THE UNIVERSE OF PHARMACEUTICAL TRADEMARKS IN RUSSIA 2017

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I. OVERVIEW

In this comprehensive paper, now in its second edition (2017), we set out to provide a status report on the trademark aspects of the pharmaceutical industry in Russia today. As Russia continued its long transition away from communism, there was always a strong mandate to establish an effective and innovative pharma industry in Russia that would be all its own. This left multinational innovators wondering what long-term presence they could hope to have in Russia. Recent events have fuelled this uncertainty exponentially. These events have included the expulsion of Russia from the G8, sanctions, countersanctions and so-called "soft" sanctions, a pro-active localization mindset, the drastic devaluation of the ruble, plummeting foreign investment, unemployment and an economic recession that had been in the works even before the recent events concerning Ukraine.

This review begins with a general overview of the pharma industry in Russia today. It then looks at the legal foundation for trademark protection in Russia, recent decisions concerning trademarks are then discussed, the concluding sections look at the issues of counterfeiting and parallel importation.

The concept of the regional trademark was introduced in draft legislation in early 2017 and this is reviewed in the section dealing with the Eurasian Economic Union.

II.
ECONOMIC OVERVIEW OF THE PHARMACEUTICAL INDUSTRY IN RUSSIA

2.1 THE ECONOMIC CLIMATE IN RUSSIA IN REGARDS TO MULTI-NATIONAL 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 multi-national business. The Russian pharmaceutical industry is one of the fastest growing industries in the world, increasing at more than a ten percent annual growth.[1] In 2013 the Russian Pharmaceutical market value reached 1,045 Billion Rubles (16.4 Billion USD) while experiencing a 14% market growth.[2]

In Q1 2014 the Russian Pharmaceutical market grew by 5.4% (284.9 Billion RUB or 4.5 Billion USD); however, the sales volume of pharmaceuticals decreased by 3.6 percent. This likely indicates that the Russian pharmaceutical market may have been affected by the devaluation of the Ruble and Russians are continuing to buy these imported, now much more expensive drugs, upon which they have become dependent.[3]

The Russian pharmaceutical market has recently shown signs of a reduction in its annual growth rate, as the growth rate fell to approximately 7% in H1 of 2014.[4] However, in 2015 the market has grown by 8,2% in Rubles and IMS health expects that it has grown by 8% in 2016.[5] The Economist Intelligence Unit (EIU) expects that by 2020 Russia will drop down from being 14th largest country in the world by volume of sales in U.S. dollars to 16th.[6] However, it still shows a higher growth rate than other European countries.

The British analytical company "GlobalData" estimates that the pharmaceutical market in Russia is set to rise from $20.91 billion in 2016 to $38.56 billion by 2021.

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 expects this plan to increase domestic products to 50% of the total internal market and increase innovative products to 60%.[7] To accomplish this goal Russia has, thus far, invested over 4 billion USD. This provides significant opportunities for international pharmaceutical producers as the Russian government will provide favorable market treatment to encourage companies to bring technologies and move their production to Russia.[8]

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 Russian people and to health care 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.

According to IMS Health, most of the largest international pharmaceutical companies, including Astra Zeneca, Novartis, Sanofi, GlaxoSmithline, have localized their production to one extent or another. The most recent example is a joint venture of Pfizer and Russian Novamedica.[9] Under the agreement reached in July, 2016 Pfizer will invest in constructing a local pharmaceutical company and will transfer licenses for the production of more than 30 medicines. The cost of the project is estimated as 60-100 mln. USD. The start of production is planned for 2020.[10]

To incentivize local production, the Russian Government has imposed restrictions on public procurement of medicines. According to Decree No.1289 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 second in line in favor of offers made by local manufacturers, provided that they can deliver. However, restrictions are only applied to the public procurement of those medicines that are on the list of vital and most important medicines.

A new wave of restrictions on public procurement that would cover all medicines, not only those in the list of vital and most important medicines, is now under consideration by the Russian Government.

2.3 THE EFFECT OF SANCTIONS ON THE RUSSIAN PHARMACEUTICAL INDUSTRY

Gennady Onishchenko, at the time an aide to the Russian Prime Minister, reassured Russians in 2015 that Russian countersanctions on Western products would not extend to foreign pharmaceuticals and that position remains unchanged.[13]

A report by STEM-Pharma emphasized that it is unlikely that Russia will introduce sanctions against the importation of pharmaceutical products, especially innovative medicines. Doing so would have significant negative impact on the advancement of the *Pharma 2020* strategy. Most significantly,

the introduction of sanctions on imported medicines and medical devices would be political suicide[14], because despite localization efforts, the share of imported medicines in the commercial segment by value is significant (74%) and did not change significantly since 2014 (was 76%).[15] This will evolve gradually.

The average Russian is likely thinking: "you can take away my French cheese and you can take away my American beef but you can't take away my heart medication!"

The drastic devaluation of the ruble and the rebound effects of the sanctions appear to have affected the pharmaceutical industry in Russia. The country's previously strong economic performance had contributed to the rapid growth of the pharmaceutical sector in Russia; a country where most forms of medication can be dispensed indefinitely to anyone by pharmacies without ever having 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. This growth has been hindered by the increasingly unpredictable Russian financial market.

