for the grant of a compulsory licence was upheld. Among the reasons for granting the licence were the economic merits of the generic drug potentially being sold at a considerably lower price than would be the case under patent exclusivity. In spite of this decision, the practice of granting compulsory licences has not yet become widespread in Russia.

In addition to granting a compulsory licence, the government may grant permission to use a given patented object without the patentee's permission if it is done in the interests of national security and defence.

There is currently a bill under consideration to amend Article 1360 of the Civil Code. The proposed bill states that the above-mentioned permission only be granted if absolutely necessary for the protection of citizens' right to life and healthcare. In such a case, the amount of compensation owed to the patentee will be set by the government.

V COMPETITION ENFORCERS

In Russia, competition enforcement is vested in the FAS. However, the powers of the FAS include not only control over compliance of the economic entities with the competition law,[10] but also cover a number of other areas.

In the pharmaceutical sector, the following powers of the FAS are applicable:

a control over entities occupying a dominant position in the markets and prevention of abuse of their dominant position (e.g., when the owner of a patent for a unique drug sets monopolistic prices in Russia, compared with the prices for the same drug in other countries);

b detection and suppression of cartels, 'vertical' and other agreements resulting or likely to result in limitation of competition (e.g., collusions of monopolist suppliers in public procurement tenders organised by the government, price fixing and division of markets between the distributors of the drugs);

c merger control (e.g., in cases of multi-jurisdictional mergers of pharmaceutical companies having presence or turnover in Russia, or when a major pharmaceutical company acquires a Russian producer or distributor of drugs);

d identification and investigation of cases of unfair competition (e.g., when a company sells its drug under the guise of a more popular competitor's drug, or a pharmaceutical company discredits the products of another company to boost the sales of its own drug);

e investigation and enforcement connected with violations of advertising law (e.g., when a drug producer communicates misleading or false statements regarding the effectiveness of the drug against specific diseases); and

f control over public procurement procedures (in cases of violations of bid-submission procedures by the suppliers of drugs and medical equipment during the procurement procedures, refusal to compete for a bid with each other, etc.).

The FAS also has a specific function of monitoring the process of granting state and municipal preferences (specific incentives granted by public authorities to various economic entities for purposes expressly provided by law, such as for conducting scientific research).

The FAS's priorities in regulation of pharmaceutical sector can be summarised as follows.

i Ensuring availability of and fair prices for mainstream drugs (including innovative drugs)

This goal is particularly important in the context of the covid-19 pandemic.

In this field, the FAS has shown a particular interest recently to the development of mechanisms aimed at the limitation of intellectual immunities of manufacturers that abuse their intellectual rights especially in relation to the high-demand drugs.

One of the most important such mechanisms is compulsory licensing,[11] which allows the regulator to limit the rights of patent holders in the public interest.

10 Federal Law No. 135-FZ on protection of competition, dated 26 July 2006.

11 As stated in the Report on the State of Competition in Russia 2019, p. 37, published on 17 July 2020 at https://fas.gov.ru/documents/686911.

At present, Russian legislation contains limited mechanisms allowing the government to authorise the production of a drug in Russia despite the original drug owner's patent rights. In view of the FAS, this may create issues where a foreign patent owner unreasonably increases its prices or refuses to supply a particular drug to Russia.

The FAS has developed a draft law to amend Article 1360 of the Russian Civil Code so as to make it possible for the government to decide to use an invention without the consent of the owner of the patent in the case of urgent need related to the protection of the lives and health of citizens. The draft law is currently considered by the state Duma.[12]

Another mechanism being discussed in the context of the provision of essential drugs is parallel imports, which may currently be restricted in Russia by the original product owner. The FAS has been advocating a liberalisation of parallel imports, arguing that it could allow more suppliers to enter the markets of such new goods, including drugs, without the need to obtain consent from the right holders and eventually ensure fair prices for them.

