

THE UNIVERSE OF PHARMACEUTICAL TRADEMARKS IN RUSSIA 2021

David Aylen



GOWLING WLG



David Aylen

Managing Partner, Gowling WLG

Russia/CIS

e. david.aylen@gowlingwlg.com

t. +7 (495) 502 1250

David Aylen is an internationally renowned intellectual property lawyer with extensive experience advising foreign companies on the procurement and protection of intellectual property rights in Russia, the CIS countries and Canada. His areas of specialization include strategic IP advice and complex cross-border IP litigation, trade secrets as well as strategic patent and trademark portfolio management.

Repeatedly recognized as a leading IP lawyer by *Who's Who Legal*, *IAM Patent*, *Managing Intellectual Property* and *World Trademark Review*, he regularly serves as an adviser to major global corporations in pharmaceutical, biotechnology, telecommunications and manufacturing based industries.

As managing partner of Gowling WLG's Russia/CIS practice, David is a client's first point of contact to the Russian market. He provides strategic, practical legal advice on a full range of IP issues and is known for providing timely, responsive service and delivering innovative solutions that achieve results.

Having practised in Canada for many years, David has acted as senior counsel on numerous landmark intellectual property cases in Canada. He is also the only INTA-certified Alternative Dispute Resolution expert in Russia.

This paper was originally co-authored in 2018 with Ryan Kleinman. Ryan is currently practising law in Canada. Since that time it has been regularly updated and edited with the kind assistance of Denis Kolesnikov, a lawyer practising in Moscow, Russia. My sincerest thanks to both Ryan and Denis.

© 2021 copyright Gowling WLG International Inc.

CONTENTS

I. OVERVIEW	1	3.1.4.4 Designations Confusingly Similar to a Company or Trade Name	9
II. ECONOMIC OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN RUSSIA	2	3.1.5 Consequences of Non-Use	9
2.1 The Economic Climate in Russia in Regards to "Multinational" Pharmaceuticals	2	3.1.6 Civil Liability for Trademark Infringement	10
2.2 Pharma 2020 and the Development of the Russian Pharmaceutical Market	3	3.2 Pharmaceutical Trademarks: ROSPATENT Practice, Procedures and Regulations	10
2.3 Preferential Procurement of Locally Produced Medicines	4	3.2.1 Russian Ministry of Healthcare Guidelines for Naming Medicines	10
2.4 Draft Pharma 2030	4	3.2.1.1 Principles for Naming a Medicine	10
2.5 The Effect of Sanctions on the Russian Pharmaceutical Industry	4	3.2.1.2 Constructing Names for Pharmaceuticals	12
		3.2.1.3 Principles for Determining Trademark Similarity	13
		3.2.1.4 Trademark Names and International Non-proprietary Names	13
III. THE LEGAL FOUNDATION FOR THE PROTECTION OF TRADEMARKS IN RUSSIA	6	3.2.2 Russian Ministry of Healthcare Mandatory Rules for Naming Medicines	13
3.1 Part IV of the Civil Code	7	3.2.3 Recent Decisions of the Chamber for Patent Disputes on Pharmaceutical Trademarks	15
3.1.1 The Basic Trademark Provisions in the Civil Code	7	3.2.3.1 The Guard	15
3.1.2 Trademark Rights and Legal Protection	7	3.2.3.2 NanoXray	15
3.1.3 Trademark Practice & Procedure	7	3.2.3.3 Progressa/Librax	15
3.1.4 Grounds for Rejecting a Pharmaceutical Registration	8	3.2.3.4 Beta-Calcij	15
3.1.4.1 Lack of Distinctiveness (designation without distinguishing capability)	8	3.2.3.5 Loractiv	16
3.1.4.2 Designations with False or Misleading Elements	8	3.2.3.6 Epigenorm Forte	16
3.1.4.3 Designations Confusingly Similar to a Registered Trademark	8	3.2.3.7 Myramistin	16

CONTENTS

3.3	Criminal Code of the Russian Federation	17	5.2.1	Legislative Measures Directed at Combating Pharmaceutical Counterfeiting	24
3.3.1	Illegal Use of a Trademark (Article 180 of the Criminal Code)	17	5.2.1.1	Part IV of the Civil Code of the Russian Federation	25
3.3.2	Federal Law No.352-FZ Pharmaceutical Trademarks	17	5.2.1.2	The Competition Law (135-FZ) of July 26, 2006	25
IV.	DECISIONS FROM THE IP COURT AND THE SUPREME ARBITRATION COURT	18	5.2.1.3	Code of Administrative Offences (195-FZ) of December 30, 2001	25
4.1	The Supreme Arbitration Court: "KARNITON"	19	5.2.1.4	The Law on Customs Regulations in the Russian Federation (311-FZ) of November 27, 2010 and the Customs Code of the Customs Union	26
4.2	The Supreme Arbitration Court: "VECHERNIE"	19	5.3	Counterfeit Pharmaceuticals and Russian Criminal Law	26
4.3	Intellectual Property Court: "ХОНДРОЛОН (Hondrolon)"	20	5.3.1	Recent Changes to Russian Criminal Law on Counterfeit Pharmaceuticals	26
4.4	The Seventh Court of Appeal: "Холосас Cholosas"	20	5.3.2	Enforcement of the New Legislation	28
4.5	The Intellectual Property Court: "Bravadin"	20	5.3.2.1	Criminal Cases	28
4.6	The Intellectual Property Court: "АСД" (ASD)	21	5.3.2.2	Administrative Cases	28
V.	COUNTERFEIT PHARMACEUTICALS	22	5.3.3	Other Sources of Criminal Liability for Counterfeit Pharmaceuticals	29
5.1	General Overview of Counterfeit Pharmaceuticals in Russia	22	5.3.3.1	Illegal Use of a Trademark (Article 180 of the Criminal Code)	29
5.1.1	What are Counterfeit Pharmaceuticals?	23	5.3.3.2	Additional Criminal Offences	29
5.1.2	Counterfeit Pharmaceuticals in Russia	23	5.4	Mechanisms in Russia to Prevent Dissemination of Counterfeit Pharmaceuticals	29
5.1.3	Counterfeit Trade of Pharmaceuticals: What are the Consequences?	24	5.4.1	Roszdraznadzor	29
5.2	Anti-Counterfeiting and Trademark Enforcement	24	5.5	The Common Barriers to Anti-Counterfeiting Enforcement in Russia	30

CONTENTS

5.6	Online Pharmacies and Counterfeit Pharmaceuticals	30	6.3.1.5	Criminal Liability for the Unlawful Use of a Trademark	38
5.6.1	Online Pharmacies in Russia and around the Globe	31	6.3.2	Exhaustion of Rights in Russian Legislation	38
5.6.2	The Legality of Online Pharmacies in Russia	32	6.3.3	Case Law on Parallel Importation: Before the Sony V. PAG Case	38
5.7	Introduction of the Track-and-Trace System	33	6.3.3.1	Parallel Importation: the Porsche Case	38
VI.	THE PARALLEL IMPORTATION OF PHARMACEUTICALS IN RUSSIA	34	6.3.3.2	Parallel Importation: Case Law after the Porsche Case	39
6.1	Background	34	6.3.4	Case Law on Parallel Importation: Sony Corp. V. PAG and Afterwards	40
6.1.1	What is Parallel Importation?	34	6.3.4.1	Sony Corp. V. PAG	40
6.1.2	The Doctrine of Exhaustion of Rights	35	6.3.4.2	Sony V. PAG	42
6.2	The Parallel Importation Debate	36	6.3.5	The Eurasian Economic Union	42
6.2.1	The Arguments in Favour of Parallel Importation	36	6.4	The Changing Legal Environment for Gray Markets in Russia	42
6.2.2	The Arguments against Parallel Importation	36	6.5	The Regional Common Economic Space trademark	43
6.3	Parallel Importation: the Current Legal Situation in Russia	37			
6.3.1	Trademark Rights and Pharmaceutical Importation	37			
6.3.1.1	Part IV of the Civil Code & Importation	37			
6.3.1.2	The Competition Law of the Russian Federation	38			
6.3.1.3	Civil Liability for the Unlawful Use of a Trademark	38			
6.3.1.4	Administrative Liability for the Unlawful Use of a Trademark	38			



I. OVERVIEW

In this comprehensive report, now in its third edition, we present a detailed and current review of the trademark aspects of the pharmaceutical industry in Russia today – a market that Deloitte valued at almost 30 billion USD in a [recent study](#).

At an accelerating pace over the last decades, there has been a strong mandate to establish an effective and innovative pharma industry in Russia that will stand and succeed on its own. This has left multinational innovators wondering what long-term term presence they could hope to have in Russia. Observers and participants see dynamic changes and long-ranging opportunities, but these are also weighed against a backdrop of possible further sanctions and counter-sanctions, Russian economic stagnation, and other challenges.

In 2009, the Russian government introduced its ambitious “Pharma 2020” plan to develop and foster innovation and the localization of the Russian pharmaceutical market. Among other things, this incentivized international pharma companies with long-term interests in Russia to localize production. It also clearly guided the market to reshape in favor of locally produced medicines.

In 2018, Pharma 2020’s successor, “Draft Pharma 2030,” was unveiled, identifying key problems remaining in the industry, and pushing a still more aggressive localized and innovation

program. It allocates funds for the further development of the Russian pharmaceutical sector, for example, not only for the localized production of the medicines themselves, but for every aspect of their manufacture.

COVID-19 has of course compounded the government’s determination to push its localization agenda forward and to move quickly on many other healthcare-related initiatives, such as online pharmacies. Here, we examine where things now stand with Pharma 2020, as well as the ground being rapidly laid for Pharma 2030.

This review begins with an economic overview of the pharmaceutical industry in Russia and the drive for growing the market of locally produced medicines. It then takes a detailed look at the legal foundations for the protection of trademarks in Russia, followed by a guide to recent decisions by Russia’s IP Court and the RF Supreme Arbitration Court. Next, it examines the counterfeit pharmaceuticals market, as well as the ongoing anti-counterfeit effort to fight it. Finally, there is an analysis of the parallel importation of pharmaceuticals in Russia and concerns about what the possible legalization of parallel importation could mean for the pharma sector.

A large, colorful photograph of St. Basil's Cathedral in Moscow, Russia, featuring multiple onion-shaped domes in various colors like red, green, and gold. The image is set against a blue sky and is framed by a large, semi-transparent white circle. The background of the entire page is a gradient of blue and purple.

II. ECONOMIC OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN RUSSIA

> 2.1 THE ECONOMIC CLIMATE IN RUSSIA IN REGARD TO MULTINATIONAL PHARMACEUTICALS

Russia is geographically the largest country in the world and has a population of over 140,000,000 people. Consequently the Russian Federation poses an attractive opportunity for expansion of a multinational business. The Russian pharmaceutical industry is one of the fastest growing industries in the world and the largest market on an absolute basis in the Central and Eastern European (CEE) region. In 2018, per capita spending on medicines was \$140 per person, placing Russia 17th out of 32 CEE economies www.export.gov/article?id=Russia-Pharmaceuticals

In 2017, the Russian pharmaceutical market grew by 7.9% in rubles and by 5.9% in volume terms according to a Deloitte report. In 2018 the Russian pharmaceutical market value reached 1,682 billion rubles (27.5 billion USD), which is 2.6% higher than in 2017, and the sales of medicines grew by 1.5% in volume terms according to a DSM Group report.¹

According to an analytical report by RNC Pharma, between January and October 2019, Russia manufactured 341.3 billion rubles worth of pharmaceutical drugs (manufacturers' prices, VAT included), which is, in monetary terms (rubles), 23.6% higher than that of the same period in 2018.²

Russia is the 14th largest country in the world by volume of sales in U.S. dollars and according to a forecast by the Economist Intelligence Unit (EIU) it will keep this position at least for five years more.

Russia still shows a higher growth rate than other European countries.³ The British analytical company GlobalData estimates that the pharmaceutical market in Russia is set to rise from 20.91 billion USD in 2016 to 38.56 billion USD by 2021.

In summary, Russia's pharmaceutical market continues to grow and Russia's aging population is expected to be a further growth driver in the coming years.

2.2 PHARMA 2020 AND THE DEVELOPMENT OF THE RUSSIAN PHARMACEUTICAL MARKET

In 2009, the Russian government introduced its "Pharma 2020" plan to develop and foster innovation and localization by the year 2020. The state sought to increase domestic products to 50% of the total internal market and increase innovative products to 60%. To accomplish this goal Russia has, thus far, invested over 4 billion USD. This also provides significant opportunities for international pharmaceutical producers as the Russian government promises to provide favorable market treatment to encourage companies to bring technologies and move their production to Russia.

Pharma 2020 involves a multi-stage strategy:

- localization of design and manufacture of drugs in Russia;
- development of a pharma industry locally within Russia; and
- development of a pharma industry that extends into the international market.

Overall, the goals set out by the Russian Federation for Pharma 2020 are:

- improving the supply of drugs to the Russian people and to healthcare institutions;
- providing the defense sector and other federal uniformed

services with nationally produced essential and rare disease treatment medicines;

- improving the competitiveness of the national pharmaceutical industry by harmonization with GMP — good manufacturing practices;
- fostering development of R&D directed to innovative medicines;
- protecting the internal market against unfair competition and levelling out market access requirements for national and foreign producers;
- upgrading technology within the Russian pharmaceutical industry;
- improving quality control, removing excessive bureaucratic registration barriers; and
- professional training of pharmaceutical personnel in line with international standards.

The Russian government, by its Decree of December 28, 2017 No. 1673, sought to complete Pharma 2020 ahead of schedule.

In general, Pharma 2020 incentivized those international pharmaceutical companies, having long-term commercial interests, to localize production. According to IMS Health, most of the larger international pharmaceutical companies, including Abbott, Abbvie, Amgen, Astra Zeneca, Bayer, Boehringer Ingelheim, Gedeon Richter, Janssen, Johnson & Johnson, Merck Serono, Novartis, Pfizer, Sanofi, Servier, GlaxoSmithkline, Roche etc. have localized their production to one extent or another.

One example is a joint venture of Pfizer and Russian Novamedica.⁴ Under an agreement reached in July, 2016, Pfizer invested in constructing a local pharmaceutical company and transferred licenses for the production of more than 30 medicines. The cost of the project is estimated as 60-100 million USD. The start of production is planned for 2020.⁵

Another recent example is the international pharmaceutical company Besins Healthcare that has invested more than 700 million RUB (11.1 million USD approx.) in localizing production of the finished pharmaceutical form of the original medicine - micronized progesterone.⁶ The project involves technology transfer and construction of production facilities in Russia's Yaroslavl region. The first commercial batch of this medicine, for treatment of infertility, is planned for 2020 and it is expected that the medicine will be supplied not only for Russian patients but will also be exported to the members of the Eurasian Economic Union.

One of the aims of Pharma 2020 was to reshape the pharmaceutical market in favor of locally produced medicines. According to the Draft Pharma 2030 plan (described below) the percentage of locally produced medicines in 2018 grew significantly in comparison to 2012 thanks to the execution of Pharma 2020:

- 31.6% for the treatment of hepatitis (5.28% in 2012);

- 46.96% for the treatment of oncology diseases (13.24% in 2012);
- 27.24% for the treatment of HIV (9.92% in 2012); and
- 11.14% for insulenic medicines (6.33% in 2012).

But imported medicines still prevail on the Russian pharmaceutical market. In 2018, the overall market share of imported medicines was 70.2% in rubles and 39.4% in packages.⁷

The decline of imported medicines in the commercial segment remains less significant than in the state segment.

2.3 PREFERENTIAL PROCUREMENT OF LOCALLY PRODUCED MEDICINES

To incentivize local production, the Russian government has imposed restrictions on public procurement of imported medicines. According to Decree No.1289 "On Restrictions And Participation Requirements for Foreign Medicines Included in the Essential Drug List for the Purpose of Procurements for Federal and Municipal Needs" of November 30, 2015, in the course of procurement of a medicine for public and municipal needs, all offers made by foreign pharmaceutical manufacturers are to be declined in favor of medicines originating from one of the EAEU countries, provided that at least two offers to deliver a medicine with the same INN have been made by local manufacturers. However, restrictions are only applied to the public procurement of those medicines that are on the list of vital and most important medicines. The Draft Pharma 2030 program, described in more detail below, is skeptical as to the efficiency of the measures to incentivize local production set out in Decree No.1289, because in practice it is only applied in 5-10% of all public tenders.

In 2018, the Russian government introduced additional preferences to manufacturers with full-cycle production, including synthesis of a molecule, in any of the EAEU countries. Starting from January 1, 2019, pharmaceutical companies that localized the full cycle of production in Russia, or in any other EAEU countries, enjoy a preference of 25% of the initial maximum contract value.

2.4 DRAFT PHARMA 2030

In 2018, as the successor to Pharma 2020, the Russian Ministry of Industry and Trade released its draft strategy for the development of the Russian pharmaceutical industry until 2030 (the "Draft Pharma 2030 program"). Draft Pharma 2030 identifies key problems in the industry:

- inefficient regulation of new medicines and insufficient control and the circulation of medicines;
- insufficient technological expertise;

- lack of qualified personnel; and
- inefficiency of state investments and support of the industry, etc.

Draft Pharma 2030, on the one hand, preserves Pharma 2020's goal of growing the market share of locally produced medicines, and eliminating dependency of the Russian pharma market over imported medicines. On the other hand, Draft Pharma 2030 adds new ambitious goals to create an innovative export- oriented industry and increase export of locally developed medicines abroad, especially to developing countries of the EAEU, Latin America, Africa and Asia. Albeit a net importer, Russia, nonetheless, targets growing its exports significantly by the year 2030.

The Russian Ministry of Industry and Trade forecasts that by the year 2030, Russia's export of medicines could increase by five times or by up to 1 billion USD per year.⁸

At the time of this writing, Draft Pharma 2030 has not been adopted and can be further amended. Some experts claim that Draft Pharma 2030 should be more focused because it does not contain firm benchmarks for measuring progress.⁹

2.5 THE EFFECTS OF SANCTIONS ON THE RUSSIAN PHARMACEUTICAL INDUSTRY

A report by STEM-Pharma emphasized that it is unlikely that Russia will introduce sanctions against the importation of pharmaceutical products, especially innovative medicines. Most significantly, the introduction of sanctions on imported medicines and medical devices would be political suicide¹⁰, because despite localization efforts, the share of imported medicines in the commercial segment by value is significant (71.5%) and has not changed significantly since 2012 (76%).¹¹ This will evolve gradually.

On July 4, 2018, in response to Western economic sanctions, Federal law No.127-FZ (the "Law on Countersanctions") came into force. This law introduced a list of retaliatory measures that the president and the government of Russia can undertake as a response to "unfriendly actions of the United States of America and other foreign states", including restrictions on importation of goods. The law on countersanctions, however, expressly exempts vital goods that do not have substitutes in Russia.

Assurances that Russian counter-sanctions will not affect the importation of foreign medicines has also been given by public authorities. For instance, the speaker of the upper house of the Russian parliament, Valentina Matviyenko, recently said: "Geopolitical trade wars must not harm citizens of the countries. Sanctions must not touch upon goods of vital necessity, such as medicines. This problem is especially acute now, and we must answer it – it is absolutely inadmissible when in the 21st century people are deprived of goods of vital necessity".

But the economic crisis of 2014 and the rebound effects of all of the sanctions appear to have affected many industries, including the pharmaceutical industry in Russia with increased prices and weakened consumer purchasing power.

The country's previously strong economic performance had contributed to the rapid growth of the pharmaceutical sector in Russia, a country where many forms of medication can be dispensed to anyone by pharmacies without a prescription. Today medical institutions have cut back on inventories of more expensive imported medicines, yet local industries are often incapable of filling the gap.