ii Ensuring effective state control over prices for vital and essential drugs

The FAS acts as a regulator of prices for vital and essential drugs (VED); for instance, it agrees upon ex-works prices with the manufacturers of drugs, and sets up limits for wholesale and retail increments on them. The FAS has recently developed new rules for registration and re-registration of manufacturers' maximum ex-works prices for drugs included in the list of VED.[13] The government decree with the relevant rules entered into force on 17 December 2019, and by 23 January 2020 the FAS has already agreed upon the first price for the Hungarian-made reference drug bromocriptine.[14]

iii Countering abuses and other unlawful acts occurring in the course of public procurement processes

In this area, the FAS is often faced with violations that lead to limitation of competition at public auctions (e.g., violations of procurement documentation requirements and contract execution procedures, and unlawful modification of contract terms).

But the most significant harm to competition in public procurement, particularly in the sector of pharmaceuticals and medical equipment, is caused by cartels and anticompetitive agreements with state customers. The FAS aims to ensure an uninterrupted supply of drugs necessary for the state at fair prices. In recent years, the number of cartel-related cases for the supply of drugs or equipment has only been increasing. For instance, the FAS has recently initiated the following cases: the case in relation to four regional suppliers of drugs and medical equipment and the regional Ministry of Healthcare (referred to as the 'Dagestani

12 See: https://sozd.duma.gov.ru/bill/842633-7.

13 Federal Law No. 134-FZ on amendments to Federal Law on medicine circulation, dated 06 June 2019, with regard to state regulation of prices for drugs included in the list of vital and essential drugs, as well as Decree No. 1683 of the Government of the Russian Federation, dated 16 December 2019, which has also been developed at the initiative of the FAS.

14 See, the Decision of FAS dated 23 January 2020: https://br.fas.gov.ru/ca/upravlenie-kontroly a-sotsialnoy-sfery-i-torgovli/f37cad50-84f4-4a53-9abf-3cf7d81dbcc6/?query=%D0%B1%D1%80%D0% BE%D0%BC%D0%BE%D0%BA%D1%80%D0%B8%D0%BF%D1%82%D0%B8%D0%BD.

cartel' case in the media);[15] the case against two affiliated companies that maintained prices at various public auctions between 2016 and 2018[16] (see Section VII.iii); and cases involving the National Medical Research Centre named after E Meshalkin's clinic,[17] and others.

iv Fighting against cartels and other anticompetitive agreements

The pharmaceutical industry in Russia was ranked second[18] in 2019 by the number of anticompetitive agreements identified by the FAS. According to FAS statistics, the majority of anticompetitive agreements are concluded in the process of public procurement, where the FAS has significant powers of control (see above).

While fighting against cartels, the FAS actively cooperates with investigative authorities of the Ministry of Internal Affairs and the Investigative Committee (e.g., via participation in inspections, and preparation of materials on the basis of which criminal cases are initiated against individual involved in cartels).

v Fighting against unfair competition in the context of the covid-19 pandemic

Just as many other governmental agencies in 2020, the FAS has taken certain measures in connection with the covid-19 outbreak.

The FAS has been actively fighting with various abuses of market players in connection with the pandemic (e.g., monopolistically high prices for medical protective equipment).[19]

However, where relevant (e.g., in the area of control over procurements connected with the prevention and relief of consequences of the covid-19 outbreak),[20] a number of relaxations have been introduced.

The regulator also decided to grant a three-month deferral for payments of administrative fines imposed on companies by the competition officials between April and June 2020.[21]

VI MERGER CONTROL

Over the past two years, the FAS has reviewed and approved 16 multi-jurisdictional mergers in the pharmaceuticals sector.[22] In 11 cases, the FAS made its approval conditional; for instance, the FAS granted clearance subject to specific remedies aimed at reducing negative effects from limitation of competition in the market.[23]

15 https://fas.gov.ru/news/29426.

16 https://fas.gov.ru/publications/20159.

17 https://fas.gov.ru/news/29904.

18 See draft Report on the State of Competition in Russia 2019, p. 42.

19 Thus, for example, the Moscow Regional office of the FAS together with the Prosecutor's Office have recently identified and suppressed a tenfold increase in prices on medical masks set by one of the regional wholesalers. See: https://en.fas.gov.ru/press-center/news/detail.html?id=54916.

20 https://fas.gov.ru/ckeditor_assets/attachments/1102/sovmestnoe_pismo_mf_mchs_fas_pdf.pdf.

21 https://fas.gov.ru/news/29843.

22 As commented by Nadezhda Sharavskaya, deputy head of the Department for Control over Social Sphere and Trade of the FAS, at the meeting of the BRICS working group and international working group on research of competition problems at the pharmaceutical market on 13 March 2020. See www.hse.ru/news/expertise/348913648.html.

23 While reviewing the mergers, the FAS has increasingly used waivers of confidentiality in interaction with foreign competition authorities. See, Recommendations of the Presidium of FAS 'On applying waivers of confidentiality when considering merger control transactions' as approved by the minutes of the Presidium of FAS No. 2, dated 13 March 2019.

One of the most recent international transactions reviewed by the FAS was the acquisition of a controlling stake in an Indian drug producer, JB Chemicals & Pharmaceuticals, by KKR, an investment company. The Russian part of the transaction pertained to the acquisition of rights in LLC Unique Pharmaceutical Laboratories by a subsidiary of KKR and was approved by the FAS.[24]

A noteworthy recent transaction in the domestic market was the acquisition of JSC Sintez and JSC Biocom by JSFC Sistema (2019). Completion of the transaction, which took place in August 2019, required FAS consent. JSFC Sistema is reported to be planning to incorporate the acquired companies into Alium – an integrated pharmaceutical company, which is expected to have a product portfolio of more than 500 drugs and to become one of the major companies in Russia's commercial pharmaceutical market.[25]

Decisions of the FAS on approval of mergers are often not available to the public. Even if available, it is usually impossible to learn from them the considerations taken into account by the FAS for each merger, unless the FAS made its consent conditional on the execution of its order containing specific remedies to be taken by the merging parties. However, such orders of the FAS are also rarely available.

One of the few recent examples (although not in the pharmaceutical sector) where the FAS published orders with detailed remedies to be taken by the parties is the famous *Bayer/Monsanto* merger decision of 2018.[26]

In the pharmaceutical sector, the FAS issued notable orders to the following transactions.

Approving the merger of Russian divisions of Johnson & Johnson and Actelion (2017), the FAS established that Actelion Pharmaceuticals Rus was the sole holder of rights for certain drugs in the Russian market. Since the position of the company was dominant in the relevant markets, the FAS concluded that the merger could limit market access to other players and lead to market abuse. Accordingly, the FAS instructed the acquirer to develop and publish on its website the requirements for its counterparties, and the terms for concluding supply agreements with them. The acquirer was also required not to discontinue production or sales of the above-mentioned drugs if these were demanded.[27]

With respect to the acquisition by San Pharmaceutical Industries, a major Indian generic manufacturer, of the Russian company JSC Biosintez (2016), the FAS issued a similar order.[28] For San Pharmaceutical Industries, the transaction provided access to the production base of a wide range of dosage forms and allowed the effective saturation of the Russian market with its goods.

As can be seen from the above, the currently existing criteria for assessment of transactions by the FAS are mainly aimed at preventing the abuse of the dominant position by the producers of original drugs.

24 See: https://br.fas.gov.ru/ca/upravlenie-kontrolya-sotsialnoy-sfery-i-torgovli/5c5a5a7e-6a28-493a-b78e-7085d51c62ec.

25 See, the press release of the seller of Sintez and Biocom, Marathon Group: https://marathongroup.ru/070619.

26 https://en.fas.gov.ru/press-center/news/detail.html?id=52417.

27 https://fas.gov.ru/documents/527239.