The current political climate has also increased concern and speculation that the government might nationalize key facilities and limit the freedom of capital repatriation.

The average Russian may now continue to face limited or exhausted supplies of imported drugs and medications at twice or greater cost, underperforming generic equivalents or even worse, potentially dangerous counterfeits.

The recent increase of the VAT rate in Russia from 18% to 20% on January 1, 2019, also plays against the ability of Russians to buy imported medicines.

Experts also note that the drop or stagnant consumer income will likely encourage consumers to buy low cost drugs, thereby enhancing the market for branded generics.

RUSSIAN PHARMACEUTICALS QUICK REFERENCE:

-  **145,000,000 people**
market size
-  **70.2%**
of medicines in the commercial segment are imported
-  **27.5 billion USD**
market value 2018
-  **7.9%**
market growth 2017
-  **14th largest market**
in the world by volume of sales
-  **4 billion USD**
invested by Russian government into domestic production
-  **33.75 million units of counterfeit medicine**
confiscated by Interpol in 2012



III.

THE LEGAL FOUNDATION FOR THE PROTECTION OF TRADEMARKS IN RUSSIA

“A trademark in Russia can be a word, image, or three-dimensional designation; as well as any combination of the three ... in any combination of colours.”



The Russian legal system is a civil law system, thus the system is based on both substantive and procedural codified laws. Presently, the substantive legislation that pertains to the protection of pharmaceutical trademarks and their rights are as follows:

- Part IV of the Civil Code (230-FZ) of December 18, 2006;
- the Law on the Circulation of Medicines (61-FZ) of April 12, 2010;
- the Criminal Code of the Russian Federation (63-FZ) of June 13, 1996; and
- the Code of Administrative Offences (195-FZ) of December 30, 2001.

In August 2012, Russia joined the World Trade Organization. By that time Russian law had become compliant with the minimum requirements for “trademarks” established by Part II Section 2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In 2020, collectively these laws provide the rules and regulations relating to pharmaceutical trademarks in Russia. They also provide for civil, administrative and criminal liability for those who violate exclusive trademark rights.

3.1 PART IV OF THE CIVIL CODE

Intellectual property rights are predominantly captured in Part IV of the Civil Code. Part IV came into force in January 2008 and revised and consolidated the intellectual property laws that had been enacted following the collapse of the Soviet Union in 1992. The 1992 laws shifted intellectual ownership to citizens that otherwise during communist times would have been designated as property of the state.

Part IV of the Civil Code, Chapter 76 § 2 on the “Right to a Trademark and a Service Mark”, in addition to several other clauses, provides the legal basis for trademark protection, the requirements and processes for registering a trademark, the scope of a trademark owner’s rights, and the remedies available for trademark infringement.

3.1.1 THE BASIC TRADEMARK PROVISIONS IN THE CIVIL CODE

Article 1477 defines a trademark as a designation for the purpose of individualising the works or services performed/ provided by legal entities or individuals. Article 1479 establishes that marks registered by the governing federal body or by circumstances set forth by international treaties are protected in the Russian Federation.

Article 1482 of the Civil Code establishes that a trademark in Russia can be a word, image, or three-dimensional designation; as well as any combination of the three. A trademark may be registered in any colour or combination of colours.

3.1.2 TRADEMARK RIGHTS AND LEGAL PROTECTION

Russia is a registration country and few rights exist without the benefit of a registration. A registration confers both a right to use and a right to exclude others.

If a designation is registered as a trademark, Article 1484 accords to the trademark owner an exclusive right to use the trademark in any manner not conflicting with the law.

This exclusive right may be exercised to individualize goods within the class of goods for which the trademark was registered. Specific examples of such uses are provided for in the Civil Code, including placing the trademark:

- on goods manufactured, offered for sale, sold, exhibited at exhibitions or imported into the territory of the Russian Federation;
- when work is performed or services are provided;
- on documents relating to the introduction of goods in civil law transactions;
- in offers for the sale of goods;
- in advertisements; and
- on the Internet, including in a domain name.

Paragraph 3 of Article 1484 accords the right to exclude others, stating that no one has the right to use a designation, without the permission of the mark owner, if it is similar to a trademark for the goods which a trademark has already been registered or if such use might result in confusion.

Articles 1488-1499 also provide a trademark owner with the power to assign or license the exclusive right associated with a trademark. Under Article 1490, an assignment or a grant to another of the contractual right to use a trademark must be expressed in writing for valuable consideration and the agreement or notice thereof must be registered with Rospatent in order to be effective.

Trademark rights in Russia are valid for a period of 10 years from the date of filing the application. They may be renewed for consecutive 10-year periods at the owner’s request.

3.1.3 TRADEMARK PRACTICE AND PROCEDURE

Trademark rights can be acquired by way of Russian national stage applications for registration with Rospatent or by way of International Registration with the World Intellectual Property Organization via the Madrid Agreement and Protocol.

As regards basic formalities, a national trademark application must be submitted in the Russian language. A trademark application should cover one mark and comprise:

- references to relevant information on the applicant (for example, place of residence);
- the designation being declared;
- the list of goods for which the trademark is sought under the classes established by the International Classification of Goods and Services for Marks Registration; and
- a description of the designation being declared.

Article 1494 states that the priority of an application for registration is established on the day the trademark application is filed with Rospatent or its international filing date in accordance with the international treaties of the Russian Federation.

Under Article 1497 of the Civil Code, examination of the application will be conducted by Rospatent first as regards formalities and later as to substance. Examination as to formalities is conducted within one month of filing. This process ensures that the application has the necessary documents and that they are compliant with the minimum requirements. During this process, the applicant may amend or update the application until a decision is made by the examiner. The substantive examination of the trademark is conducted within 12 months and is focused on compliance with the substantive requirements set out in the Civil Code. The examiner may also request information from the applicant if it is determined that additional information is required for the examination and a response must be submitted by the applicant within three months of the request.

If a trademark application is rejected, Article 1500 of the Civil Code states that an appeal against an objection to a trademark registration by Rospatent must be filed within four months of the rejection.

3.1.4 GROUNDS FOR REJECTING A PHARMACEUTICAL REGISTRATION

Article 1483 of the Civil Code deals with registrability and the grounds for refusing to register a trademark. Notable reasons for rejecting an application include that:

- the mark lacks distinctiveness;
- the mark makes a false representation or is capable of misleading customers;
- the mark is identical or similar to trademarks previously registered in Russia; or
- the mark is identical or confusingly similar to a company or trade name.

3.1.4.1 LACK OF DISTINCTIVENESS (DESIGNATION WITHOUT DISTINGUISHING CAPABILITY)

A trademark is not registrable if it is not inherently distinctive. Trademarks are deemed to lack sufficient distinctiveness if they consist solely of elements:

- that have come into general usage as designations for goods of a certain kind;
- that are composed of generally-accepted symbols and terms;
- that characterize goods (for example: kind, quality, properties, or intended purpose); or

- that represent a form of goods that is defined exclusively or mainly by the properties or purpose of the goods.

These elements may nonetheless form part of a trademark as unprotected (disclaimed) elements unless they represent the dominant features of the mark. They may also qualify for registration if it can be shown that they have acquired distinctiveness by reason of extensive use.

3.1.4.2 DESIGNATIONS WITH FALSE OR MISLEADING ELEMENTS

A trademark application will be rejected if the mark comprises of elements that:

- are false or capable of misleading the consumer about the goods or manufacturer of the goods; or
- are in conflict with the public interest and the principles of humanity and morality.

This article of the Civil Code should be read concurrently with Clause 37 of the Rules for compiling, submitting and considering documents, constituting grounds for commitment of legal acts on registering trademarks, service marks and collective marks affirmed by the Order of the Russian Ministry of Economic Development No. 482 of July 20, 2015 (the Rules) which states that such designations should be rejected if they generate in the consumer's mind a certain idea as to the quality of the product, its manufacturer, or its place of origin which is not true. The designation will be deemed to be false or misleading if any one of its elements may be so characterized.

3.1.4.3 DESIGNATIONS CONFUSINGLY SIMILAR TO A REGISTERED TRADEMARK

An application to register a trademark will be rejected in Russia if the designation is identical or confusingly similar to:

- a third party's registration for goods/services of the same class or an earlier application that has priority;
- a third party's trademark registration, or application with earlier priority, protected under an international treaty (Madrid Agreement), for goods of a similar class; or
- a third party's trademark registration that has been accorded well known status even retroactively.

This article of the Civil Code should be taken in concurrence with the Rules. According to Clause 42, the similarity of trademarks for homogeneous goods should be compared according to sound (phonetic), graphic (visual) and notional (semantic) similarities that may be taken individually and in combination.

Phonetic similarities will be assessed based on the following aspects:

- presence of similar or coinciding sounds in comparable designations; similarity of sounds constituting designations;
- arrangement of similar sounds and sound combinations in respect of each other;
- presence of coinciding syllables and their arrangement;
- number of syllables in designations;
- place of coinciding sound combinations within the composition of designations;
- similarity of the composition of vowels;
- similarity of the composition of consonants;
- nature of coinciding parts of designations;
- one designation's entry into another one; and
- accent.

Visual similarities will be assessed based on the following features:

- general visual impression;
- print type;
- graphical way of writing subject to the nature of letters (for instance, block-letters or writing letters, capital or small letters);
- arrangement of letters in respect of each other;
- alphabet whose letters are used for writing words; and
- colour or colour combination.

Semantic similarities will be assessed based on the following features:

- similarity of notions and ideas contained in the trademarks; in particular, coincidence of the meaning of the trademarks in different languages;
- coincidence of one of the elements in the trademarks which is emphasized and which has an independent meaning; and
- differences in the notions and ideas contained in the respective trademarks.

The Rules also state that, to be regarded as being homogenous goods, the question to ask is whether it is possible that customers would regard the respective goods as being made by the same producer. This should take into account the type of goods, their purpose, the material they are made of, the conditions of sale and other features.

The Civil Code does allow for similar trademarks to be registered if the applicant is able to obtain written consent from the original trademark owner. This exception only applies to marks that are confusingly similar and not identical. However, the examiner may choose to refuse to register a similar mark even with a letter of consent if it is felt that co-existing marks on the register goes against the public interest.

3.1.4.4 DESIGNATIONS CONFUSINGLY SIMILAR TO A COMPANY OR TRADE NAME

In Russia, a trademark application may be refused or a registration may be cancelled if the designation is identical or confusingly similar to a company name or commercial name already protected in the Russian Federation. This means that pharmaceutical companies wishing to protect a pharmaceutical mark must also be mindful of performing a search in the Uniform State Register of Legal Entities to determine if there are any conflicts that would represent a potential bar to registration. Trademark examiners are not required to compare the applied-for mark to business names listed in this database but they may take "judicial notice" of famous business names from time to time. A third party can later emerge and demand that the mark be cancelled on this ground.

3.1.5 CONSEQUENCES OF NON-USE

A registered trademark becomes vulnerable to cancellation for non-use three years after it is registered. Once an action has been instituted, the initial burden is on the requesting party to demonstrate that it has a legitimate interest in cancelling the mark. This burden is not a light one. If that burden is met, then the burden lies on the right holder to prove that the trademark is in use. However, there is an exception for non-use for circumstances beyond the control of the owner that prevented the use of the trademark within the three-year period. This is particularly relevant in the pharmaceutical industry as the Chamber for Patent Disputes will also often take into consideration the various additional legal requirements that must be completed before a pharmaceutical can be introduced into circulation.

According to Article 1484 of the Civil Code, the following may be deemed to satisfy the use requirement:

- placement of the trademark on goods, labels and packages of goods which are manufactured, offered for sale, sold, or exhibited at exhibitions; the placement of the trademark on goods which are introduced into civil circulation in Russia in some other way than as previously listed, as well as goods that were stored or transported into Russia for the purpose of introducing them into civil circulation; in addition, any goods that were imported to the territory of the Russian Federation;
- featuring the mark when work is performed or services are provided;
- featuring the mark on documents relating to the introduction of goods into civil circulation in Russia;
- placement of the trademark on offers for the sale of goods, performance of works, provision of services, and also on announcements, billboards and advertisements; and placement of the trademark on the Internet, including in a domain name.

The provisions of the Russian Civil Code were clarified by the Supreme Court of Russia in its Resolution No. 10 dated April 23, 2019 (the Resolution). The Supreme Court explained in sec. 167

of the Resolution that the trademark holder in a non-use cancellation proceeding may put forward evidence that a contested trademark was not used due to circumstances beyond its control, e.g. restrictions of imports or other government prescriptions in relation to trademarked goods. Conversely, a trademark holder's bankruptcy cannot be deemed a legitimate excuse for non-use of a trademark.

3.1.6 CIVIL LIABILITY FOR TRADEMARK INFRINGEMENT

Under Article 1515, the use of a mark, without consent, in association with goods or services which is deemed to be confusingly similar to a registered trademark is illegal. The owner of the trademark is entitled to enjoin continued use of the trademark in commerce and to require the destruction of the goods. The owner of the trademark may also claim compensation in the amount of 10,000 to 5,000,000 RUB (160 USD to 80,000 USD) at the court's discretion or alternatively may claim double the value of the counterfeit goods or double the standard license fee for the right to use the trademark.

The Supreme Court provided additional clarification in sec. 155 of Resolution No. 10 that any use of a designation, before its official registration as a trademark by third parties, cannot be considered as infringing and, therefore, no compensation can be claimed for the period before the trademark was registered even if an application for registration may have been pending. Before this clarification, there were conflicting decisions of lower courts regarding whether the use of a trademark which was the subject of a pending application could be deemed retractively to be infringing use once the mark became registered.

3.2 PHARMACEUTICAL TRADEMARKS: ROSPATENT PRACTICE, PROCEDURES AND REGULATIONS

Article 1483 of the Civil Code deals with registrability and the grounds for refusing to register a trademark. Notable reasons for rejecting an application include that:

- the mark lacks distinctiveness;
- the mark makes a false representation or is capable of misleading consumers;
- the mark is identical or similar to trademarks previously registered in Russia; or
- the mark is identical or confusingly similar to a company or trade name.

3.2.1 RUSSIAN MINISTRY OF HEALTHCARE GUIDELINES FOR NAMING MEDICINES

In 2005, the Russian Ministry of Healthcare and Social Development issued non-binding guidelines for "the rational choice of names of medicines" in the Russian Federation. This document was intended to provide pharmaceutical manufacturers with a scientific methodology for choosing a safe and economically efficient name for a medicine. While they remain useful, they were superseded in 2016 with binding rules.

3.2.1.1 PRINCIPLES FOR NAMING MEDICINES

The guidelines set out the following principles for manufacturers and producers on how to rationally select a brand name for a medicine:

- the name of a medicine should be intended to help professionals (medical and pharmaceutical workers) and consumers to unambiguously identify medicines that have different compositions and effects;
- names of medicines should be short if possible, easy to pronounce, harmonious, sounding typical or normal in the Russian language;
- names of medicines must be distinctive in sound and spelling. It is not permitted to register for medicines any false names or confusingly similar names capable of passing off to consumers the nature of the goods or its manufacturer, or names conflicting with the public interest, humane and moral principles;
- names of newly registered medicines should not be identical or graphically recognized and (or) phonetically similar to the names of previously registered medicines which are distinctly different in composition and effect;
- brand names of medicines should not use structural elements, which are INN's (international non proprietary names) or components thereof;
- INNs or names graphically or phonetically similar to them should not be used for a medicine with a different chemical composition or effect, word or parts of words characteristic for names of medicinal products of other chemical and (or) pharmacological groups;
- medicinal products issued in various dosage forms should refer to the pharmaceutical substance contained in them. Different names for different dosage forms of the same medicine are allowed only as an exception, if the effect of the medicine changes substantially along with the alteration of the dosage, and indications for use change accordingly;



- the dosage form is not to be mentioned in the medicine's name, with the exception of starting materials of herbal origin and herbal medicinal products (Annex 2) (11), and unparalleled innovative technical devices;
- for names of medicines comprising one pharmaceutical substance (monocomponent medicine preparations) that has an INN or NNN, it is expedient to use this non-proprietary name. For identification of the manufacturer (developer) it is advisable to include their title or abbreviations into such name;
- similar names should not be used for combination products distinct in composition or ratio of dosages of pharmaceutical substances in them;
- it is not advisable to use names that are capable of passing off or misleading consumers in respect of the genuine composition and effect of the medicine. This category encompasses designations that evoke associations in the minds of consumers about certain qualitative parameters (composition and/or pharmacological properties) of the medicine, which may not reflect reality (i.e. puffery);
- the name of the medicine should not be a laudatory and suggest it is unique, the most efficient, the safest, or exclusive in terms of lack of adverse effects;
- it is permissible to use Latin and Greek words and portions thereof that are already accepted in scientific and medical terminology;
- it is not advisable to reproduce, in the names of the medicinal products, the names of diseases and symptoms of diseases, anatomical and physiological terms, proper names, geographical names, or generally accepted symbols and words from colloquial vocabulary. It is not allowed to use words graphically and (or) phonetically similar to coarse language; one shouldn't use as names, any designations that are identical or have graphic and(or) phonetic similarity to the official names of most valuable objects of cultural heritage of the people of Russia, or objects of world cultural or natural heritage.

The guidelines were in effect until November 11, 2016. They were replaced with mandatory rules (see 3.2.2), though they remain instructive, as the principles have not changed.

3.2.1.2 CONSTRUCTING NAMES FOR PHARMACEUTICALS

In the process of developing a brand name, the guidelines suggest that pharmaceutical manufacturers use the following model for word formation:

1. Stem composition

- a. Using interconnected stems (object-action)
- b. Using the stems that are not interconnected
- c. Using connecting vowels
- d. Not using connecting vowels

2. Suffixation

- a. Using suffixes -in, -ol, -al, -id, etc.
- b. Using prefixes ex- and des- as suffixes
- c. Using final elements

3. Prefixes

4. Abbreviation of words

- a. Retaining the beginning of the source word
- b. Retaining the end of the word
- c. Retaining the middle part of the word
- d. Retaining letters and syllables randomly selected from the word

5. Formation of abridgements

6. Overlapping parts of the word

7. Rearrangement of the word components

- a. Rearranging adjacent letters or letter combinations
- b. Rearranging adjacent syllables
- c. Rearranging randomly selected parts of the name
- d. Reversal of letters, starting from the end of the word, or a part of it

8. Acronyms (abbreviated names)

9. Borrowing words

10. Borrowing existing (finished) word

11. Substantivization of adjectives (conversions of adjectives into nouns) words

3.2.1.3 PRINCIPLES FOR DETERMINING TRADEMARK SIMILARITY

Rospatent Guidelines set out the following rules to determine if a pharmaceutical product is visually or phonetically similar to another pharmaceutical product:

- the name is deemed to be similar to another name if it is associated with it in general, in spite of minor differences; or
- names might be found to have auditory (phonetic) or graphic (visual) similarities.

Sound similarity is determined by the following features:

- presence of the cognate or concurring sounds in compared designations;
- close distance of the sounds in the designation;
- arrangement of adjacent sounds and an acoustic pattern in respect of each other;
- presence of concurrent syllables and their arrangement;
- number of syllables in designations; and
- place of concurrent acoustic patterns in the composition of designations, which can be taken into consideration separately or in various combinations.

The most common reasons for sound similarity are:

- identical sound of the initial parts of designations and identical sound of the end parts: for example, glyoten — glyophen, imigyl — imidyl and timpyl - timonyl;
- similar sound in the initial parts of designations and identical sound of the end parts: for example, abufen — ibufen and imigran- migran;
- identical sound of the initial and end parts of designations and similar sound of the middle parts: for example pinovit — pikovit and eclin - ecalyn; and
- identical sound of the middle parts of designations and similar sound of the initial and end parts: for example, ocoden — acodyn.

The general rule is that a distinction between two names can be made if there are three or more letters (characters) in any combination that are different (the "Three Letter Rule"). Even though the "Three Letter Rule" is not the law to be followed strictly, the Chamber for Patent Disputes and the courts willingly use the rule in cases where pharmaceutical trademarks are at issue.¹²

3.2.1.4 TRADEMARK NAMES AND INTERNATIONAL NON-PROPRIETARY NAMES

As a means to avoid confusion, and therefore help promote patient safety, the guidelines state that trademarks in Russia should not be based on an International Non-proprietary Name (INN). An INN is a unique name of a pharmaceutical substance

that is globally recognized as public property. In Russia, the most common source of conflict is with organizations attempting to secure as a trademark a designation that uses the "common stem" established by the WHO for an INN.

3.2.2 RUSSIAN MINISTRY OF HEALTHCARE MANDATORY RULES FOR NAMING MEDICINES

On November 11, 2016, the guidelines were replaced with the binding Rules for the rational choice of names of medicines ("the Rules"), adopted by the Russian Ministry of Health Decree No. 429n dated June 29, 2016. The Rules can be found [here](#). The Rules are mandatory for every applicant for registration of a medicine with the Russian Ministry of Health.

According to the Rules, INNs cannot be used as brand names of medicines, except when:

- an INN forms part of a brand name as a full word with no abbreviations; or
- an INN is followed with the trade name of a company.

Names of newly registered medicines must not be capable of passing-off or misleading consumers in respect of ingredients, characteristics and effects of a medicine or its manufacturer. The brand name must not conflict with the public interest, humane and moral principles. Additionally, no brand name of a medicine can contain profane language, words and expressions in violation of Russian linguistic rules, words that are phonetically or visually similar to the official names of most valuable objects of cultural heritage of the people of Russia, or objects of world cultural or natural heritage, geographical names and proper nouns.

The brand name of a newly registered medicine must not:

- be identical to the brand name of a previously registered medicine; or
- be confusingly similar to the brand name of a previously registered medicine (e.g. FLOXAN – FLOXAL, GLIOTEN – GLIOFEN, IMIGIL – IMIDIL, TIMOPIL – TIMONIL, ABUFEN – IBUFEN, MIGRAN – IMIGRAN, PINOVIT – PIKOVIT, EKLIN – EKALIN, OKODEN – AKODIN).

Abbreviations (letters, Arabic or Roman numerals) can be used as part of a brand name when they can be instructive regarding characteristics of a medicine, e.g. its dosage form, duration, administration route etc.



3.2.3 RECENT DECISIONS OF THE CHAMBER FOR PATENT DISPUTES ON PHARMACEUTICAL TRADEMARKS

The Chamber for Patent Disputes (CPD) is a division of the Federal Institute of Intellectual Property in Russia (FIPS). It acts essentially as a quasi-judicial administrative body operating within FIPS. The CPD is responsible for hearing appeals of final rejections of office actions in prosecution. It also hears cancellation actions in the first instance (save for non-use cancellation actions which are instituted directly in the Intellectual Property Court).

Decisions of the Chamber for Patent Disputes may be appealed to the IP Court. Considerable deference is given to the decisions of the CPD, as it is regarded as having special expertise in matters concerning registrability of trademarks. Its decisions are therefore instructive as regards questions of registrability on both absolute and relative grounds.

3.2.3.1 THE GUARD¹³

[KOWA COMPANY, LTD v. Rospatent](#)
Case No. 0001074843 (1074843)
May 27, 2013
[Chamber for Patent Disputes](#)

In a 2013 decision by the CPD, the designation THE GUARD was rejected for its similarity with the registered trademark ULTRA GUARD. The CPD separated each trademark into its dominant and non-dominant elements as part of its analysis. The presence of the elements "The" and "Ultra" as part of the marks did not serve to distinguish the core element "Guard" and were considered to be non-dominant elements of secondary importance.

Based on this approach, the dominant element "Guard" for each designation was identical and therefore had the potential to lead to confusion.

3.2.3.2 NANOXRAY¹⁴

[Nanobiotix v. Rospatent](#)
Case No. 0001102537 (1102537)
May 30, 2014
[Chamber for Patent Disputes](#)

In this 2014 decision, the CPD found that registration of the designation NanoXray was not allowable under Article 1483 of the Civil Code for not being sufficiently distinctive. The CPD concluded that the trademark could be broken down into its multiple individual elements in order to determine if the trademark violated any of the statutory considerations as regards registrability. In this case the CPD found that "Nano" and "Xray" were distinct individual elements. As such, the trademark could be interpreted to refer to nanotechnology

based radiation used for the detection and treatment of tumours. Based on this interpretation, the CPD determined that the designation was not distinctive and was merely descriptive of the kind and purpose of the product.

3.2.3.3 PROGRESSA¹⁵ I LIBRAX¹⁶

[BASF SE v. Rospatent](#)
Case No. 0001088375 (1088375)
August 9, 2013
[Chamber for Patent Disputes](#)

A letter of consent will not suffice in all cases. In this case, an application to register the designation "Librax" was rejected despite there being a letter of consent from the owner of an existing registration for an identical mark with earlier priority. The CPD found that consent of the owner did not satisfactorily remove all obstacles to legal protection because in this case the marks were identical and not merely confusingly similar.

[Egis v. Rospatent](#)
Case No. 0001088375 (1088375)
August 14, 2014
[Chamber for Patent Disputes](#)

In a 2014 decision by the CPD, the Chamber chose to grant trademark protection for the trademark PROGRESSA despite its similarity to the registered mark PROGRESS PROGRESS. In this case, the applicant, Dial Engineering, had a letter of consent from the owner of PROGRESS PROGRESS that stated that they had no objection to the grant of trademark protection for PROGRESSA. The CPD held that since the marks were not identical, a letter of consent served to eliminate doubt as to granting allowance of the application.

3.2.3.4 BETA-CALCIY¹⁷

[Teva LLC v. Rospatent](#)
Case No. 2012733338
March 25, 2015
[Chamber for Patent Disputes](#)

In a 2015 decision regarding the trademark BETA-CALCIY the examiner had rejected the application on the grounds that it might be capable of misleading consumers as to source of origin. The examiner had conducted an Internet search and found evidence to suggest the mark could be misleading. In particular s/he found use in the German language of a reference to a product from a German company called CALCIUM BETA.

The CPD, at the urging of the applicant, rejected the objection and allowed the application. There was no evidence that the CALCIUM BETA brand product was in actual use in the Russian market. There was no presence of the mark in the Russian pharmaceutical market and information on the product was

only available on German websites. Moreover, the product was not listed on the State Register of Medicines of the Russian Federation.

3.2.3.5 LORACTIV¹⁸

[ALVIS Patent LLC v. Rospatent](#)
Case No. 2013725319
November 26, 2015
[Chamber for Patent Disputes](#)

The prior use of a designation and the registration of drug with a confusingly similar name in Kazakhstan, a member of the Customs Union, prevented the registration of a trademark in Russia.

In the 2015 decision, the CPD refused to grant trademark protection for LORACTIV on the grounds that it could mislead consumers. The applicant maintained that the registration of the medicine in Kazakhstan and its sales in that country could not mislead Russian consumers as to the source of origin. The applicant further claimed that the Kazakh medicine LORACTIV was not listed in the Russian State Register of Medicines and, thus, could not be imported and sold in Russia.

The CPD maintained the objection and noted that the Kazakh websites that promote LORACTIV are in the Russian language and Russian consumers may easily reach them. Both Russia and Kazakhstan are members of the Customs Union with a common market for goods and services, which makes medicines more accessible to consumers in Russia. The CPD decided that medicines labeled with a potentially misleading designation may be imported for personal needs or under a special permit of public officials even if Kazakh products were not authorized for sale in Russia.

This decision is very significant because the application was rejected on the basis that the trademark was confusing with a trademark that was neither registered nor in use in Russia; weight was given to the unitary market aspect associated with the Eurasian Economic Union (EAEU).

3.2.3.6 EPIGENORM FORTE

[Doctor Kornilov LLC v. Rospatent](#)
Case No. 2016746504
May 21, 2018
[Chamber for Patent Disputes](#)

In a 2018 decision, the CPD decided that dietary supplements and medicines are homogenous goods.

The applicant, Russian company Doctor Kornilov LLC, appealed to the CPD against Rospatent's decision where Rospatent

rejected registration of the EPIGENORM FORTE trademark on the ground of its confusing similarity with the EPIGEN international trademark registered by Chemigrup International Limited Inc.

The CPD compared the "EPIGENORM" and "EPIGEN" designations, excluding the descriptive element "FORTE", and held that the two designations are confusingly similar. The CPD further analyzed whether medicines and dietary supplements are homogenous goods and found that: (1) dietary supplements and medicines can be used for similar purposes: disease prevention and health improvement, (2) they can be made of similar raw materials: organic, mineral etc., (3) their respective marketing conditions and target consumers correlate.

Therefore, the CPD concluded that consumers of EPIGEN medicine might be confused if EPIGENORM FORTE were to be registered for dietary supplements.

3.2.3.7 MYRAMISTIN

[Megainpharm HMBH v. Rospatent](#)
Case No. 2017747231
February 28, 2019
[Chamber for Patent Disputes](#)

In this 2019 decision, the CPD rejected registration of the "MYRAMISTIN" designation for medicine as being identical to the prior registration of the same mark by the same rightholder – Megainpharm HmbH.

The applicant argued that the prior trademark was depicted in a different font and was not capitalized in comparison to the application, and the trademarks comprised a family of trademarks. The CPD, however, reasoned that the prior trademark and the application are identical in every element: the standard font and Latin letters were used in both. The CPD concluded that registration of the identical trademark for the same ICGS classes is against the public interest, even when the applicant is the right holder of the prior trademark.

This is consistent with general examination practice. An applicant may wish to register a mark that is already registered in its favour for the same goods or services. There must be a material difference between the marks or the list of goods and services must be different in some respect.

3.3 CRIMINAL CODE OF THE RUSSIAN FEDERATION

3.3.1 ILLEGAL USE OF A TRADEMARK (ARTICLE 180 OF THE CRIMINAL CODE)

According to Article 180 of the Criminal Code, the illegal use of any trademark, if committed repeatedly or if causing substantial damage (exceeding 250,000 RUB - approximately 4,000 USD), is punishable with a fine in the amount of 100 to 300 thousand rubles (1,500 to 4,800 USD) or imprisonment for up to two years.

3.3.2 FEDERAL LAW NO.352-FZ PHARMACEUTICAL TRADEMARKS

On January 23, 2015, Russia introduced legislation that also criminalizes pharmaceutical counterfeiting and the distribution of counterfeit or falsified medicines and medical devices. Prior to the enactment of the new law, the counterfeiting of pharmaceuticals was regarded as being no different than the counterfeiting of luxury goods. The new, harsher, sanctions include five to eight years imprisonment for the unauthorized manufacture of medicines and medical devices by a criminal organization. This issue is discussed in greater detail later in the section on counterfeit pharmaceutical products





IV. DECISIONS FROM THE IP COURT AND THE SUPREME ARBITRATION COURT



The relevant courts and the path for appeals have changed in recent years. With regards to the review of a decision of an examiner concerning registrability of a trademark, the tribunal of first instance is the Chamber for Patent Disputes (CPD). Since 2014, appeals from decisions of the CPD are heard by the IP Court which is a division of the Commercial (Arbitration) Court. Appeals from the Presidium of the IP Court were, previously, heard by the Supreme Arbitration Court. Recently the Supreme Arbitration Court was merged into the Supreme Court of the Russian Federation. Decisions of the IP Court may now only be appealed, with leave, to the Supreme Court. The Supreme Arbitration Court, for all practical purposes, has ceased to exist.

What follows is an overview of interesting trademark court decisions presented here in chronological order.

4.1 THE SUPREME ARBITRATION COURT: "KARNITON"¹⁹

LLC Pik Farma and LLC Consortium Pik v. Rospatent

Case No. 12436/11

February 28, 2012

Supreme Arbitration Court of the Russian Federation

In this 2012 case, the Supreme Arbitration Court issued an opinion regarding the registration of trademarks for International Non-proprietary Names (INN) and their derivative notations.

An INN is a unique name given to a pharmaceutical drug or an active ingredient. The names are chosen by the World Health Organization (WHO) to promote international consistency for pharmaceutical products as a means to avoid confusion that could ultimately jeopardize patient safety.

The Supreme Arbitration Court in this case was reviewing, by way of appeal, an objection that had been made by Rospatent. Rospatent had rejected the designation KARNITON because it was derived from the INN "carnitine". The issue raised at the hearing was that the WHO resolution did not form part of the Russian Constitution and therefore could not legally form the basis for rejecting a trademark.

The Court found that, although not binding on Russia, the use of marks derived from INN's were illegal as being against the public interest.

The Court held that,

"[C]ourts should take into consideration that the registration of a trademark ... may create obstacles for the manufacture and access of medical products belonging to the same pharmaceutical stem... since the right holder has an exclusive right to prohibit the use of any designations confusingly similar to its trademark in respect to homogeneous goods. Any actions impeding the free use of the INN in the Russian Federation is contrary to the public order and the right of everyone to health and medical care, guaranteed by Article 41 of the Constitution of the Russian Federation."

To determine if a designation can be considered to have been derived from an INN, the Supreme Court said that Rospatent should use the same technique it uses to determine if marks are similar to the point of confusion (phonetics, semantics, graphics).

This decision has served to establish the rule of practice to the effect that if a trademark is derived from an INN (similar to the point of confusion) then its registration should be denied on public interest grounds.

4.2 THE SUPREME ARBITRATION COURT: "VECHERNIE"²⁰

Pharmacy Doctor LLC v. Rospatent

Case No. VAS-17411

December 4, 2013

Supreme Arbitration Court of the Russian Federation

In this case, the Supreme Arbitration Court considered how dietary supplements should be classified in accordance with the International Classification of Goods and Services established by the Nice Agreement.

Prior to recent amendments regarding the Nice classification, there was no obvious class within which dietary supplements or biologically active additives would fall. As a result, trademarks for dietary supplements were registered in various classes depending on their composition. To help provide clarity, a letter released by Rospatent in 2008 stated that dietary substances were to be considered as drugs and therefore they belonged in Class 5. However, some Russian laws distinguished between drugs and dietary supplements. Additionally, advertising of dietary supplements prohibited claims of any therapeutic properties. Therefore, there was some legislative and administrative inconsistency on the question as to whether medicines and dietary supplements were homogenous goods or not.

In the Pharmacy Doctor LLC v. Rospatent case, Pharmacy Doctor had registered the trademark VECHERNIE (which may be loosely translated as "nocturnal") under Class 5 (pharmaceutical preparations, dietetic substances adapted for medical purposes). A third party, Biokor, filed an application for early termination of this trademark on the grounds of non-use. Rospatent (the administrative body empowered at this time to hear non-use cancellation requests) determined that because Pharmacy Doctor was using the trademark in association with the sale of dietary supplements, this did not represent use for goods in Class 5. As a result, the VECHERNIE registration was cancelled for non-use notwithstanding that there were in fact sales of dietary supplements in Russia in association with the trademark.

After three appeals, all of which upheld the decision, the case was ultimately referred to the Presidium of the Supreme Arbitration Court (No.8817/11). The court found that dietary supplements were a special species of goods that did not fall under Class 5 and therefore the cancellation of the trademark registration was justified.

The Presidium came to the conclusion that Rospatent was correct because biologically active additives are an independent type of product different than pharmaceutical or dietary

substances for medical purposes. The Court concluded that the product should have been registered under Class 10.

Although dietary substances have since been included in Class 5, there is still uncertainty for trademarks that were registered before this was adopted.

Manufacturers of dietary substances should ensure that there is direct reference to dietary supplements or biologically active additives in the classes of goods registered for a trademark.

4.3 THE INTELLECTUAL PROPERTY COURT: "ХОНДРОЛОН" (HONDROLON)²¹

Federal State Unitary Enterprise Mikrogen v. LLC Farmaktivy
Case No. A40-165106/2013
January 27, 2015
Intellectual Property Court

The plaintiff, Federal State Unitary Enterprise Mikrogen, filed a claim of trademark infringement seeking to enjoin the defendant, LLC Farmaktivy, from using the registered trademark "ХОНДРОЛОН" and "HONDROLON" on the certificate of state registration, and obliging the defendant to withdraw its state registration for a biologically active food supplement together with compensation to the plaintiff.

The plaintiff had registered the trademarks ХОНДРОЛОН in 1993 and HONDROLON in 2005 in Class 5. The defendant obtained a certificate for state registration of the biologically active food supplement ХОНДРОЛОН in the Federal Service for Supervision of Consumer Rights Protection and Human Welfare (Rosпотребнадзор) in 2013.

The Intellectual Property Court refused the claim of the plaintiff on two grounds. First, the challenged goods had not been placed into circulation and therefore there were no grounds to declare unlawful conduct by the defendant. According to paragraph 7.4.6 of the Decree of the Chief Medical Officer of the Russian Federation from 17.04.2005 N 50, companies are prohibited from selling dietary supplements without state registration. Therefore the actions of the defendant were merely preparatory actions for the entry of goods into civil circulation. It was the opinion of the court that such actions could not be considered as use of a trademark in violation of Article 1484 of the Civil Code of the Russian Federation.

Second, because the defendant was placing the trademark on dietary supplements, the court found that the product was not homogeneous with the goods of the plaintiff. Consistent with the "VECHERNIE" Presidium decision, the court stated that dietary substances should not be considered to be

pharmaceutical or dietary substances for medical purposes. Therefore there were no grounds to establish that the goods were homogeneous.

4.4 THE SEVENTH COURT OF APPEAL: "ХОЛОСАС" (CHOLOSAS)²²

CJSC Altaivitamini v. Manufacturing company Pharm-Pro LLC
Case No. A45-23311/2014
June 11, 2015
Seventh Court of Appeal

In this case, Altaivitamini filed a claim against Pharm-Pro for the illegal manufacture of medical preparations bearing the trademark "Холосас Cholosas". Pharm-Pro had manufactured the products for Geneses LLC, who had the authority to use the trademark through a licensing agreement. Pharm-Pro were not involved in the introduction of the goods into circulation in Russia.

According to Article 1238 of the Civil Code, with the written consent of the licensor, the licensee has the right to grant under a contract the right to use a result of intellectual activity or a means of individualization to another person (sublicense contract). Under a sublicense contract, the sub-licensee is granted the right to use a result of intellectual activity or means of individualization only within the limits of those rights and those means as provided for by the license contract.

The Court of Appeal found that the defendant Pharm-Pro was not a party to the license agreement for the trademark and Geneses had no right to conclude licensing contracts to "have made" with third parties or to use the trademark without the consent of the licensor. Therefore, Pharm-Pro was violating the plaintiff's exclusive right to manufacture or sell goods bearing their trademark. The defendant Pharm-Pro was required to remove all goods bearing the mark from circulation and to pay compensation of 100,000 RUB (1,587 USD).

4.5 THE INTELLECTUAL PROPERTY COURT: "BRAVADIN"

Les Laboratoires Servier v. Rospatent
Case No. SIP-525/2015
October 31, 2016
Intellectual Property Court

Similarly to the KARNITON case (see 4.1 above), the issue before the court was whether a designation confusingly similar to an

International Non-proprietary Name (INN) can be registered as a trademark.

In 2010, Krka, a generic pharmaceutical company, registered the "BRAVADIN" trademark in Class 5 using the Madrid system with an extension for Russia.

In 2014, the plaintiff, Les Laboratoires Servier, filed a post-grant opposition to the registration of the "BRAVADIN" trademark, claiming its confusing similarity with the INN "ivabradine". Rospatent, however, noted that Krka's trademark was arbitrary (fanciful) and could not be viewed as confusingly similar with the INN "ivabradine". The plaintiff successfully appealed to the IP Court.