28 See, the Report on the competition policy of the Russian Federation in 2016 for the OECD, p. 15: https://fas.gov.ru/attachment/153236/download?1515591913, and the Decision of FAS dated 12 December 2016: https://fas.gov.ru/documents/496705.

The FAS has recently been paying increasing attention to the problem of 'killer acquisitions'.[29] The term refers to acquisitions by large companies of start-ups for the purpose of terminating their operations or integrating new companies into their value chains. Killer acquisitions became a topic for a recent discussion at the OECD session on the conglomerate effects of mergers and start-ups (organised by the FAS)[30] especially because they quite often fall outside the ambit of the regulator's review and the regulator would like to have more visibility in this area.

VII ANTICOMPETITIVE BEHAVIOUR

i Abuse of dominance

In the pharmaceutical sector, the FAS mostly deals with abuses of dominant position by manufacturers of original drugs, cartels, other types of anticompetitive agreements, various forms of unfair competition and violations of the advertising law in relation to the drugs.

In the field of intellectual property, the FAS has the right to prevent unfair competition where it relates to the acquisition and use of the exclusive right to a company's means of individualisation; and illegal use by the producers of competitors' intellectual property when introducing their products to the market.

However, the FAS powers are limited if the anticompetitive behaviour involves the actions of drug manufacturers abusing their own patent rights. The FAS came up with the initiative of entitling the government with the power to allow compulsory licensing when there is a need to protect the lives and health of citizens.

Currently, the possibility of obtaining a compulsory licence in Russia is limited to the situations described in detail in Section IV.

Arguably, existing licensing mechanisms are not always suited to cases where drug manufacturers abuse their patent rights. Those advocating a wider use of compulsory licensing (including the FAS and certain domestic industry players) are claiming that this should serve the interests of the public.

ii Other anticompetitive behaviour and agreements

With respect to other common types of anticompetitive behaviour, the FAS has a different approach.

In December 2018, the FAS issued a warning to a Latvian producer SIA Tamro on inadmissibility of abusing its dominant position on the market of a drug for the treatment of chronic hepatitis called Sovaldi. SIA Tamro was held to have unjustly refrained from the conclusion of an agreement with the Russian company R-Pharm to supply the drug. After the warning was issued, the company returned to negotiations with R-Pharm.[31]

There have recently been cases where the facts of such abuses as established by the FAS were successfully challenged by the drug producers in court. This was the case with Novartis

29 See, for example, the comments of Alexey Ivanov, director of the BRICS Antimonopoly Centre, made at the meeting of BRICS working group and international working group on research of competition problems at the pharmaceutical market on 13 March 2020: www.hse.ru/news/expertise/348913648.html.

30 https://fas.gov.ru/news/29978.

31 A similar case in which, however, the warning of FAS was not executed was Teva v. Biotech (2013). Teva refused to supply the Copaxone drug to CJSC MFPDK Biotech (the company intended to import it through its own subsidiary in Russia). FAS required Teva to resume negotiations with Biotech, but Teva

Pharma's establishment of prices for the Tyverb drug. The FAS found that the increase of the price for the drug by more than 35 per cent of the previously set price was unjustified and considered it as monopolistic price fixing. The courts, however, took Novartis's side in this case. They concluded that the regulator, while analysing the case, had not identified substitutes to Tyverb, and this fact distorted the regulator's idea about the product's market borders. In addition, when rendering its decision, the FAS was guided by the calculation of the price for Tyverb, which was based on the sales plan for 2016 and the data from the previous seller of Tyverb, which did not reflect the actual profitability of the product's sales. The courts stated that the price of the drug should reflect, among other things, promotion, sales and management costs. Therefore, the regulator's decision was reversed.

iii Public procurement cartels

Cartels and vertical agreements in the pharmaceutical sector are very commonly revealed in public procurement procedures.