In line with the Supreme Arbitration Court (see "KARNITON" case 4.1 above), the IP Court analyzed phonetics, semantics and graphics of the "BRAVADIN" trademark and concluded that it was similar to the point of confusion with the INN "ivabradine". The court further stated that registration of trademarks comprising INNs is contrary to the public interest because an INN is a unique example of an international standard in healthcare and its registration as a trademark, on the one hand, unreasonably puts the right holder in a privileged position and, on the other hand, damages the reputation of Russia as a member of World Health Organization. The court pointed out that as a WHO member, Russia committed to discourage the use trademarks derived from or including INN stems in accordance with Resolution WHA 46.19. The court rejected Rospatent's argument that the trademark at issue did not include an INN stem and, thus, did not fall under resolution WHA 46.19. According to the court, INNs belong in the public domain and trademarks confusingly similar to INNs cannot be granted protection.

4.6. THE INTELLECTUAL COURT: "АСД" (ASD)

Agrovetzashita v. Rospatent
Case No. SIP-615/2017
May 15, 2018
Intellectual Property Court

In this case, the IP Court considered whether the registration of a commonly known abbreviation used in medical and veterinary science was nevertheless justified due to its long and intense use in commerce.

The plaintiff, Agrovetzashita, had registered the "АСД (ASD)" trademark under Class 5 in 2013.

In 2017, a third party, BIOSTIM, filed an opposition to registration of the trademark with Rospatent on the ground that, first, "АСД (ASD)" is commonly known in medical and veterinary science as

an abbreviation for antiseptic stimulators invented by Alexey Dorogov and, second, the trademark describes the product, namely, the antiseptic and stimulatory effect of the medicine, which impedes its registration as a trademark. Rospatent found the third party's arguments persuasive and cancelled the trademark registration.

On appeal to the IP Court, the plaintiff claimed that, despite the fact that the trademark is known as an abbreviation for a particular medicine, it has nonetheless acquired distinctiveness as a trademark through its long-term and intense use in commerce by the plaintiff and its affiliated company. To show acquired distinctiveness of the "АСД (ASD)" trademark the plaintiff presented samples of advertising materials, medicine labels, copies from magazines and books of reference, advertising expenses data, volume of sales data, product packages samples, sales contracts, invoices, bills of lading etc. for the period between the trademark's priority date in 2012 and the date when the opposition to registration was filed in 2017.

The IP Court held that the presented documents evidenced acquired distinctiveness of the "АСД (ASD)" trademark because the medicine had a wide range of consumers in Russia, was sold in large amounts and on vast territories.

Therefore, the IP Court overturned Rospatent's decision and reinstated the protection of the trademark.



V. COUNTERFEIT PHARMACEUTICALS

> 5.1 GENERAL OVERVIEW OF COUNTERFEIT PHARMACEUTICALS IN RUSSIA

The World Health Organization defines a counterfeit medication as "one which is deliberately and fraudulently mislabelled with respect to identity or source". Comparatively, the Russian Federal Law on the Circulation of Medicines differentiates between falsified, inferior and counterfeit medicines



"The trend is certainly toward high craftsmanship in counterfeits."

5.1.1 WHAT ARE COUNTERFEIT PHARMACEUTICALS?

Falsified medicine "is medicine accompanied with false information as to its composition and/or manufacturer".

Inferior medicine is "a medicine falling short of the requirements of a pharmacopoeian article or missing some of the requirements of regulatory documentation or a regulatory document".

Counterfeit medicine is "a medicine that is in circulation in violation of civil legislation". Although the differences in definitions may seem trivial, how the State decides to characterize the case and classify the offending pharmaceutical will determine how the matter is handled by law enforcement agencies.

5.1.2 COUNTERFEIT PHARMACEUTICALS IN RUSSIA

It is difficult to know how prevalent counterfeit pharmaceuticals actually are in Russia. There is no question that the circulation of counterfeit medicines in Russia is a significant concern. Opinions are varied on the subject. Some doctors warn that up to 50% of over-the-counter medications such as analgesics could be fakes — they tell patients to stock up when travelling abroad - just to "be safe". The first counterfeit pharmaceutical confirmed by the Ministry of Health in Russia was discovered in 1997, when the stock of an anticoagulant named rheopolyglucin was discovered to be spurious.²³ Since then counterfeit pharmaceuticals have been a growing concern.

According to the official statistics released by Roszdravnadzor, less than 1% of all medicines in Russia are counterfeit. Roszdravnadzor recently reported that for the first nine months of 2019 it had seized 10 trade names and 17 series of counterfeit medicines²⁴ (in comparison with 18 trade names and 27 series in 2018).²⁵ These statistics, however, do not take into account the rising sales of counterfeit medicines on the Internet.

On the other hand, in 2012 the Russian Academy of Sciences estimated that the counterfeit pharmaceutical trade in Russia was valued at approximately 2.5 billion USD.²⁶ This number is consistent with the estimate of the deputy Prosecutor General Alexander Buksman who claimed that up to 15% of medicines sold in Russia are counterfeit.²⁷

A report conducted by the World Health Organization estimates that the figure may actually be higher, finding that as much as 20% of all pharmaceuticals in Russia may be counterfeit; which would put Russia at a similar level to developing countries.²⁸

According to recent polls, 40% of Russians believe that they have been the victims of counterfeit medication²⁹ Conversely, Spiegel, former deputy chair of the Federal Assembly Council for Science, Culture, Education, Health and Ecology estimated that

only 1.2% of the pharmaceuticals marketed in Russia are counterfeit. However, this estimate has been criticized as being unrealistic since that figure is comparable to that for countries with a much more effective anti-counterfeiting system.³⁰

In a report released in 2016 by Russia's Higher School of Economics (HSE), the counterfeit market as a whole appears to be worsening. With an economic downturn that has now lasted several years, consumers are looking more and more for cheaper alternatives for everyday items. The HSE estimated in 2016 that up to 20% of dairy products, 50% of fish products and 38% of some categories of wine may be counterfeit. There is reason to believe that the same troubling trend exists for drugs in Russia.

The Russian counterfeit pharmaceutical market has become increasingly sophisticated, focusing on making counterfeit medicine that is visually indistinguishable from legitimate medicine. Many counterfeit pharmaceuticals are being made in legitimate factories that run a "night shift" to increase revenue. These drugs usually do not pass muster in terms of quality control; often they are made with less active ingredients in order to reduce costs.³¹ In 2006, a private investigation conducted by Pfizer found that Russian counterfeits were "the finest counterfeits" they had seen.³² As Gennady Shirshov, executive director of the Union of Professional Pharmaceutical Organizations, said, "I wouldn't call them 'high-quality' but the trend is certainly toward high craftsmanship in counterfeits."³³

While historically counterfeit pharmaceuticals in Russia were imitations of locally produced pharmaceuticals - 67% in 2002 - there has been a complete shift towards counterfeiting foreign originating medications. By 2006, 73% of counterfeit drugs were copies of foreign drugs.³⁴ The most common counterfeit drug found by Roszdravnadzor during inspections in 2006 were "high volume, low cost" antibiotics which made up to 38% of counterfeit medicines.³⁵

Other drugs that are counterfeited in Russia include "lifestyle drugs" that are directed to erectile dysfunction or weight loss.

More disturbingly, counterfeits of life saving drugs such as anti-stroke pills, cardiovascular medication, and HIV-related medication have also been found in Russia.³⁶

Most counterfeit drugs in circulation in Russia are manufactured domestically; however, there appears to be a shift towards international manufacturers, specifically South East Asia. In 2006, approximately 70% of counterfeit medicine in circulation in Russia was manufactured inside of the Russian Federation.³⁷ In early 2009 a report indicated that approximately 62% of all counterfeit drugs in circulation in Russia were manufactured domestically.³⁸ However, other estimates have claimed that this number is much lower, and that 50% of counterfeits in Russia are domestically produced.³⁹ In 2013, the Russian Ministry of Health released a report explaining that of the 1103 substandard drugs that were withdrawn from circulation, 60% of the drugs were manufactured in Russia.⁴⁰ While most of Russia's counterfeit medicine seemed to be domestically produced, a study in 2012

revealed that as much as 31% were manufactured in South East Asia.⁴¹ Other CIS countries (former Soviet republics) account for 2% of Russia's counterfeit pharmaceuticals.⁴² However, there is difficulty in accurately determining what the correct distribution is, as most reports rely on detected counterfeits, which may distort the statistics towards domestic production. Furthermore it is difficult to determine the origin of counterfeit medicines that are buried in the supply chain of otherwise legitimate manufacturers and distributors.⁴³

5.1.3 COUNTERFEIT TRADE OF PHARMACEUTICALS: WHAT ARE THE CONSEQUENCES?

Counterfeit pharmaceuticals represent an enormous challenge to the health care system in Russia. Counterfeit medication "knows no rules": it is not subject to regulation or quality control to ensure consistency, purity and stability of active ingredients, as well as the removal of impurities and toxic substances.⁴⁴ As a result, counterfeit pharmaceuticals may be contaminated; they may come without an active pharmaceutical ingredient; or they may contain an insufficient quantity of the active ingredient; or worse still, they may contain a dangerously high quantity of the active ingredient; or they may contain the wrong active ingredient.⁴⁵ Because of this, counterfeit pharmaceuticals, if they deliver the promised result at all, often fall below the necessary standard of quality needed for the effective treatment of diseases.⁴⁶ Mislabelled drugs create the risk that patients will overdose on medication or be harmed from unintentional drug-to-drug interactions.⁴⁷ Additionally, counterfeit drugs that contain insufficient quantities of the active ingredient facilitate the growing problem of drug resistant diseases such as shigella, cholera, salmonella and tuberculosis.⁴⁸ Indirectly, counterfeit pharmaceuticals can contribute to improper healthcare management associated with dosage changes or the unwarranted dismissal of the proper medication as a result of their lack of effect.⁴⁹

As Ranjit Roychoudhury, President of the Delhi Society for the Promotion of the Use of Rational Drugs said, "[I]n the next ten years, spurious drugs will be the single biggest problem in public health."⁵⁰

The dangers of counterfeit pharmaceuticals can be felt around the world. The Medicines and Healthcare Products Regulatory Agency has estimated that counterfeit medicines are responsible globally for approximately half a million deaths a year.⁵¹ According to the World Health Organization, approximately one hundred thousand deaths a year occur in Africa as a result of counterfeit drugs.⁵² However, some reports claim that this number can be as high as 450,000 deaths caused by counterfeit anti-malaria drugs alone.⁵³ The president of the U.S.-based

Center for Medicine in the Public Interest, Peter Pitts, estimated that between 200,000 and 300,000 people in China die each

year as a result of counterfeit medicine.⁵⁴

The harmful effects of counterfeit drugs are not exclusive to developing countries. In 2006, a Canadian woman died as a result of taking counterfeit medication that was purchased online from an unlicensed pharmacy⁵⁵; 149 Americans died in 2007 and 2008 as a result of a contaminated counterfeit blood thinner.⁵⁶ In 2012 it was discovered that counterfeit vials with no active ingredient of the cancer medication AVASTIN had entered the U.S. market.⁵⁷

"In 2010, the counterfeit medicine trade cost the pharmaceutical industry 75 billion USD of lost revenue; a 90% increase since 2005."

Beyond the dangers to human health, the counterfeit pharmaceutical trade has significant consequences for the pharmaceutical industry and the Russian economy. Counterfeit drugs represent a substantial source of lost revenue for the pharmaceutical industry. The National Association of Boards of Pharmacy estimated that in 2010 the counterfeit medicine trade cost the pharmaceutical industry 75 billion USD of lost revenue; a 90% increase since 2005.⁵⁸ Allied Market Research estimates that global trade in counterfeit drugs will reach approximately 142.7 billion USD by the year 2020.⁵⁹ In 2006, it is estimated that counterfeit medicine cost the pharmaceutical industry 300 million USD in Russia alone.⁶⁰ Additionally, because customers are unable to differentiate between genuine and counterfeit pharmaceuticals, counterfeiting poses serious reputational risks to the pharmaceutical industry associated with decreased product quality and safety.⁶¹ On the government side, counterfeit pharmaceuticals hinder the development of the Russian economy and provide additional costs to the government. As the Organization for Economic Co-Operation and Development explained, counterfeiting decreases economic growth by diminishing the incentives for companies to innovate. Industries, like pharmaceuticals, with high research and development costs, are particularly vulnerable to the adverse affects of counterfeiting.⁶² Counterfeit pharmaceuticals also increase the burden on the government to scale up anti-counterfeiting measures.

5.2 ANTI-COUNTERFEITING AND TRADEMARK ENFORCEMENT

5.2.1 LEGISLATIVE MEASURES DIRECTED AT COMBATING PHARMACEUTICAL COUNTERFEITING

As previously mentioned, the Russian legal system is a civil law system based on both substantive and procedural codified laws. Trademark infringement in regards to pharmaceutical products can involve several different federal laws:

- part IV of the Civil Code (230-FZ) of December 18, 2006;
- the Competition Law of the Russian Federation (135-FZ) of July 26, 2006;
- the Criminal Code (63-FZ) of June 13, 1996;
- the Code of Administrative Offences (195-FZ) of December 30, 2001;
- the Law on the Circulation of Medicines (61-FZ) of April 12, 2010;
- the Law on Customs Regulations in the Russian Federation (311-FZ) of November 27, 2010;
- the Arbitration Procedural Code (95-FZ) of July 24, 2002; and
- the Criminal Procedural Code (174-FZ) of December 18, 2001.

Additionally, Russia is a party to the following treaties relevant to trademark enforcement and counterfeiting:

- the Paris Convention for the Protection of Industrial Property;
- the Customs Code of the Eurasian Economic Union;
- the Madrid Agreement; and
- the Agreement on Trade-Related Aspects of IP Rights.

5.2.1.1 PART IV OF THE CIVIL CODE OF THE RUSSIAN FEDERATION

As mentioned in an earlier section, intellectual property rights in Russia are provided for in Part IV of the Civil Code. In 2008, this legislation consolidated and revised the numerous intellectual property laws that were implemented in 1992 following the collapse of the Soviet Union. It represented the first attempt to fully consolidate intellectual property laws. Part IV of the Civil Code, Chapter 76 § 2 on the “Right to a Trademark and a Service Mark” provides the legal basis for trademark law, the requirements and process for registering a trademark, the scope of a trademark owner’s rights, and the remedies available for trademark infringement.

According to Article 1484, the owner of a trademark has the exclusive right to the use of a trademark, and therefore may permit or prohibit others from placing the trademark on goods introduced into Russia. In addition, it regulates the use of documents related to the introduction of goods into commerce, the use of trademarks on the Internet and offers for sale of trademarked goods or services such as advertisements. Additionally, no person has the right to use a designation without permission if it is confusingly similar to a registered trademark.

Under Article 1515, the use of a mark on the packaging of goods that is confusingly similar to a registered trademark is illegal and considered to be counterfeit. The owner of the trademark is

entitled to seek the withdrawal of the counterfeit goods from circulation and their destruction. The owner of the trademark may also claim compensation in the amount of 10,000 to 5,000,000 RUB (170 to 85,000 USD) at the court’s discretion. The trademark owner may also choose to claim double the value of the counterfeit goods or double the standard cost for the right to use the trademark.

5.2.1.2 THE COMPETITION LAW (135-FZ) OF JULY 26, 2006

On October 10, 2015 a new chapter 2.1. was added into the Competition Law, which now covers a broader array of acts that might represent unfair competition, including:

- passing-off (art. 14.2);
- unfair competition aimed at acquiring and using an exclusive right in a means of individualization of a legal entity, goods, works or services (art. 14.4);
- unfair competition aimed at unlawful use of an IP object (14.5); and
- unfair competition aimed at creating confusion (including illegal copying or imitation of a product’s design that can cause confusion amongst consumers) (art. 14.6).

5.2.1.3 CODE OF ADMINISTRATIVE OFFENCES (195-FZ) OF DECEMBER 30, 2001

The Code of Administrative Offences provides for administrative sanctions and procedures relating to quasi- criminal conduct including trademark infringement.

Article 14.10 of the Code of Administrative Offences provides for liability for the illegal use or manufacture of trademarks, service marks, and the good’s place of origin and has the potential to create significant fines for counterfeiters. According to this Article, any illegal use of a foreign trademark can lead to an administrative fine for individuals of 5 to 10 thousand RUB (80 to 158 USD) in addition to the confiscation of the items bearing the illegal trademark as well as the materials and equipment used for their manufacture. The fine increases to 10 to 50 thousand RUB (158 to 790 USD) for officials, and increases to 50 to 200 thousand RUB (790 to 3,161 USD) for legal entities.

The manufacture for the purpose of sale of goods bearing an illegal trademark can lead to a fine for individuals of double the value of goods with the confiscation of the goods bearing the illegal mark and the equipment and materials used to manufacture them. For officials, this fine increases to three times the value of the goods and increases to five times the value of the goods for legal entities.

5.2.1.4 THE LAW ON CUSTOMS REGULATIONS IN THE RUSSIAN FEDERATION (311-FZ) OF NOVEMBER 27, 2010, AND THE CUSTOMS CODE OF THE EURASIAN ECONOMIC UNION

The Law on Customs Regulation in the Russian Federation, taken concurrently with the Customs Code of the Eurasian Customs Union, provides mechanisms to prevent illegal cross-border traffic of counterfeit goods into Russia. Article 183 sets out the procedure for the seizure of goods during a customs inspection.

According to this article, customs inspectors can seize goods if they appear to be counterfeit. The seizure of goods can also be achieved through Article 132 of the Customs Code of the Customs Union, which enables on site customs to check and withdraw counterfeit goods from circulation.

To implement regular routine customs inspections, the trademark owner must apply to record its registered marks with the Federal Customs Service of the Russian Federation. Customs officials may then suspend the circulation of counterfeit goods. To be recorded on the Customs Register the trademark owner should provide:

- full corporate details, address and corporate status of the trademark owner and its representatives;
- a power-of-attorney in the name of the representative, if any;
- a list of valid trademarks in Russia and their registration certificates;
- information about other parties that are authorised to use the IP rights;
- sufficient information to allow the customs authority to identify the goods;
- information on cases of trademark infringement;
- the term requested for the recordal;
- a document confirming that the trademark owner will reimburse any damages suffered as a result of an unlawful customs suspension; and
- a bank guarantee or insurance of liability for the amount of 500,000 RUB (8,000 USD).

When a registered trademark is recorded with Russian customs, they will monitor the importation of goods that bear the trademark. If the customs inspection reveals goods appearing to be counterfeit, the goods are detained for ten days (with the possibility to extend for an additional ten days) and the rights owner is informed of the situation. The rights holder has the right to examine the goods (take samples and photos) and inform Customs if the goods are counterfeit.

If the goods are counterfeit, the trademark owner must either ask customs to initiate an administrative proceeding or initiate a

civil legal proceeding on its own within the twenty-day limitation period or the goods will be released.

In order for a customs recordal to be effective, the requesting party should appoint a local representative to coordinate daily inquiries from customs and have an expert who is authorized to determine if the detained goods are counterfeit; in which case the expert will provide Customs with a supporting opinion that will justify a seizure.

Customs officials also recommend that right holders provide specific information such as risk profiles for genuine goods such as lifestyle drugs so that officials can more readily hunt down counterfeits. Russian Customs officials are also open to be trained by rights holders as to how best to identify counterfeits.

5.3 COUNTERFEIT PHARMACEUTICALS AND RUSSIAN CRIMINAL LAW

5.3.1 RECENT CHANGES TO RUSSIAN CRIMINAL LAW ON COUNTERFEIT PHARMACEUTICALS

On December 31, 2014, the President signed Federal Law No.352-FZ amending the Criminal Code, the Code of Administrative Offences, and other regulatory acts. The purpose of the law was to provide a more appropriate level of criminal liability, and therefore a more effective counter to Russia's growing counterfeit pharmaceutical trade. The new law is part of Russia's effort to give effect to the Council of Europe's Medicrime Agreement signed in 2011, ratified in 2017, and which came into force in Russia on January 09, 2018.

The law directly addresses the issue of counterfeit pharmaceuticals. Historically the Russian government and brand owners had to rely on safety violations, fraud and trademark law to criminally charge counterfeiters.⁶³ Prior to the enactment of this new law, the circulation of counterfeit medicine and medical devices was treated no differently than the circulation of counterfeit luxury goods where the primary penalty was seizure of the counterfeit goods and a nominal fine. As a result of these changes, the Russian government no longer needs to establish that the sale of counterfeit medicines or medical devices is causing serious harm to health as a prerequisite to establishing criminal liability punishable by imprisonment.

The amendments introduce five notable improvements that increase criminal liability for crimes related to the production, storage, transportation and circulation of counterfeit drugs and medical devices.

1. Unlicensed Production of Medicines and Medical Devices

Under Article 235.1, the production of medicines or medical devices without obtaining a state license is punishable by 3 to 5 years in prison and a fine of 500,000 to 2,000,000 RUB (8,000 to 31,600 USD). If this crime is committed by a criminal organization or on a scale exceeding 100,000 rubles worth of counterfeit medicines and devices, the penalty increases to a prison sentence between 5 to 8 years and a fine between 1,000,000 and 3,000,000 RUB (15,806 and 47,000 USD).

2. Production, Circulation or Importation of Medicines, Medical Devices and Biologically Active Supplements

Under Article 238.1, the production, import or sale of falsified, inferior, or unregistered medicines or medical devices, as well as the circulation of unregistered falsified active additives containing pharmaceutical substances exceeding the value of 100,000 RUB, are punishable by 3 to 5 years in prison and a fine of 500,000 to 200,00 RUB. If any of these are committed by a criminal organization or result in grave harm to health of individuals these acts are punishable by 5 to 8 years imprisonment and a fine of 1,000,000 to 3,000,000 RUB (15,806 to 47,000 USD). Additionally, if these actions result in the death of two or more people, the conviction increases to 8 to 12 year's imprisonment and a fine between 2,000,000 and 5,000,000 RUB (31,600 to 79,000 USD).

3. The Forgery of Documents Relating to Medicines or Medical Devices

Under Article 327.2, the manufacture of forged documents relating to medicines or medical devices for the purpose of sale or use, is punishable by up to three years imprisonment and a fine of 500,000 to 1,000,000 RUB (7,900 to 15,800 USD). The manufacturing of forged primary or secondary packages for medicines is punishable by up to three years imprisonment and a fine between 500,000 and 1,000,000 RUB (7,900 to 15,800 USD). If either of these offenses is committed by a criminal organization the punishment increases to 5 to 10 years imprisonment.

4. Changes to the Russian Administrative Code

Under Article 6.33 of the Russian Administrative Code, the production, sale or import of falsified, counterfeit, and inferior medicines and medical devices, as well as the circulation of falsified biologically active supplements, that are not punishable as a criminal act, are punishable by:

- a fine of 70,000 to 100,000 RUB (1,100 to 1,580 USD) for individuals;
- a fine of 100,000 to 600,000 RUB (1,580 to 9,483 USD) for public officials;
- a fine of 100,000 to 600,000 RUB (1,580 to 9,483 USD) for individual entrepreneurs, or an administrative suspension of activity for up to 90 days; and
- a fine of 1,000,000 to 5,000,000 RUB (15,800 to

79,000 USD) for legal entities or a suspension, or an administrative suspension of activity for up to 90 days.

- 5. Definitional Changes
- Amendments to Federal Law No.323-FZ of November 21, 2011, on the Principles for Protecting the Health of Citizens in the Russian Federation was extended to define the following terms:
- Falsified Medical Article – a medical article accompanied by false information on its characteristics and/or its manufacturer.
- Inferior Medicine – a medicine falling short of the requirements of the pharmacopoeian article or missing some requirements of regulatory documentation or a regulatory document.
- Counterfeit Medicine or Medical Article – a medicine or medical article that is put into circulation in violation of civil legislation, i.e. bears a falsified trademark.

Prior to the enactment of the new law, there was no universally accepted definition of falsified, inferior or counterfeit medication. Rather, the Russian Federation used diverse and disconnected definitions under the umbrella of, for example, "counterfeit" from Article 1252 Para. 4 and Article 1515 Para. 1 of the Civil Code, and Article. 48 Para. 3 of the Law of the Russian Federation On Copyright and Related Rights.

A universal definition of falsified, low standard and counterfeit medication will help police, judges, lawyers and businesses to understand the distinction between counterfeit and falsified medication.⁶⁴ For example, judicially, universal definitions allow more focused efforts for protecting against counterfeit medicine and determining an appropriate punishment.⁶⁵ Analytically, a universal definition creates consistency between sources and reduces distortions of statistical findings (both wilful and otherwise).⁶⁶

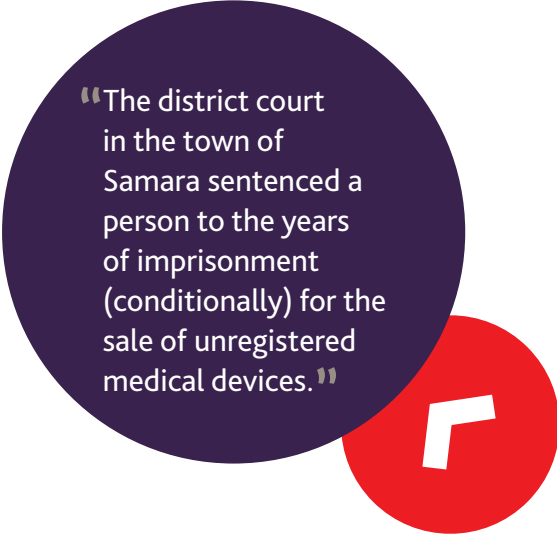
5.3.2 ENFORCEMENT OF THE NEW LEGISLATION

5.3.2.1. CRIMINAL CASES

Criminal jurisprudence under the new legislation is not substantial yet, but the number of criminal sentences in this category is constantly growing. For example, in 2015 there were 12 criminal cases investigated under Art. 238.1 of the Criminal Code and four of them were brought to trial; in 2016, 29 cases were investigated and six were brought to trial; in 2017, 101 cases were investigated and 19 were brought to trial.⁶⁷

Criminal cases under Art. 235.1 (unlicensed production) are less common: no person was sentenced in 2015; in 2016, four persons were sentenced; and in 2017, five persons were sentenced.⁶⁸

Cases concerning the illegal manufacturing and sale of unregistered medicines, medical devices and biologically active supplements appear quite often in Russian criminal jurisprudence. For example, on April 2, 2019, the Presidium of the Moscow City Court confirmed the lower court's decision according to which a person was sentenced to three years of imprisonment (conditionally) for the manufacture and sale of unregistered ultrasound paper to a local hospital (case No. 44y-121/19). The court commissioned a forensic examination to confirm that ultrasound paper was a medical device and did not comply with the label.



“The district court in the town of Samara sentenced a person to the years of imprisonment (conditionally) for the sale of unregistered medical devices.”

Legal entities are also often involved in criminal activities associated with the manufacture and sale of unregistered medicines. For instance, in one case, two companies contracted to manufacture and sell to a hospital, medical oxygen in the absence of state registration. The label of the product contained wrong information about the manufacturer (case № 1-257/2017). On April 4, 2017, the Leninskiy district court of the Town of Krasnoyarsk sentenced each of the CEOs to five years of imprisonment (conditionally) and fines amounting to 1,000,000 RUB (16,300 USD approx.).

Russian courts sometimes seemingly confuse medicines that are subject to mandatory registration under the law and pharmaceutical active ingredients that are not. On April 26, 2017, the Dzerzhinsk District Court of Volgograd sentenced a person to three years of imprisonment (conditionally) for selling unregistered medicine for the treatment of erectile dysfunction on the Internet (case № 1-180/2017). The court did not study the argument that the accused person was in fact selling pharmaceutical active ingredients, and not the medicine itself.

There is also case law regarding unlicensed production of medicines. For example, on July 3, 2017, the Moscow District Court of Kazan sentenced to five years of imprisonment (conditionally) a CEO of a company that was producing medical devices without a license (case № 1-230/2017).

5.3.2.2. ADMINISTRATIVE CASES

Administrative cases based on Art. 6.33 of the Code of Administrative Offences are common: on April 28, 2016, the Arbitration Court of the Irkutsk Region held an individual entrepreneur liable for the sale of inferior medical devices and levied a fine of 50,000 RUB (800 USD) (case No.A19-3703/2016).⁶⁹ The district court in the Rostov Region held the CEO of the company liable for sales of medicines that were not registered on the State Register of Medicines and levied a fine of 100,000 RUB (1,600 USD) (case No. 5-366/2016).⁷⁰

The Arbitration Court of the Rostov Region on August 22, 2016, confirmed Roszravnadzor's decision to impose an administrative fine of 1,000,000 RUB (16,300 USD approx.) upon a legal entity for the sale of falsified surgical silk: the packages were labeled with the wrong manufacturer (case No. A53-16617/2016).

In another case, The Arbitration Court of the North-Western Circuit held on September 27, 2016, that a medicine's inconsistency with labeling requirements is not enough to trigger liability under Art. 6.33 of the Administrative Code of the Russian Federation and the evidence that the medicine in question falls short of the requirements of a pharmacopoeian article or normative documentation should be provided (case No.A21-9765/2015).⁷¹ In a more recent case, Roszdravnadzor, in cooperation with police, fined couriers of unregistered cosmetology medicines "OTESALY BTXA" and "NEURONOX", that were ordered on the Internet, under Art. 6.33 of the Administrative Code amounting to 35,000 RUB (570 USD approx.).⁷²

5.3.3 OTHER SOURCES OF CRIMINAL LIABILITY FOR COUNTERFEIT PHARMACEUTICALS

5.3.3.1 ILLEGAL USE OF A TRADEMARK (ARTICLE 180 OF THE CRIMINAL CODE)

According to Art. 180 of the Criminal Code, the illegal use of a trademark, if committed repeatedly or if causing substantial damage (exceeding 250,000 RUB / approximately 4,000 USD), is punishable with a fine in the amount of 100,000 to 300,000 RUB (1,580 to 4,700 USD) or imprisonment for up to two years.

5.3.3.2 ADDITIONAL CRIMINAL OFFENCES

In addition to these laws, the production, storage, and circulation of counterfeit medication can also result in criminal charges for the violation of the following laws:

- infringement of patent rights (Article 147 of the Criminal Code);
- murder (Article 105 of the Criminal Code);
- negligence resulting in death or grievous bodily harm (Article 109 & 118 of the Criminal Code);
- intentionally inflicting bodily harm (Article 111, 112 & 115 of the Criminal Code);
- fraud (Article 159 of the Criminal Code);
- forgery (Article 327 of the Criminal Code);
- smuggling of potent substances (Article 226.1 of the Criminal Code);
- manufacture, storage, transportation or sale of goods that do not meet safety requirements (Article 238 of the Criminal Code);
- causing damage to property by deception or abuse of trust (Article 165 of the Criminal Code);
- production, purchase, storage, transportation or sale of unmarked goods and products (Article 171.1 of the Criminal Code);
- smuggling super-potent, poisonous, toxic, explosive and radioactive substances, radiation sources, nuclear materials, firearms or basic parts thereof, explosive devices, munitions, mass destruction weapons, their delivery vehicles, other armaments and other military hardware, as well as the materials and equipment that can be used in the creation of
- mass destruction weapons, their delivery vehicles, other armaments and other military equipment, as well as strategic commodities and resources or cultural valuables (Article 226.1 of the Criminal Code);
- illegal acquisition, storage, transportation, making or

processing of narcotic drugs, psychotropic substances or analogues thereof, as well as illegal acquisition, storage and transportation of plants containing narcotics or psychotropic substances, or parts thereof containing narcotics or psychotropic (Article 228 of the Criminal Code);

- theft or extortion of narcotic drugs or psychotropic substances (Article 229 of the Criminal Code);
- illicit cultivation of illicit crop plants containing narcotic substances (Article 231 of the Criminal Code);
- illegal circulation of strong or poisonous substances with a view to marketing (Article 234 of the Criminal Code); or
- corruption (Article 204, 285, 258.1, 290 and 292 of the Criminal Code).

5.4 MECHANISMS IN RUSSIA TO PREVENT DISSEMINATION OF COUNTERFEIT PHARMACEUTICALS

5.4.1 ROSZDRAVNADZOR

The Federal Service on Surveillance in Healthcare and Social Development (or Roszdravnadzor) oversees the regulation of domestic and imported medicines and medical devices.

Roszdravnadzor was established in 2004 by decree of the President, No.314. Roszdravnadzor has a Central Office (with eight divisions), 11 federal laboratory complexes and 80 regional offices.⁷³

Roszdravnadzor is responsible for Russia's quality control of medical care, control over the circulation of medicines and control over the circulation of medical devices.

As regards counterfeit medications, Roszdravnadzor is responsible for:

- licensing of medical activity;
- quality and safety checks of medical practices via audits and inspections;
- federal state supervision in the sphere of the circulation of medicines and medical devices;
- monitoring the safety of medicines in circulation; and
- issuing permits for the importation (and exportation) into Russia of potent substances, which are not precursors of narcotic drugs and psychotropic substances.⁷⁴

To perform these functions, Roszdravnadzor⁷⁵ works with several international organizations, including:

- the Pharmaceutical Inspection Co-Operation Scheme (PIC/S);

- The Working Group of Enforcement Officers of the Head of Medicines Agencies (HMA WGEO);
- The Organization of the Black Sea Economic Cooperation (BSEC);
- The International Medical Device Regulation Forum (IMDRF); and
- The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).⁷⁶

Additionally, Roszdravnadzor works with the regulatory agencies of other countries, including the China Food and Drug Administration (CFDA), the National Institutes for Food and Drugs Control, China (NIFDC), and the United States Food and Drug Administration (USFDA).⁷⁷

5.5 THE COMMON BARRIERS TO ANTI-COUNTERFEITING ENFORCEMENT IN RUSSIA

Despite the new laws, there are several barriers in Russia that pose serious limitations on their effectiveness:

- Established criminal networks – Russian counterfeit pharmaceutical producers and distributors have increasingly organized large-scale structures with close ties to more traditional sectors of organised crime (prostitution, drugs, arms dealings, etc.). These large-scale criminal organizations are able to take advantage of local and national corruption in Russia and use their advanced criminal networks to increase speed and efficiency of trade channels. This is a significant concern in Russia, where there remains significant corruption within regulatory and law enforcement agencies as well as some of the courts.
- Night-shift drugs – Many of the counterfeit pharmaceuticals sold in Russia are associated with otherwise legitimate sources of production. A significant portion of Russia's counterfeit pharmaceuticals emanate from legitimate producers who run "night shifts" to produce more certified drugs. These drugs are not subject to the usual internal checks and quality controls and oftentimes they have reduced levels of active ingredients. This results in the intermingling of high quality and low quality "night shift" drugs in the same supply chain.
- Multiple variables associated with treatments – the nature of counterfeit pharmaceuticals makes them difficult to detect. Counterfeit medicines are often virtually identical in appearance to legitimate medicines. Additionally, if a patient's condition deteriorates as a result of receiving

spurious medication, the noted change in condition is often attributed to the illness itself or to patient idiosyncrasies, rather than to the counterfeit medication. If counterfeit medication is suspected, the amount of time it takes to eliminate other variables, such as a doctor misdiagnosis or a unique medical condition, often gives the counterfeiters time to "cover their tracks" before the medication itself is suspected as being fake.

- The attraction of cheap medicines – consumers are often unaware of the significant potential dangers of counterfeit pharmaceuticals and are often willing to purchase cheap medicines, turning a blind eye to the risks. A study conducted in 2012 found that 89% of Russians were complicit towards counterfeit pharmaceuticals. This ranked second only to China for consumer complicity towards counterfeits. Many factors are at play such as pharmaceutical pricing and social marketing, and personal factors such as education, income and ideology.

"A significant portion of Russia's counterfeit pharmaceuticals emanate from legitimate producers who run "night shifts" to produce more certified drugs."

- Ineffectual laws – Until now, Russia has historically had inadequate legislation to deal with counterfeit pharmaceuticals. Before enacting the recent legislation, counterfeit medicine was treated in the same manner as counterfeit luxury goods, which carried a nominal fine and no criminal remedies. Trademark infringement only had penalties ranging between 5,000 and 8,000 USD. As such, there was little or no disincentive for criminals to engage in the multi-billion dollar counterfeit pharmaceutical market. However, as previously mentioned, the Russian State Duma has, within the decade, enacted legislation making it a criminal offence to produce, circulate or store counterfeit drugs.

5.6 ONLINE PHARMACIES AND COUNTERFEIT PHARMACEUTICALS

5.6.1 ONLINE PHARMACIES IN RUSSIA AND AROUND THE GLOBE

E-health, the convergence of the health industry and the Internet, has brought with it legitimate online health education, outreach disease surveillance, collaboration and communication between patients and providers, and support of clinical decisionmaking.⁷⁸ According to the Internet market research organization eMarketer, the global online pharmacy trade was ahead at 1 billion USD a year by 2012.⁷⁹

However, the convergence of healthcare and the Internet also provides new opportunities for criminal organizations and other illicit actors to sell counterfeit pharmaceuticals by means of online pharmacies.

In the online pharmaceutical industry, more than 80% of the pharmacies that advertise are in some way illegal, mostly in regards to selling counterfeit drugs.⁸⁰ As previously discussed, fake drugs pose a serious global health risk over and above the economic challenges to innovative pharmaceutical companies. In addition to these concerns, online pharmacies pose a challenge to the pharmaceutical industry by undermining the credibility of legitimate online pharmacies as a new business model for growth.

According to the International Institute of Research Against Counterfeit Medicines, there are three types of online pharmacies:

- 1. Online delivery services** – Pharmacies that deliver medicines to patients after receiving a prescription sent electronically from a doctor;
- 2. Online diagnosis and prescription services** – Pharmacies that employ doctors to prescribe medication based on a questionnaire filled out by the patient online, after which, the medication is prescribed and sent to the patient; and
- 3. Unregulated delivery without a prescription** – “Pharmacies” that are willing to deliver internationally, without requiring a prescription, as long as the patient is willing to pay.⁸¹

According to a 2011 study by the National Association of Boards of Pharmacy, more than 96% of online pharmacies can be traced to rogue networks with questionable drug sources, and of those pharmacies, 85% fall into the third more nefarious type of online pharmacy that does not even require a prescription.⁸²

The use of online pharmacies in Russia is not uncommon. Representatives in the industry are forecasting that online pharmacy marketshare will be at least 10-12% of the Russian pharma market by the end of 2020, up from 6-7% in 2019. Russia ranked 4th globally in visitors to websites connected to illicit pharmaceuticals, comprising 6.5% of the total traffic.⁸³ The online sale of pharmaceuticals accounts for approximately 1% of the total pharmaceutical market in Russia.⁸⁴ The Russian search engine Yandex lists 279 websites in its catalogue of online pharmacies. The largest of these websites is www.Piluli.ru which has been active online for over ten years. Piluli is estimated to receive nearly 1,300,000 visitors a month and is amongst the top 800 most viewed websites in Russia.⁸⁵

“Online pharmacies pose substantial challenges for agencies wishing to enforce regulations and criminal liability.”