One of the notorious recent cases within this field, is the case in relation to four regional suppliers of drugs and medical equipment and the regional Ministry of Healthcare (2019).[32] The FAS identified a collusion between formally unaffiliated suppliers[33] that jointly participated in regional public tenders for several years, and price-fixing arrangements between the suppliers and regional authorities represented by the Dagestani Ministry of Healthcare. Having established these arrangements and analysed other evidence common to cases involving anticompetitive agreements (identity of IP addresses of all suppliers, relevant email correspondence, changes made by the authorities in the volume of products to be supplied, etc.) The FAS held all four suppliers liable to fines of 253 million roubles in aggregate, while the cartel's revenues exceeded 2 billion roubles.

Article 11 of the Competition Law provides for an exception from the rules on liability for anticompetitive agreements if these are concluded between members of one group, and one member controls the others. In this context, the interpretation of control given by the FAS in *FAS v. CJSC Firma Euroservice and LLC Mega Pharma* (2019)[34] case.

The FAS found that companies have colluded to maintain prices at electronic auctions for the purchase of drugs for state medical institutions for several years. Firma Euroservice referred to Article 11 and argued that it owned 60 per cent of the shares in Mega Farm under a trust agreement, namely that it had control over Mega Farm. The FAS, however, concluded that since there was no transfer of ownership to the stake under the contract, there was no control over Mega Farm in the meaning of Article 11. This approach was later confirmed by the courts. Experts consider this case to be a precedent, as it essentially formed the concept of control applicable to the analysis of admissibility of anticompetitive actions between affiliated entities.

failed to comply with the regulator's warning. The company was held liable to an administrative fine of 300,000 roubles. Following this, Biotech recovered another 408 million roubles from Teva in the form of lost profits.

32 The Decision of the Commission of FAS No. AC/11390/19 dated 15 February 2019.

33 More precisely, only two of the suppliers were members of one group.

34 The Decision of FAS No. 1-11-183/00-22-18 dated 20 February 2019.

iv Unfair competition (marketing)

Most unfair competition practices include deceptive practices (commonly including violations of advertising law) and the creation of confusion with competitors' products.

Manufacturers of nutritional supplements are increasingly accused of creating confusions with the drug producers. Although the markets of drugs and nutritional supplements do not coincide,[35] producers of nutritional supplements in developing products that look similar to known drugs can gain advantages over other nutritional supplements' producers. Thus, in 2019 the FAS sent a warning to LLC Kvadrat, a producer of 'Fermentosim Forte' supplement, which looked similar to the drug called 'Mesim Forte'.[36]

Also, attention should be given to actions aiming at having the consumers of drugs deceived of the features of the drugs in question. If deception is made through advertising, the FAS has the right to hold violating companies liable for breaching the advertising law.[37]

The number of violations in advertising of drugs for 2019 amounted to only 4.42 per cent of all violations in advertising.[38] However, given the covid-19 outbreak, some drug manufacturers began to communicate information about effectiveness of their drugs in the treatment of covid-19 to the public to increase their sales. The FAS immediately reacted to such actions. Thus, at the end of April 2020, the Moscow regional office of the FAS issued a warning against LLC Brand Pharm and LLC Alvils for posting a letter on Brand Pharm's website containing information about the effectiveness of 'Allokin Alfa' against covid-19. The regulator warned LLC Brand Pharm against such allegations on the network. Similarly, an order was issued for JSC OTCPharm to cease the radio advertisement of 'Arbidol', a drug stating its efficacy against the disease.

VIII OUTLOOK AND CONCLUSIONS

There are strong plans to develop the pharmaceutical industry in Russia in the coming years. Thus, a number of strategic documents have been adopted to increase the share of domestically produced drugs to treat many diseases. Although some barriers remain for development in the pharmaceutical area, there are a number of measures of state support

35 Although drug producers do not always share this position. For example, it was recently reported about the intention of JSC 'Polisorb' to appeal against the decision of the FAS, according to which the FAS refused to consider the actions of LLC 'Farmfabrika' on the use of package design, confusingly similar to the design of the Polisorb drug, in the production of its dietary supplements as acts of unfair competition. JSC 'Polisorb' believes that drugs and nutritional supplements essentially occupy the same market. See: https://pharmvestnik.ru/content/news/Polisorb-gotovit-isk-k-FAS-Rossii-v-Arbitrajnyi-sud-Moskvy.html.