Online pharmacies located in Russia are not just a risk to the people of Russia. Rather, the global reach of the Internet means that counterfeit pharmaceuticals can reach across the world. For example, Russian programmers have pretended (sometimes referred to as spoofing) to be Canadian pharmacies, using spam to lure naive customers across the globe into purchasing counterfeit pharmaceuticals.⁸⁶ The United States was by far the number-one visitor to websites associated with pharmaceutical spam, amounting to 54% of total traffic; followed by China and the United Kingdom, who generated 26.5% and 8.9% respectively.⁸⁷ The products offered are mostly lifestyle pharmaceuticals, diet pills, growth hormones, melatonin and products promising to help to quit smoking.⁸⁸

Online pharmacies pose substantial challenges for agencies entrusted with the enforcement of national regulations and criminal sanctions. First, it is difficult to determine the location of online pharmacies, and once they are discovered, it is easy for illicit actors to reopen the online pharmacy at another address.⁸⁹ This is particularly challenging by reason of the large volume of illegal online pharmacies.⁹⁰ Secondly, jurisdictionally, it is difficult for agencies to take action against online pharmacies located outside of their national borders. This is especially difficult because many online pharmacies place multiple operating divisions in different geographic areas across several countries.⁹¹

One example of this is the illegal pharmaceutical website “medichopperx” that “registered its domain name in Russia, used website servers located in China and Brazil, processed payments through a bank in Azerbaijan, and shipped its prescription drugs from India.⁹² Despite the challenges, there have been success stories. In 2008 Interpol launched Pangea IV as a measure to combat against illegal online pharmacies; in 2012 the operation confiscated 3.75 million units of counterfeit medicine and over 18,000 websites were shut down.⁹³

In 2010 the Russian authorities charged Igor Gusev with illegal operation of the online pharmacies SpamIt and GlavMed without a license. This case provides interesting insight into the breadth and nature of illegal online pharmacies in Russia. GlavMed worked by using affiliate programs; one affiliate, SpamIt, would use spamming campaigns and other suspect activities to sell medicine, while the other affiliates, such as the Canadian Pharmacy network, would showcase GlavMed as a legitimate online pharmacy. It would often be promoted under the pretense of being a Canadian pharmacy selling lifestyle drugs online.⁹⁴ GeRa, an affiliate of SpamIt, was connected to a spambot that was capable of generating 18 billion emails per day.⁹⁵ This practice is not uncommon among illegal online pharmacies, as it is standard practice for them to use spam, botnets, and malware to advertise their products and websites.⁹⁶ In total GlavMed had about 1,800 affiliate websites used to promote and sell online pharmaceuticals.⁹⁷ In three years of operation these websites sold knockoff prescription drugs to more than 800,000 customers and generated over 150 million



USD in revenue from over 1.5 million orders. Although there was a minor drop in spam emails for illegal online pharmacies after the charges were laid, the numbers bounced back to their previous high shortly afterwards.⁹⁸

5.6.2 THE LEGALITY OF ONLINE PHARMACIES IN RUSSIA

Until the pandemic, online pharmacies in Russia were completely illegal. There was ambiguity about what was exactly prohibited. Most of the legislation affecting online pharmacies in Russia deals with the delivery of pharmaceuticals.

Under Article 5 of Decision No.612 of the Government of the Russian Federation, dated September 27, 2007, on the Approval of the Regulation on the Selling Goods by Distance Methods, it was "prohibited to sell by distance methods... goods whose free realisation is prohibited or limited under the laws of the Russian Federation".

The sale of goods by "distance methods" means the sale or purchase of goods on the basis of the association of the buyer with the description of the goods offered by the seller using telecommunications networks, such as the Internet. This law

may be taken in conjunction with the February 22, 1992, Decree of the President of the Russian Federation No.179, on the Types of Products and Production Waste Whose Free Sale is Banned; this lists medicine (not including medical herbs) and medical equipment that use radioactive substances and isotopes, as products whose free sale is prohibited in Russia.

Medicines are therefore in a category of products whose sale by "distance methods" (including the Internet) was, until recently, prohibited.

There were no legislative exceptions for online or remote pharmacies. Therefore, an online pharmacy must obtain a standard medical retail license. According to Article 55 of the Federal Law on the Circulation of Medicines No.61-FZ, April 12, 2010, retail trading of medicines can only be conducted by pharmacies, individual entrepreneurs holding a license for pharmaceutical activity, and medical establishments holding a license for pharmaceutical activity (and their subdivisions). Because of this, online pharmacies are required to act in accordance with the Russian rules regulating pharmacies.

According to Article 4 of the Decision of the Government of the Russian Federation No.1081 on Licensing Pharmaceutical Activity of December 22, 2011, for a pharmacy to receive a

license it must own the equipment and premises required for pharmaceutical activity. This requires that the pharmacy conduct its business at a stationary address. Additionally, according to Article 1 paragraph 4 of the Rules for Sales of Particular Types of Goods, adopted by the government's Decree No.55 of January 19, 1998, the sale of medicine is restricted to stationary places of sale.

"It is prohibited to sell by distance methods ... goods whose free realisation is prohibited or limited under the laws of the Russian Federation."

Until the new COVID driven amendments pharmacies employed a series of tactics to bypass these laws. One way is to effect an in-person sale directly between the pharmacy and the courier at the location of the pharmacy. This allows them to avoid the use of the prohibited "distance method". Online pharmacies claim that the courier is acting within an agency agreement creating a fiduciary relationship between the buyer and the courier, or claiming that the courier is acting on behalf of the buyer without a commission. As a result, the pharmacy claims that it is not delivering any medication.

To act in strict accordance with Russian law, online pharmacies can either give the information about their locations and inventory without making sales online, or restrict online sales to the pick-up of pharmaceuticals, where the patient can register online for a prescription and pick it up at the pharmacy.

In addition to the general illegality of online pharmacies as a means for selling medication, the general provisions in Part IV of the Civil Code as regards trademarks apply with equal force to online activities and cyber squatting.

Prior to the COVID pandemic, the Russian Ministry of Healthcare and Social Development had recently introduced an initiative to legalize distance sales of medicines. It proposed that only licensed pharmacies would be allowed to sell medicines via the Internet. The bill passed its first reading in the Russian Parliament in 2017. It was first planned to legalize the sale of over-the-counter medicines by July 1, 2020, and the sale of prescription drugs by January 1, 2022. However, the draft law was criticized by the government because, among other things, it did not provide for a procedure of checking authenticity of e-prescriptions sent to a pharmacy, nor did it set out a procedure for the identification of buyers.⁹⁹

Many of the restrictions outlined above were removed by Presidential Decree on an urgent basis as a response to the COVID pandemic.

The Decree came into effect in April of 2020. It allows for the online sale of over the counter drugs but only by otherwise licensed pharmacies and further strengthens the controls over counterfeit or otherwise unauthorised drugs. The decree does not allow for the online sale of prescription drugs or narcotic drugs. A detailed set of online sale regulations is expected very soon.

Note also, that since July 2017, Russian doctors are able to prescribe medicines electronically. The e-prescriptions must be signed with a qualified electronic signature of a doctor. Before prescribing medicines in the form of e-prescription, a doctor must examine a patient face-to-face.

5.7. INTRODUCTION OF THE TRACK-AND-TRACE SYSTEM

On December 28, 2017, Russia's President signed a law introducing mandatory identification marks on medicine packaging and a track-and-trace system for all medicines in circulation. The primary goal of the new law is to eliminate the illegal trafficking of medicines in Russia and to allow the government to monitor the flow of medicines on the market.

All packaging for medicines other than those imported for the purpose of conducting clinical trials or intended for export must be labelled with a special code that encodes information about a particular medicine (e.g. its manufacturer and expiration date). Based on publicly available information, consumers can check the legality of a particular medicine with a smartphone or a scanner in a pharmacy.

In addition to the package labelling requirement, the new law obliges manufacturers, distributors, pharmacies and hospitals to ensure that medicine information is entered into the state information system. Market participants and regulators can use this information to track the circulation of medicines at every stage in the supply chain, especially for medicines supplied under state contracts. Medicine manufacturers will have access to information about batches and many of their products circulating in Russia.

The system became law in July, 2020, and manufacturers are now required to apply a 2D-data matrix barcode to packaging, including OTC medicines.¹⁰⁰ There may be some exceptions.



VI.

THE PARALLEL IMPORTATION OF PHARMACEUTICALS IN RUSSIA

> 6.1 BACKGROUND

6.1.1 WHAT IS PARALLEL IMPORTATION?

The notion of parallel importation refers to legitimate branded goods or products that are imported into a country or market and sold in that market without the consent of the trademark owner. These products are therefore genuine goods that have been manufactured by (or with consent of) the trademark owner, but which have entered into the market through an unauthorized trade channel; they are often referred to as "gray market" goods.

Why do gray markets exist? Often they emerge because there is a price differential for the identical products in different geographical markets or because a product is not yet available in a particular market.

Hays, in *Parallel Importation under European Union Law*, identified intellectual property rights, transaction costs, technical barriers, trade policies, vertical constraints, and previously existing parallel trade as factors affecting the demand for parallel importation of products from one market to another.¹⁰¹

In his paper, *The Parallel Importation of Unauthorized Genuine Goods*, Richard M. Andrade identified three reasons why gray markets may emerge¹⁰²:

- a. **Currency fluctuations** – Gray markets may emerge as a result of fluctuation in currency exchanges. Currency fluctuation can result in discrepancy in cost between markets when one market's currency stays strong relative to another currency;
- b. **Deliberate price discrimination** – Gray markets may emerge as a result of price discrimination by international manufacturers. As is cited by proponents of parallel importation, foreign companies may manipulate the price of their product through anti-competitive behaviour and artificially inflate the price of their product; and
- c. **Additional cost burdens** – Gray markets may emerge as the result of cost differentials among nations. As Andrade explains, price discrepancies can result from legitimate cost differentials such as "increased manufacturing costs... or due to disparities in raw material accessibility, labour costs, utility expenses, tax liabilities, efficiency of production facilities, [and] government subsidies... in a high manufacturing cost nation... the price of the good will have to adjust accordingly."¹⁰³

There can be and often are therefore justifiable reasons why products might be more expensive in one market than in another. Economies of scale can also be the reason. For every dollar invested it would be much more cost effective to deliver a product onto the shelves in the USA than in Canada for example. At the other end of the spectrum, the time and cost to establish a new distribution network in Russia with the attendant risks would be far greater than for either the United States or Canada.

6.1.2 THE DOCTRINE OF EXHAUSTION OF RIGHTS

As explained by Dozortsev, the development of intellectual property emerged as a result of the "need to include the results of intellectual efforts in economic turnover".¹⁰⁴ In order to recognize the value of intellectual capital, various types of intellectual property rights emerged to accord to owners the exclusive right to manufacture, sell, import, and use their products. IP rights are often established at the discretion of each state government but are usually compliant with minimum standards established in the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) and the World Trade Organization (WTO). However, as a means to achieve a balance between the rights of consumers and the desire to promote investment in intellectual capital, intellectual property rights are not absolute.

Parallel importation as a permitted act, is premised on the concept of exhaustion: once a product has been placed in a market or sold with the consent of the trademark owner, the rights of the trademark owner to control the geographical movement of the product are deemed to have exhausted. Once the right holder has exhausted its rights, it is no longer able to control the circulation of that product and therefore it cannot stop the purchaser of that product from reselling the product or crossing borders with the product. First introduced in the 19th century by German legalist Joseph Kohler, the exhaustion doctrine is an attempt to balance the rights of the trademark owner with the free movement of goods in a market.¹⁰⁵

There are three types of exhaustion doctrines in international trade:

- national exhaustion of rights;
- regional exhaustion of rights; and
- international exhaustion of rights.

National Exhaustion of Rights – Under the national doctrine, a jurisdiction adheres to the principle that a right holder has consented only to the offering for sale of a product within the country where the goods were introduced into commerce. This provides brand owners with the highest degree of control of the supply chain. The import and sale of products that have been sold outside of the country is considered a violation of the trademark owner's explicit right to introduce the goods in to commerce in that country. This approach is currently used in Brazil and Turkey and until recently, Russia.

Regional Exhaustion of Rights – Somewhat like national exhaustion, a trademark owner's rights are exhausted in a region when it introduces the product into commerce in that region, for example a customs and free-trade area such as the European Economic Area (EEA) or the new Eurasian Economic Union (EEU).

International Exhaustion of Rights – Under the international doctrine, once a trademark owner authorizes the sale of a product anywhere in the world, it is deemed to have exhausted its right to control the free movement of that product anywhere else in the world. This approach is recognized for example, in Canada, China, Japan, and Switzerland.

6.2 THE PARALLEL IMPORTATION DEBATE

6.2.1 THE ARGUMENTS IN FAVOUR OF PARALLEL IMPORTATION

The first and foremost argument in favor of parallel importation is that the legitimate purchasers of goods should be permitted to trade in the goods entirely as they wish. The second argument is that it increases inter-brand competition and therefore reduces the price of products, in this case, pharmaceuticals for consumers.

According to a study conducted by Peter West and James Mahon, *Benefits to Payers and Patients from Parallel Trade*, the savings from parallel importation to pharmaceutical consumers can be both direct and indirect.¹⁰⁶ The direct savings could result from the opportunity for the consumer to choose the best priced goods amongst domestically and parallel sourced pharmaceutical products. Indirectly, consumers can save through the “the erosion of prices that the competing parallel-distribution brings to products that are often under patent”.¹⁰⁷ This competition reduces the price of domestically sourced products by creating competition where there was none. Although these indirect savings are difficult to quantify they may be more than the direct savings.¹¹⁸

There are those who say that there is empirical evidence that supports the claim that parallel importation reduces the price of pharmaceutical products for consumers. The study by West and Mahon claims that, in Denmark, where about 10% of pharmaceuticals are parallel imports, there was approximately 15.7 million EUR worth of direct savings in 2002 passed on to consumers. In the United Kingdom, there was direct savings of approximately 228 million EUR for the purchase of parallel distributed pharmaceuticals. In Sweden, there were direct savings to the Swedish reimbursement system and patients of 46.7 million EUR in 2002; 78% of which were savings by the government.¹⁰⁹ This study also claims that, although there was insufficient data to establish the exact savings by countries from increased competition, there was sufficient evidence to conclude that it existed.¹¹⁰ These findings are apparently backed also by the research of Glanslandt and Maskus, whose study on the effect of parallel imports on the price of pharmaceutical products in Sweden, concluded that prices were reduced by up to 19%.¹¹¹

These results are not exclusive to countries within the European Union; a study conducted by Stephan Vaterlaus in 2005 claims that, if Switzerland adopted regional exhaustion, the price of wholesale pharmaceuticals would be reduced by 9% to 20%, and by 14% to 32% if the country adopted international exhaustion.¹¹²

Proponents of parallel importation argue that the prohibition on parallel importation allows organizations to behave in an

anti-competitive manner.¹¹³ It is argued that national or regional exhaustion allows companies to engage in international price discrimination and keep the price of trademarked goods artificially high. By this argument, parallel importation allows the price of pharmaceutical products to actually reflect the quality of the product or the goodwill of the trademark owner.¹¹⁴ Additionally, the threat of accessing parallel imported medicine provides health care providers with some negotiating leverage with manufacturers, thereby assisting price control programs.¹¹⁵

American legal scholar, Fredrick M. Abbott, has argued that the prohibition of parallel importation goes against the goals of the World Trade Organization to “lower barriers to trade in goods and services in the international markets and thereby enhance global economic productivity”.¹¹⁶ Abbott writes that “the rules of the World Trade Organization proceed from one very basic idea: that the elimination of barriers to the movement of goods and services across and within national boundaries is beneficial to global economic welfare because this encourages specialization and efficiency in production and distribution, and results in an increased output of goods and services.”¹¹⁷ Therefore he argues that the prohibition against parallel importation takes advantage of the territorial nature of the international IPRs system and should be prohibited unless they can be proven to serve a social welfare need more valuable than their negative trade-restricting effect.¹¹⁸

6.2.2 THE ARGUMENTS AGAINST PARALLEL IMPORTATION

Lower prices are not always the ultimate consideration in regards to the public interest. Liberalizing the flow of goods across borders through parallel importation has been criticized for its potential to facilitate an increased flow of imported counterfeit products; this is a real and substantial risk for products such as medicines.

The delegation of responsibility to customs officials to supervise the cross border flow of potentially counterfeit goods intermingled with parallel imports can be daunting and overly burdensome. It is increasingly challenging for border guards to recognize counterfeits given the high quality look and feel that fakes now have.

Moreover, packaging of pharmaceuticals often varies from country to country. This further complicates matters and makes it more difficult for customs officials to develop a risk profile to assess whether a product is counterfeit or not.

Additionally, parallel importation poses logistical challenges as regards quality and spoilage.¹¹⁹ Some pharmaceutical products need to be stored under special conditions such as temperature or exposure to light; parallel importation by third parties introduces a further degree of uncertainty in the distribution chain.

Pharmaceutical products often differ in terms of the amount of active ingredients based on patient preferences and national regulations. The packaging of products may also be in another

language. This can create a significant health hazard for patients who are taking quantities of substandard medicine or who may improperly use the medicine because the packaging is in another language.

A study conducted by the National Economic Research Associates (NERA) found “a number of parallel import products whose repackaging did not conform to legal requirements” with some labels containing an “inaccurate description of the active ingredient”.

Parallel trade can also undermine the ability of innovators to invest in the research and development of new products. The International Trademark Association has argued that parallel importation leads to reduced profits for innovators thus reducing their ability to reinvest in new research and development. This concern is quite broadly supported in other academic literature. Changying Li and Keith Maskus in “The Impact of Parallel Imports on Investments” in Cost-Reducing Research and Development found that the legalisation of parallel importation would reduce final-stage profits and result in companies investing less money in research and development up front. Similarly in Differential Pricing, Parallel Trade, and the Incentive to Invest, Tommaso Valletti, using a different economic model found that, based on the market, a uniform price may increase welfare ex post and reduce ex ante investment in research and development.

The Association of European Businesses has attempted to persuade the Russian government not to permit parallel importation, arguing that it will discourage investors away from the local market. This argument is premised on a survey they conducted which found that 12 of the 34 companies surveyed declared that they would decrease localised production if parallel imports were legalized. The survey also found that company heads believed that they might have to cut jobs by approximately 40-60%.

Some economists have expressed a further concern that, allowing the parallel importation of pharmaceutical products will lead to a “free-rider” issue for wholesalers and countries. The argument is that authorized distributors often have to spend significant resources on advertising, discounting, post-sale services, and educating medical physicians in order to develop demand and insure trademark integrity.

However, if unauthorized distributors can “free-ride” on these services without incurring any of the expenses, it will decrease the incentive for distributors to provide these important services. The “free-rider” phenomenon can also occur on a macro level between countries. Countries may regulate and subsidize certain products to achieve social objectives; however there is the risk with parallel importation that other countries will free-ride on these subsidies and regulations.¹²⁰

Another argument against parallel importation is that the major benefactor of parallel importation is primarily the parallel importer and the benefits to consumers are only moderate. This argument was made in a study on parallel importation conducted by Dr. Panos Kanavos for the London School of Economics. The article

claims that parallel importers and health insurance organizations have little incentive to significantly lower the prices of pharmaceutical products relative to their local equivalent. Parallel importation therefore results in the creating of a duopoly rather than healthy market competition. Additionally, there is often a time and cost element associated with the importation of pharmaceutical products into a country that diminishes the ultimate benefit to consumers.

Based on these factors, the author concluded that consumers only gained nominal benefits of between 0.3% and 2.2%, while parallel importers gained over 700 million EUR in 2002.¹²¹

6.3 PARALLEL IMPORTATION: THE CURRENT LEGAL SITUATION IN RUSSIA

6.3.1 TRADEMARK RIGHTS AND PHARMACEUTICAL IMPORTATION

The control of parallel importation is mostly a trademark question. The pertinent law in Russia dealing with trademark rights and the importation of goods comprises:

- Part IV of the Civil Code;
- Competition Law of the Russian Federation (135-FZ) of July 26, 2006;
- Code of Administrative Offences (195-FZ) of December 30, 2001; and
- Criminal Code (63-FZ) of June 13, 1996.

6.3.1.1 PART IV OF THE CIVIL CODE & IMPORTATION

The Russian Federal Antimonopoly Service (FAS) has been advocating legalization of parallel imports in Russia since 2014. The FAS recently came out with an initiative to amend Art. 1487 of the Civil Code to allow the Russian government to temporarily (for a period of up to five years) introduce industry exceptions where parallel importation would be legal. The government would be able to allow parallel importation from those industries where:

- the goods are not available on the Russian market or there is a deficit of such goods on the Russian market;
- the goods are of inferior quality in comparison to the same goods offered for sale in other developing countries; and
- the goods are overpriced. This FAS's initiative has not yet been completed.

6.3.1.2 THE COMPETITION LAW OF THE RUSSIAN FEDERATION

The claim of unfair competition relating to acts aimed at creating confusion under Art. 14.6 of the Competition Law of the Russian Federation provides a right owner with the legal means to stop the importation of a genuine product if importation has not been approved by the owner of the trademark. However, there is still no case law on the interpretation of this article.

6.3.1.3 CIVIL LIABILITY FOR THE UNLAWFUL USE OF A TRADEMARK

The unlawful use of a trademark in Russia can give rise to civil, administrative and criminal liability.

To protect against the unlawful use of this exclusive right, Article 1252 of the Civil Code provides right holders with the right to claim the payment of damages. Notably the article also gives the right holder the ability to deem the goods counterfeit and have them withdrawn from circulation and destroyed.

In addition to the withdrawal and destruction of the goods, a trademark owner, according to Article 1515 may claim compensation in the amount of 10,000 to 5,000,000 RUB (160 to 80,000 USD) as the court may determine; or double the price of the goods illegally trademarked; or double the price of the right to use a trademark based on the price usually charged for its lawful use.

6.3.1.4 ADMINISTRATIVE LIABILITY FOR THE UNLAWFUL USE OF A TRADEMARK

Article 14.10 of the Code of Administrative Offences provides for liability for the illegal use of trademarks, services marks, and reference to source of origin; this article may lead to significant fines for counterfeiters. According to this article, any illegal use of a foreign trademark may lead to an administrative fine, for individuals, from 5 to 10 thousand RUB (80 to 160 USD) in addition to the confiscation of items bearing the illegal trademark, as well as the materials and equipment used for their manufacture. The fine increases to 10 to 50 thousand RUB (160 to 800 USD) for officials, and increases to 50 to 200,000 RUB (800 to 3,125 USD) for legal entities.

6.3.1.5 CRIMINAL LIABILITY FOR THE UNLAWFUL USE OF A TRADEMARK

According to Article 180 of the Criminal Code, the illegal use of a trademark, if committed repeatedly or if causing substantial damage (exceeding 250,000 RUB which is approximately 4,000 USD), is punishable with a fine in the amount of 100 to 300,000 rubles (1,500 to 4,800 USD) or imprisonment for up to two years.

6.3.2 EXHAUSTION OF RIGHTS IN RUSSIAN LEGISLATION

The doctrine of exhaustion has always been a controversial one. Article 6 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) explicitly states that nothing in the agreement should be deemed to address the issue of the exhaustion of intellectual property rights. The World Trade Organization acknowledged the doctrine left it to each member state to determine for itself.

As earlier mentioned, Article 1487 of the Civil Code establishes the principle of national exhaustion for trademarks. The exclusive right to a trademark is exhausted only in respect of goods that have been introduced into civil-law transactions into the territory of the Russian Federation directly by the right holder or with their consent. Therefore the trademark owner cannot prohibit the use of its trademark if they introduced or consented to the introduction of that product into circulation within the Russian Federation. However, the import and sale of products that have been obtained by third parties outside of the country are considered to be a violation of the trademark owner's exclusive right of importation.

The concept of national exhaustion under Article 1487 has been expanded to regional exhaustion by operation of the terms in the EAEU.

6.3.3 CASE LAW ON PARALLEL IMPORTATION: BEFORE THE SONY V. PAG CASE

Although the Russian legal system is a codified civil law system, case law is nevertheless instructive. The cases demonstrate that the legitimacy of parallel importation is not yet entirely clear cut despite the apparently clear wording of the legislation.

6.3.3.1 PARALLEL IMPORTATION: THE PORSCHE CASE¹²²

[Central Excise customs v. Genesis LLC](#)
Case No. 10458/08
February 3, 2009
[Supreme Arbitration Court of the Russian Federation](#)

One of the most instructive parallel importation decisions is the landmark 2009 case from the Supreme Arbitration Court (as it then was) dealing with the importation of a Porsche Cayenne (known as the "Porsche Case").

The Russian Customs authorities seized an individual Porsche coming into Russia at the border; the routinely provided expert opinion was that the car was being imported without consent of the trademark owner. Although the car had been legally

acquired outside of Russia, it was confiscated without compensation and deemed to be a counterfeit. The case was heard at the first instance and on two further appeals, all courts ruling in favour of Porsche (who opposed the importation).

The Supreme Arbitration Court however, determined that, because the trademark was legally placed on the Porsche, the mere importation of the vehicle was not an illegal use of the trademark and the vehicle was not a counterfeit, at least under the provisions of the Code of Administrative Offences. But the highest court pointed out that although the trademark owner could not pursue a claim under the Code of Administrative Offences, the trademark right holder could nevertheless pursue a civil claim based on trademark infringement seeking the remedies provided for under Article 1515 such as an injunction and damages.

6.3.3.2 PARALLEL IMPORTATION: CASE LAW AFTER THE PORSCHE CASE

There is no completely discernible trend of consistency in the Russian courts when it comes to parallel importation. A trademark owner should be able to obtain an injunction and damages for the unauthorized parallel importation of goods into Russia provided that there is a registered trademark in Russia. The Porsche case was decided in 2009 and the cases which followed are of interest:

JSC Nestle Waters and JSC SAN PELLEGRINO v. Akvalife LLC
Case No. A40-153306/2013
May 12, 2015
Intellectual Property Court

Nissan v. Avtologistika LLC
Case No. VAS- 3737/14
April 7, 2014
Supreme Arbitration Court

JSC Nestle Waters France v. Elitvoda LLC
Case No. VAS- 1966/12
March 11, 2012
Supreme Arbitration Court

A most significant case was the 2015 decision from the Intellectual Property Court regarding the importation of San Pellegrino branded products without consent of the trademark owner.¹²³ This case affirms that parallel importation will be deemed to be infringement if importation is without the owner's consent. The court of first instance and courts of first and second appeals (IP Court) decided in favour of Nestle Waters and San Pellegrino and enjoined Akvalife from parallel importation.

Under Articles 1515 and 1252 of the Civil Code, goods are deemed to be counterfeit if they involve illegal i.e. unapproved use of an authentic product if the use in question violates the exclusive rights of the trademark owner.


It is irrelevant that the goods were legitimately purchased outside of Russia since Article 1227 of the Civil Code states that the transfer of ownership and right of possession does not also involve the transfer of intellectual property rights.

It is, therefore, possible that the importation and resale of imported goods will be enjoined by the court. This ruling was also made in the earlier Nissan¹²⁴ and Nestle trademark¹²⁵ cases listed above.

Rado Uhren AG, Longines Watch Co., Omega AG v. LLC Online Development, LLC Status
Case No. VAS-12583/13
July 15, 2014
Supreme Arbitration Court of the Russian Federation

Trademark owners may still also obtain monetary damages under the Civil Code. This was held to be the case in the 2014 decision involving Omega, Rado, and Longines against Online Developments.¹²⁶ In this case, the Supreme Arbitration Court required Online Development to compensate each of the claimants for the unlawful use of the trademark for amounts up to 500,000 RUB (8,000 USD) in addition to prohibiting the further importation of any trademarked goods and the destruction of any watches carrying the claimants' trademarks.

However, the courts have not consistently applied this outcome. The Russian Thirteenth Arbitration Appellate Court found in a 2013 case that seizure and destruction of original goods offered for sale without the consent of the trademark owner would be a disproportionate punishment for the violation committed.



“There is no discernible trend of consistency in the Russian courts when it comes to parallel importation.”



6.3.4. CASE LAW ON PARALLEL IMPORTATION: SONY CORP. V. PAG AND AFTERWARDS

On February 13, 2018, the Russian Constitutional Court rendered its landmark Sony Corp. v. PAG decision, interpreting the provisions of the Civil Code that prohibit parallel importation (case № A21-7328/2014 In Re: Case on Verification of the Constitutionality of Articles 1252.4 etc of the Civil Code in Connection with the Complaint of PAG LLC). The Constitutional Court declared, among other things, that Russia ought to exercise a much softer stance towards parallel importers.

6.3.4.1. SONY CORP. V. PAG

PAG LLC was a parallel importer and was found liable for trademark infringement by reason of parallel importation. The Arbitration Court awarded traditional forms of relief for trademark infringement against PAG, namely: a permanent injunction, delivery up for destruction and payment of compensation.

PAG filed a complaint with the Constitutional Court, challenging the constitutionality of the operative provisions in the Civil Code.

PAG had contracted to supply heat-sensitive paper for medical recording devices to a public hospital. The company purchased original products from a Polish supplier and attempted to import the consignment into Russia. The brand owner, a multinational, successfully sued for trademark infringement by reason of the unauthorized importation of the legally acquired goods into Russia.

In its detailed decision, the Constitutional Court began by acknowledging that the TRIPS Agreement does not impose upon member countries a particular commitment as regards trademark exhaustion of rights. And in Russia, the Court acknowledged that the choice of a particular exhaustion of rights regime (national, regional, or international) lies within the exclusive authority of the Russian legislature. The Court further acknowledged that the Civil Code when read in conjunction with Annex 26 of the Treaty of the Eurasian Economic Union (EAEU), establishes a regional exhaustion regime for Russia and the Eurasian Economic Union.

The Court concluded that a regional exhaustion of rights regime that creates a statutory ban on parallel importation does not contravene the Russian Constitution. The power to decide whether parallel importation ought to be illegal or not, they said, is within the discretion of the federal law makers.

But the 16-member panel added a substantial qualifier - intellectual property rights are not absolute and the courts shall take into account the requirements of proportionality and balance of competing rights and legitimate interests - private and public.

The exercise of registered trademark rights, the Court said, must also give due account to the rights and legitimate interests of other parties for example when considering the issue of admissibility of parallel imports. Trademark owners must come to the court only if they are acting in good faith as regards the exercise of their trademark rights.

The Court said that a trademark owner would be seen to be acting in bad faith if s/he restricted imports of specific goods into Russia, or engaged in overpricing on the Russian market or if s/he imposed a market restriction on the flow of goods in support of foreign government sanctions. And any such acts would be regarded as being especially objectionable if they restricted access to goods of vital necessity, for example, certain categories of medicines, life-support equipment, etc.

In the context of an infringement claim based on parallel importation, the Constitutional Court made two very important observations as regards enforceability and the remedies associated with infringement of those trademark rights.

Russian courts, they said, are entitled to dismiss a trademark infringement claim against a parallel importer, in full or in part, in circumstances where the bad faith conduct of a trademark holder might endanger life and health of citizens, or other significant public interests.

If a case of trademark infringement by reason of parallel importation can be made out and the claim is not asserted under circumstances of bad faith, the Court said that the traditional remedies for infringement should nonetheless be toned down. The Constitutional Court said that this is because counterfeiters and parallel importers should not be treated in the same way. The Court said that the remedies and their amounts should not be the same for the importation of gray and counterfeit goods because the amount of damage incurred by the trademark holder is not the same:

When importing counterfeit goods labelled with a trademark, the trademark holder not only incurs losses in the form of lost profits that could have been received from the importation of legally produced goods, but also faces major reputational risks due to non-conformity of goods with the anticipated characteristics and consumers' demands.

There is an obvious difference in the degree of threat to legitimate circulation of goods and the level of public danger for consumers using the goods that are actually counterfeit due to their fake origin versus legitimate goods being qualified as counterfeit solely due to their importation by an unauthorized importer.

The Court made the following additional points:

- Since the losses incurred by a trademark holder because of illegal parallel imports are not so severe in comparison to the importation of counterfeit goods, the courts are entitled to reduce the amounts of compensation to be collected from parallel importers; and,

- Remedies such as withdrawal from circulation (injunction) and destruction should only be imposed as an exception, for example if their substandard quality is established and, or, to ensure safety, protect people's lives and health, and protect nature and cultural values.

6.3.4.2. SONY V. PAG

Since the PAG case the Arbitration Court has not expressed any further doubt that parallel importation is a sound cause of action

Rosh Diagnostics Rus LLC v. Modern Medical Systems LLC
Case No. A28-8632/2017
January 25, 2019
Intellectual Property Court

In Rosh Diagnostics Rus LLC v. Modern Medical Systems LLC, the plaintiff, Rosh Diagnostics Rus was an exclusive licensee in Russia of "Roche", "Cobas" and some other international trademarks under classes 1 and 5 owned by F. Hoffman-La Roche.

The courts of first and second instances, and finally the IP Court, all held that importation and marketing of goods that have been introduced into circulation as a result of parallel importation constitute trademark infringement.

The courts rejected the defendant's argument that the plaintiff's claim was filed in bad faith and was against public interest because, first, the hospital had not accepted goods supplied by defendant that had expired and, second, the defendant failed to provide any evidence that the trademark holder or exclusive licensee are engaged in overpricing on the Russian market in comparison to foreign markets.

The courts awarded the plaintiff compensation in the amount of 190,000 RUB (3,000 USD approx.) taking into consideration the volumes and prices of grey goods supplied by defendant.

6.3.5. THE EURASIAN ECONOMIC UNION

Although Article 1487 of the Civil Code establishes the principle of national exhaustion, an agreement signed on May 29, 2014, between the members of the Eurasian Economic Union (Russia, Kazakhstan, and Belarus) establishes the regional principle of exhaustion as regards the exclusive right to a trademark. According to Addendum 25 of the EEU Agreement, the use of a trademark on goods that have been placed into civil-circulation by a trademark owner, or with their consent, in the territory of any member-states of the EEU shall be deemed to have exhausted the trademark owner's exclusive rights. This came into effect on January 1, 2015.

As these provisions are established by the Eurasian Economic Union Treaty, it prevails over the national laws of each member country.

In 2016, there was an amendment under discussion to create industry exceptions to the EEU regional exhaustion rule; this may include an exception allowing for the parallel importation of pharmaceuticals and medical products.¹²⁷

Early in 2017, the Eurasian Commission is believed to have drafted specific amendments to the Union Agreement that would serve to exclude pharmaceuticals and, likely, some categories of medical devices from the regional exhaustion of rights provisions. However, nothing further developed since that time.

6.4. THE CHANGING LEGAL ENVIRONMENT FOR GRAY MARKETS IN RUSSIA

The leaders of the Russian Federation, along with the Eurasian Economic Commission, have been in recent years discussing the possibility of legalizing parallel importation in certain special cases: notably, pharmaceuticals and medical devices and possibly other products such as car parts.

Following the suggestion of the Russian Prime Minister, the Ministry of Economic Development, the Ministry of Industry and Trade and several other ministries have submitted their proposals for legalizing parallel importation in the Russian Federation.

This liberalization has been advocated by the Russian Federal Antimonopoly Service (FAS) for some time. The FAS has proposed that Article 1487 of the Civil Code be amended to replace the current principle of national exhaustion with that of international exhaustion.

Additionally they have proposed that Article 14 of the Competition Law of the Russian Federation be amended to state that any failure to grant permission to import genuine goods into the Russian Federation would be deemed to be an act of unfair competition.¹²⁸

Meanwhile, in August 2020, the FAS declared that two multinationals abused their trademark rights by selectively blocking importation of grey goods while allowing for importation by others. The indiscriminate imposition of restrictions was deemed to be unfair (Case No. 1-14-16 3/00-08-18 Daimler et.al.; case 1-14-164/00-08-18 KYB et.al).

6.5 THE REGIONAL COMMON ECONOMIC SPACE TRADEMARK

On February 2, 2017, Russia announced that it would seek to ratify the draft Agreement on Trademarks, Service Marks and Appellations of Origin of the Eurasian Economic Union. The Agreement introduces the concept of a CES Trademark, "CES" means Common Economic Space. A CES Trademark is a regional Eurasian trademark that covers the territories of all members of the Eurasian Economic Union (EAEU). The EAEU is a political and economic union of five member states: Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia. It was established on January 1, 2015, by the Treaty on the Eurasian Economic Union.

The CES Trademark register would, if implemented, co-exist alongside national registers which would continue as before. Brand owners will have the option of applying to register either or both, CES Trademarks and national trademarks.

Under the CES Trademark regime, a brand owner may file an application in the local national trademarks office (the "Office of Filing") of any one of the member countries where it has an accredited place of business. After receiving an application, the Office of Filing performs examination as to formalities and then notifies the national trademarks offices of each member country. The application is then published on the CES website and there is a three month window to file a pre-grant opposition. If there is no opposition, the application then proceeds to substantive examination in each national office. Each national office, including the Office of Filing, delivers an examination opinion to the Office of Filing. If the mark is clear, a favorable decision is passed along to the applicant and the final fee can be paid; a registration has a ten year renewable term.

If any one country delivers a negative opinion, it can be appealed by filing an appeal directly with the national office that issued that opinion; if a negative opinion is not appealed, or if the appeal is rejected, then the Office of Filing will reject the entire CES application. In that case the applicant will have a few options: if the negative opinion can be overcome by amending the list of goods to a narrower list, then the CES application can proceed to allowance; alternatively, the applicant can elect to nationalize the CES application into those countries that provided a positive opinion. In that case the applicant would file a Notice of Conversion and the application would continue in those regional offices as a national application.

The Agreement also envisages that a person who has filed a national application in Russia, for example, can elect to convert the pending application into a CES application by giving notice and paying the requisite fees. And Article 14 of the draft allows the owner of a national registration to request a CES Trademark certificate provided that the mark, the named owner and the list of goods and services are to be the same.

The details as to how the process is to be administered will be set out in official guidelines that have not yet been released.

A CES Trademark registration can be enforced, or invalidated, in each member country under the local laws of that country.

The official English translation of the draft Agreement can be found at:

[http://www.eurasiancommission.org/ky/act/finpol/dobd/intelsobs/Documents/AG_REEM_ENT_on_Trademarks, Service Marks and Appellations of Origin in the Territories of the Customs Union and the Common E.docx](http://www.eurasiancommission.org/ky/act/finpol/dobd/intelsobs/Documents/AG_REEM_ENT_on_Trademarks,_Service_Marks_and_Appellations_of_Origin_in_the_Territories_of_the_Customs_Union_and_the_Common_E.docx). 2 Paragraph 5 of Article 4.

The creation of the CES Trademark system will ultimately be advantageous to brand owners and is consistent with the creation of the free trade zone and unified customs register for the Eurasian Economic Union.

The Agreement was ratified by Russia and the current intention is to launch the new system in 2021 once the other member states have signed on.