36 LLC Kvadrat refused to comply with the warning of the FAS. The producer of 'Mesim Forte', Berlin-Chemie AG, subsequently filed a claim against LLC Kvadrat to disallow the latter from using the package design similar to the package design of Mesim. In substantiating its position, Berlin-Chemie AG referred to the warning of the FAS previously issued to LLC Kvadrat. However, it has recently been reported that the Intellectual Property Court took the side of LLC Kvadrat and concluded that Berlin Chemie's claims were unsubstantiated (many producers of digestion improvement products use stomach images, check marks and the same fonts as those used by Berlin-Chemie). See: https://pharmvestnik.ru/content/news/Sud-po-intellektualnym-pravam-ne-uvidel-shodstva-mejdu-nemeckim-lekarstvom-i-rossiiskim-BAD.html.

37 Federal Law No. 38-FZ on advertising, dated 13 March 2006.

38 According the FAS report on results of state supervision over compliance with the Russian advertising law for 2019: https://fas.gov.ru/pages/rezultati_raboti_v_reklame.

for the production of drugs, and the number of public-private partnerships and cooperative relationships is growing. Legislation related to the online sale of pharmaceuticals is also expected to be further developed.

The pharmaceutical sector is and will remain one of key priorities of competition regulation in Russia.

In the pharmaceutical sector, the objectives of the FAS have recently been to ensure the availability and fair prices of mainstream drugs, endure effective state control over prices for vital and essential drugs, counter anticompetitive behaviour in the course of public procurement processes, fight against cartels and other anticompetitive agreements in the sector more generally and also combat unfair competition in the context of covid-19. The FAS has been quite active in opening up investigations and taking actions against the infringers. In many cases, approaches adopted by the regulator were challenged in courts.

Recently, compulsory licensing has become a popular topic in the pharma sector and the FAS has been seen as a supporter of it. It is expected that the use of compulsory licences could help deal with the issue of unfair prices especially for drugs in high demand. At the same time, some players in the industry are concerned about a potentially negative impact that a wider use of compulsory licensing could have, especially for new entrants to the Russian market, since it may equally lead to less innovative drugs being launched in the local market. The real implications of this initiative are yet to be seen. The liberalisation of parallel import is another task that the regulator has set for itself although this initiative has equally faced a lot of criticism in the industry by some players.

In the future, we expect the regulator to adopt innovative approaches in establishing dominance and anticompetitive agreements, and concerted practices to keep up with evolving trends in the industry. To this end, we hope to see the regulator enhancing the quality of its economic analysis in the coming years. This would give it a better understanding of any potential impact that unilateral conduct, agreements or mergers by key pharma players may have on the market and consumers. This would also enable the regulator to offer effective remedies tailored to specific circumstances in which such conduct, agreements or mergers are taking place.

Appendix 1

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Evgeny Yuriev is a corporate and M&A partner and head of competition and regulation in Moscow.

Evgeny has been advising both international and domestic clients on all aspects of cross-border M&A transactions, joint ventures and corporate restructurings. Among his clients are major Russian companies and international investors. He has got particular experience in energy, pharma, automotive, TMT and other sectors. Evgeny is also in charge of the regulatory offering in our Russian practice. His regulatory expertise includes advising major international investors and Russian companies on industry-specific regulation, foreign direct investments, antitrust and merger control, and many other areas.

Evgeny has a PhD in law and has been practising law since 2005. He is a frequent speaker at legal conferences and is consistently ranked by *Best Lawyers* in the categories of corporate law, antitrust, and regulatory matters and in other legal directories.

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ISBN 978-1-83862-484-2