SOURCES

1. Russian Pharmaceutical Market 2018, available at: https://dsm.ru/docs/analytics/report_2018_en.pdf
2. Database Update: Pharmaceutical Drug Production in Russia (October 2019). Available at: http://rncph.com/news/06_12_2019.
3. <https://gmpnews.ru/2019/06dlya-farmaceutiki-neobxodimozadumatsya-o-sozdanii-nacio-nalnoj-eksportnoj-strategii/>
4. Federal Law No. 127-FZ of June 04, 2018 «On Measures (Countermeasures) against Unfriendly Actions of the United States of America and Other Foreign States».
5. https://pharmvestnik.ru/content/news/Valentina-Matvienko-sankcii-na-lekarstva-nedopustimy.html?fbclid=IwAR1L7naplJRhGTBNYF-Qxcl-Jo39ySanb0vD0mj6b7K_zLrGrlqDC8Si-Z8.
6. <https://www.kommersant.ru/doc/4004537?que-ry=%D1%84%D0%B0%D1%80%D0%BC%D0%B0%202030>
7. <https://gmpnews.ru/2019/06dlya-farmaceutiki-neobxodimozadumatsya-o-sozdanii-nacio-nalnoj-eksportnoj-strategii/>
8. http://minpromtorg.gov.ru/press-centre/news/#!minpromtorg_rossii_razmesti_dlya_obshhestvennogo_obsuzhdeniya_proekt_rasporyazheniya_pravitelstva_rossiyskoy_federacii_ob_utverzhdenii_strategii_farma2030
9. <https://pharmvestnik.ru/content/news/eksperty-otmetili-osnovnye-nedo-statki-strategii-farma-2030.html>
10. STEM-Pharma. "Ousted! How Sanctions against Russia Are Expected to Affect Pharma Investments" June 2014.
11. Deloitte. "Optimization of expenses and market launch of new drugs – priority scenarios of pharmaceutical market development in Russia in 2016" (2016). Available at, <https://www2.deloitte.com/content/dam/Deloitte/ru/Documents/life-sciences-health-care/russian/russian-pharmaceutical-industry-2016.pdf>
12. <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=RAPS007;n=83828>
13. http://www.fips.ru/ConveraDocs/pps/_new/2013/2013%D0%9200486/2013%D0%9200486-2013.05.27.pdf
14. http://www.fips.ru/ConveraDocs/pps/_new/2014/2014%D0%9200136/2014%D0%9200136-2014.05.30.pdf
15. http://www.fips.ru/ConveraDocs/pps/_new/2014/2014%D0%9200736/2014%D0%9200736-2014.08.14.pdf
16. http://www.fips.ru/ConveraDocs/pps/_new/2013/2013%D0%9200823/2013%D0%9200823-2013.08.09.pdf
17. http://www.fips.ru/ConveraDocs/pps/_new/2014/2014%D0%9201889/2014%D0%9201889-2015.03.25.pdf
18. http://www.fips.ru/ConveraDocs/pps/_new/2015/2015%D0%9201237/2015%D0%9201237-2015.12.16.pdf
19. http://www.arbitr.ru/bras.net/f.aspx?id_casedoc=1_1_430edd4f-f28c-49bc-a43a-29da84d97da0
20. http://kad.arbitr.ru/PdfDocument/14e40fe4-ec1c-4912-aa30-f049ee53c600/A40-124960-2012_20131204_Opredelenie.pdf
21. http://kad.arbitr.ru/PdfDocument/b70dc529-a3fa-487e-81fb-30838d5f1ea0/A40-165106-2013_20150127_Reshenija%20i%20posta-novlenija.pdf
22. <http://base.consultant.ru/cons/cgi/online.cgi?req=doc;base=RAPS007;n=83828>
23. Gray, Nathan. "Russia vs. Fake Drugs: An International Threat", Moscow News (February 25, 2013).
24. Information about the results of state control in the field of circulation of medicines for the period of 9 months of 2019. Available at: <http://www.roszdravnadzor.ru/i/upload/images/2019/10/17/1571314772.739-1-8933.pdf>
25. Information about the results of state control in the field of circulation of medicines in 2018. Available at: <http://www.roszdravnadzor.ru/i/upload/images/2019/3/18/1552890383.7477-1-30251.pdf>
26. Maksimova, S.V. "Pharmiracy in Russia 2004-2012" The Russian Academy of Science (2012).
27. Economy News. "Генпрокуратура: до 15% лекарств в России поддельные" (December 5, 2014) available at www.vestifinance.ru/articles/50354.
28. World Health Organization. WHO Fact Sheet Counterfeit Medicines 2006.
29. Parfitt, Tom. "Russia Cracks Down on Counterfeit Drugs" The Lancet 385 (October 28, 2006) at pg 1481.
30. Pharmaceutical Security Institute. "Counter y Report Russia" (December, 2007) at pg 11.
31. Parfitt, Tom. "Russia Cracks Down on Counterfeit Drugs" The Lancet 385 (October 28, 2006) at pg 1481.
32. Pharmaceutical Security Institute. "Counter y Report Russia" (December, 2007) at pg 11.
33. ICC Report. "Promoting and Protecting Intellectual Property in the Russian Federation" at p. 11.
34. World Health Organization. WHO Fact Sheet Counterfeit Medicines 2006; Shahtinskoe Case. P. Rossokhov was found guilty of distributing counterfeit HIV medication.
35. Parfitt, Tom. "Russia Cracks Down on Counterfeit Drugs" The Lancet 385 (October 28, 2006) at pg 1481.
36. Tretyakov, El. "The Current State of Trafficking Counterfeit medicines as part of the criminological characteristics of crimes" (2009) Municipal Service: Legal Issues 4. Available at www.center-bereg.ru/f1091.html.

SOURCES

37. Ishova, M. "Поддельный левомецетин делают из мела и глюкозы". (Sep 26, 2005). <http://www.annnews.ru>.
38. Fake Medicine, a Real Danger for Health. "Enforcement: Ministry of Health, 60% of Counterfeit Drugs Produced in Russia".
39. Maksimova, S.V. "Pharmiracy in Russia 2004-2012" The Russian Academy of Science (2012).
40. Nelson, Maria et al. "Counterfeit Pharmaceuticals: a Worldwide Problem" INTA (2006) 96:5 at p. 1094.
41. Makismova, SV (ed.). "ФАЛЬСИФИКАЦИЯ ЛЕКАРСТВЕННЫХ СРЕДСТВ В РОССИИ" (2008) forum.yurclub.ru/index.p?app=core&module=attach§ion=attach&attach_id=65589.
42. Jackson G, S Patal & S Khan. "Assessing the problem of counterfeit medication in the United Kingdom", *Int J of Clin Pract* (2012), 66:3, at pg. 242.
43. Lutter, Randall W. "Hearing before the Subcommittee on Criminal Justice, Drug Policy and Human Resource at the U.S. House of Representatives", (Nov 1, 2005). Available at, <http://www.fda.gov/NewsEvents/Testimony/ucm112670.html>.
44. World Health Organization. WHO Fact Sheet Counterfeit Medicines 2006.
45. Jackson, G, et al. "Assessing the Problem of Counterfeit Medications in the United Kingdom" *Journal of Clinical Practice* (2012) at pg. 243.
46. Forzley, Michele. "Counterfeit Goods and the Publics Health and Safety" (2003), International Intellectual Property Institute at p.10.
47. Jackson, G, et al. "Assessing the Problem of Counterfeit Medications in the United Kingdom" *Journal of Clinical Practice* (2012) at pg. 243.
48. Chatterjee Patralekha. "India's Trade in Fake Drugs Bring the Counterfeiters to Book", (2001), *Lancet* at.
49. Clark Eric. "Counterfeit Medicines: The Pills that Kill". 2006 *The Telegraph*.
50. World Health Organization. WHO Fact Sheet Counterfeit Medicines 2006.
51. Karunamoorthi, Kaliyaperumal. "The Counterfeit anti-malarial is a crime against humanity: A systematic review of the scientific evidence." *Malaria J* (2014) 13:209.
52. Schwarz, Brian and Vanessa Wong. "Counterfeit Cures" *Insight* (2006) at pg 29.
53. Jackson G, S Patal & S Khan. "Assessing the problem of counterfeit medication in the United Kingdom", *Int J of Clin Pract* (2012), 66:3, at pg. 242.
54. 65 - Bate, Roger. "The Deadly World of Fake Medicine", *CNN* (July 17, 2012). Available at, <http://edition.cnn.com/2012/07/17/health/living-well/falsified-medicine-bate/>.
55. Weaver, Christopher and Jeanne Whalen. "How Fake Cancer Drugs Entered US." *The Wall Street Journal* (July 20, 2012). Available at, <http://www.wsj.com/articles/SB10001424052702303879604577410430607090226>
56. Blackstone, Erwin A. "The Health and Economic Effects of Counterfeit Drugs", (2014) 7:4 at pg. 220.
57. Allied Market Research/ "Global Anti-Counterfeit Pharmaceutical and Cosmetics Packaging Market-Industry Analysis, Size, Growth, Trends, Opportunities, and Forecast, 2014-2020" (2015).
58. Parfitt, Tom. "Russia Cracks Down on Counterfeit Drugs" *The Lancet* 385 (October 28, 2006) at pg 1481.
59. Nian, Lam Chung. "Addressing Counterfeiting and Piracy: A Development Perspective". Regional Workshop for LDCs of Asia and the Pacific Region on the Use of Intellectual Property for Enhancing Economic Competitiveness and Development (2011).
60. Organization for Economic Co-Operation and Development. "The Economic Impact of Counterfeiting and Piracy" (2008) at page 17.
61. PBN Hill & Knowlton "Russian Health Ministry Proposes Law to Criminal Counterfeit Medicine".
62. PBN Hill & Knowlton "Russian Health Ministry Proposes Law to Criminal Counterfeit Medicine".
63. Panov, SL. "Value concepts of "counterfeit" "counterfeit", "pirate" products: theoretical aspect" *Law and Politics*, 2008 2. <http://www.center-bereg.ru/k2041.html>.
64. Panov, SL. "Value concepts of "counterfeit" "counterfeit", "pirate" products: theoretical aspect" *Law and Politics*, 2008 2. <http://www.center-bereg.ru/k2041.html>.
65. Panov, SL. "Value concepts of "counterfeit" "counterfeit", "pirate" products: theoretical aspect" *Law and Politics*, 2008 2. <http://www.center-bereg.ru/k2041.html>.
66. <https://rospravosudie.com/court-pervomajskij-rajonnyj-sud-g-rostova-na-donu-rostovskaya-oblast-s/act-498133205/>
67. Bimbinov A.A., Voronin N.V. et al, *Pharmaceutical criminal law of Russia: monography*, Moscow: Prospect, 2019.
68. Bimbinov A.A., Voronin N.V. et al, *Pharmaceutical criminal law of Russia: monography*, Moscow: Prospect, 2019.
69. <https://rospravosudie.com/court-sudebnyj-uchastok-1-salskogo-rajona-rostovskoj-oblasti-s/act-231517395/>
70. <http://kad.arbitr.ru/Card/4d9e27df-ab2f-4c32-9c2b-a5608cc820fd>
71. Borzik I.K. *The Federal Service on Surveillance in Healthcare Activity*.
72. <http://www.roszdravnadzor.ru/news/10490>
73. Borzik I.K. *The Federal Service on Surveillance in Healthcare Activity*.
74. Parkhomenko, Dmitry and Sergey V. Glagole. "Struggle against counterfeit medicines in Russia: an overview" (2010) ICDRA.

SOURCES

75. Borzik I.K. The Federal Service on Surveillance in Healthcare Activity.
76. Borzik I.K. The Federal Service on Surveillance in Healthcare Activity.
77. Przyswa, Eric. "Counterfeit medicines and criminal organisations" IRACM (2013) p. 63.
78. Przyswa, Eric. "Counterfeit medicines and criminal organisations" IRACM (2013) p. 72.
79. International Institute of Research Against Counterfeit Medicines. "Fake Drugs on the Web" (2012) available at <http://www.iracm.com/en/thematic-observatory/fake-drugs-on-the-web/>.
80. NUBP. "NUBP Issues Rogue Online Pharmacy Public Health Alert" (2011), available at: <https://nabp.pharmacy/nabp-issues-rogueonline-pharmacy-public-health-alert/>
81. Mackey, Tim K, and Bryan A Liang. "Global Reach of Direct-to-Consumer Advertising Using Social Media for Illicit Online Drug Sales" (2013) J Med. Internet Res 15(5).
82. Osipov, Mikhail. "Есть ли будущее у Интернет-аптек?" available at <http://www.medinfo24.ru/blog/28/>.
83. Krebs, Brian. "Spam Nation: The Inside Story of Organized Cybercrime – From Global Epidemic to Your Front Door", (2004) Sourcebooks, Inc.
84. Osipov, Mikhail. "Есть ли будущее у Интернет-аптек?" available at <http://www.medinfo24.ru/blog/28/>. (Есть ли будущее у Интернет-аптек?)
85. Pharmvestnik Legal Barriers to the Operation of Online Pharmacies available at www.pharmvestnik.ru/publs/farmkruzhoz/consultation/pravovye-prepjatstvija-dlja-funktsionirovanija-internet-aptek.html.
86. Pharmvestnik Legal Barriers to the Operation of Online Pharmacies available at www.pharmvestnik.ru/publs/farmkruzhoz/consultation/pravovye-prepjatstvija-dlja-funktsionirovanija-internet-aptek.html.
87. Pharmvestnik Legal Barriers to the Operation of Online Pharmacies available at www.pharmvestnik.ru/publs/farmkruzhoz/consultation/pravovye-prepjatstvija-dlja-funktsionirovanija-internet-aptek.html.
88. Pharmvestnik Legal Barriers to the Operation of Online Pharmacies available at www.pharmvestnik.ru/publs/farmkruzhoz/consultation/pravovye-prepjatstvija-dlja-funktsionirovanija-internet-aptek.html.
89. Henney, Jane E. "Cyberpharmacies and the Role of the US Food and Drug Administration" (2001) J Med Internet Res 3(1)
90. INTA. "addressing the Sale of Counterfeits on the Internet" (2009) pg. 5.
91. Henney, Jane E. "Cyberpharmacies and the Role of the US Food and Drug Administration" (2001) J Med Internet Res 3(1).
92. United States Government Accountability Office. "Internet Pharmacies: Federal Agencies and States Face Challenges Combating Rouge Sites, Particularly Those Abroad" (July 2013) at p. 18.
93. Gray, Nathan. "Russia vs. Fake Drugs: An International Threat" Moscow News (February 25, 2013).
94. News (February 25, 2013).
95. Przyswa, Eric. "Counterfeit Medicines and Criminal Organizations." IRACM (2013) p.72.
96. McCoy, Damon, et al. "PharmaLeaks: Understanding the Business of Online Pharmaceutical Affiliate Programs" Proceedings of the 21st USENIX conference on Security symposium (2012) USENIX Association.
97. McCoy, Damon, et al. "PharmaLeaks: Understanding the Business of Online Pharmaceutical Affiliate Programs" Proceedings of the 21st USENIX conference on Security symposium (2012) USENIX Association.
98. Jefferson, Brandi. "The Link between Pharmaceutical Spam and Illicit Online Pharmacies" (2013).
99. https://pharmvestnik.ru/content/news/Valentina-Matvienko-sankcii-na-lekarstva-nedopustimy.html?fbclid=IwAR1L7naplJRhGTBNYF-Qx-cl-Jo39ySanb0vD0mj6b7K_zLlrGrlqDC8Si-Z8. Last visited on July 07, 2019.
100. rfxcel's Ultimate Guide to the 2020 Russian Track & Trace Requirements. Available at: <https://rfxcel.com/rfxcels-ultimate-guide-2020-russian-track-trace-requirements/>
101. Izvestiya, Drugs will be Prescribed Electronically (September 2, 2016) at <http://izvestia.ru/news/630093>
102. Richard M. Andrade, The Parallel Importation of Unauthorized Genuine Goods: Analysis and Observations of the Gray Market, 14 J. Int'l L. at p.413.
103. Richard M. Andrade, The Parallel Importation of Unauthorized Genuine Goods: Analysis and Observations of the Gray Market, 14 J. Int'l L. at p. 413.
104. Igor Aleksandrovich Drozdov and Aleksey Yurievich Ivanov. "Parallel Import: Busting the Myth" (2013) Intellectual Property and Development: Time for Pragmatism at p 47.
105. Ekaterina Shekhtman and Evgeniy Sesitsky. "Exhaustion and Parallel Importation in the Field of Trademarks".
106. Peter West, and James Mahon. "Benefits to Payers and Patients from Parallel Trade" (2003) University of York.
107. Peter West, and James Mahon. "Benefits to Payers and Patients from Parallel Trade" (2003) University of York at p. 5.
108. Peter West, and James Mahon. "Benefits to Payers and Patients from Parallel Trade" (2003) University of York at p. ii.
109. Peter West, and James Mahon. "Benefits to Payers and Patients from Parallel Trade" (2003) University of York at p. ii-iii.
110. Peter West, and James Mahon. "Benefits to Payers and Patients from Parallel Trade" (2003) University of York at p. 69.
111. Mattias Glanslandt and Keith Maskus. "Parallel imports and the pricing of pharmaceutical products: evidence from the European Union" (2004) 23 Journal of Health Economics at p.1038.

SOURCES

112. Stephan Vaterlau. "Parallelimporte in die Schweiz: empirische Resultate" (2005) Baslerschriften zur Europäischen Integration.
113. Richard Andrade. "The Parallel Importation of Unauthorized Genuine Goods: Analysis and Observations of the Gray Market" (1993) *Journal of International Law* 14:4 at p. 415.
114. Richard Andrade. "The Parallel Importation of Unauthorized Genuine Goods: Analysis and Observations of the Gray Market" (1993) *Journal of International Law* 14:4 at p. 415.
115. Panos Kanavos et al. "The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis" (2004) Special Research Paper for LSE Health and Social Care at p 55.
116. Frederick M Abbott. "First Report (Final) To the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation" (1998) *Journal Of International Economic Law* at p. 617.
117. Frederick M Abbott. "First Report (Final) To the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation" (1998) *Journal Of International Economic Law* at p.611.
118. Frederick M Abbott. "First Report (Final) To the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation" (1998) *Journal Of International Economic Law* at p. 635.
119. Barfield, Clause and Mark Groombridge. "Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy Article" (1999) *Fordham Intellectual Property, Media and Entertainment Law Journal* 10:1 at 25.
120. Keith Maskus. "Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries" (2001) Report to World Intellectual Property Organization at p.15. However in their paper, "Parallel Imports and Price Controls Property", Gene Grossman and Edwin Lai challenged this assumption and found that international exhaustion of intellectual property rights may actually increase innovation by pre-emptively avoiding the free-rider problem (Gene Grossman and Edwin Lai. "Parallel Imports and Price Controls" (2008) *Rand Journal of Economics* 39:2).
121. Panos Kanavos et al. "The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis" (2004) Special Research Paper for LSE Health and Social Care at p 15.
122. Frederick M Abbott. "First Report (Final) To the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation" (1998) *Journal Of International Economic Law* at p. 617.
123. http://kad.arbitr.ru/PdfDocument/20d31d90-dbe7-4090-aca-ca7ad4654e151/A40-153306-2013_20150512_Reshenija%20i%20posta-novlenija.pdf
124. http://kad.arbitr.ru/PdfDocument/20b8b1d7-96bb-438f-b515-fed-1e4057aa3/A41-42379-2012_20140407_Opredelenie.pdf
125. http://kad.arbitr.ru/PdfDocument/c223c612-c2cd-45b7-b54c-74a541734f31/A40-492-2011_20120311_Opredelenie.pdf
126. http://kad.arbitr.ru/PdfDocument/31f86613-9fb8-43ff-8371-75a97172fd57/A56-10416-2013_20140715_Opredelenie.pdf
127. Irina Akimova. "Parallel import to be legalized in 2015. Antitrust risks" Capital Legal Services.
128. Petosevic. "Liberalizing Parallel Imports in Russia – Clashing Views" (November 27, 2013).



Gowling WLG (International) Inc.
gowlingwlg.com

Gowling WLG (International) Inc. is an affiliated business of Gowling WLG (Canada) LLP. Gowling WLG (Canada) LLP is a member of Gowling WLG, an international law firm which consists of independent and autonomous entities providing services around the world. Our structure is explained in more detail at www.gowlingwlg.com/legal"