The current political climate has also increased concern and speculation that the Government might nationalize key facilities and limit the freedom of capital repatriation.[16]

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

Experts also note that the drop in consumer income will likely encourage consumers to buy low cost drugs, thereby enhancing the market for branded generics.[17]

RUSSIAN PHARMACEUTICALS QUICK REFERENCE:

- **140,000,000 people**
  market size
- **74 percent**
  share of imported medicines in the commercial segment by value
- **20.91 Billion USD**
  market value 2016
- **8 percent**
  market growth 2016
- **284.9 Billion Rubles**
  Q1 2015 sales
- **73 percent of counterfeit**
  drugs are foreign drugs (2006)
- **63 percent of counterfeit**
  drugs are domestically manufactured (2006)
- **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).

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 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 and
- 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 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 & PROCEDURE

Trademark rights can be acquired by way of Russian national stage applications for registration with the Federal Service for Intellectual Property (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 is to be submitted in the Russian language. A trademark application will cover one mark and will comprise of:

- references to relevant information on the applicant (ex. 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 the Rospatent must be filed within 4 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 exclusivity 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 which:

- are false or capable of misleading the consumer about the goods or manufacturer of the goods; or
- it is 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 of 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 3rd party's registration for goods/services of the same class or an earlier application that has priority;
- a 3rd party's trademark registration, or application with earlier priority, protected under an international treaty (Madrid Agreement), for goods of a similar class; or
- a 3rd 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 followings 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 followings 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 followings 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 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 3rd 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 3 years after it is registered. Once an action has been instituted 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 3-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.

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 require the destruction of goods. The owner of the trademark may also claim compensation in the amount of 10,000 to 5,000,000 RUR (160 USD to 80,000 USD) at the court's discretion and may further claim double the value of the counterfeit goods or double the standard cost for the right to use the trademark.

3.2 PHARMACEUTICAL TRADEMARKS: ROSPATENT PRACTICE, PROCEDURES AND REGULATIONS

3.2.1 RUSSIAN MINISTRY GUIDELINES FOR NAMING MEDICINES

In 2005, the Russian Ministry of Healthcare and Social Development issued 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.[18]

3.2.1.1 PRINCIPLES FOR NAMING A MEDICINE

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 for Russian language;
- names of medicines must be distinctive in sound and spelling. It is not allowed to register for medicines any false names or confusingly similar names capable of passing off to consumers in respect of goods or its manufacturer, or 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 shall 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 be named after the preparation (pharmaceutical substance) comprised 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 INN or NNN it is expedient to use this non-proprietary name. For identification of the manufacturer (developer) it is advised 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 to consumers in respect of genuine composition and effect of the medicine. This category encompasses designations that evoke associations in the mind of consumers about certain qualitative parameters (composition and/or pharmacological properties) of the medicine, which does not reflect reality;
- name of the medicine should not present it in a laudatory way as being 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, 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, designations identical or having 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.

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 of 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**
   a. Borrowing existing (finished) word
   b. Substantivization of adjectives (conversions of adjectives into nouns)

3.2.1.3 PRINCIPLES FOR DETERMINING TRADEMARK SIMILARITY

The 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;
- 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 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- imigran;
- identical sound of the initial and end parts of designations and similar sound of the middle parts: for example pinovit – pikovit and eclyn - 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 3 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 in issue.[19]

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 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. Their decisions are therefore instructive as regards questions of registrability on both absolute and relative grounds.

3.2.2.1 NANOXRAY[20]

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.

3.2.2.2 THE GUARD[21]

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.

3.2.2.3 PROGRESSA[22] / LIBRAX[23]

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.

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 confusingly similar.

3.2.2.4 BETA-CALCIY[24]

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.

3.2.2.5 LORACTIV[25]

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. 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, however, noted that the 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 a with 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.

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 a trademark, if committed repeatedly or 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 2 years.

3.3.2 FEDERAL LAW NO.352-FZ

On January 23, 2015 Russia introduced legislation that criminalizes pharmaceutical counterfeiting and the distribution of counterfeit or falsified medicines and medical devices. Prior to the enactment of the new law, counterfeiting of pharmaceuticals was regarded as being no different than counterfeiting of luxury goods. The new, harsher, sanctions include 5-8 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. As regards 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 IP Court were, until recently, 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.

4.1 THE SUPREME ARBITRATION COURT DECISION ON THE TRADEMARK "KARNITON"[26]

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 SUPREME ARBITRATION COURT: "VECHERNIE"[27]

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 International Classification of Goods and Services established by the Nice Agreement.

Prior to recent amendments to 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, dietary supplements were prohibited from claiming any therapeutic properties in advertising. Therefore, there was some legislative and administrative inconsistency on the question whether medicines and dietary supplements were homogenous goods or not.

In the Pharmacy Doctor LLC vs Rospatent case, the company 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 3rd party, Biokor, filed an application for early termination of this trademark on the grounds of non-use. Rospatent determined that because Pharmacy Doctor was using the trademark in association with the sale of dietary supplements, this did not represent use for goods under 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 Rospatent 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 now uncertainty for trademarks that were registered before this was adopted.

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

4.3 INTELLECTUAL PROPERTY COURT: ХОНДРОЛОН (HONDROLON)[28]

Federal State Unitary Enterprise Mikrogen v. LLC Farmactivy
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 the 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 (Rospotrebnadzor) 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 cannot be considered using a trademark in violation of Article 1484 of the Civil Code of the Russian Federation.

Additionally, 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 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[29]

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

In this case the 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 sublicensee 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 3rd 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 paid compensation of 100,000 RUR (1,587 USD)

V. COUNTERFEIT PHARMACEUTICALS

"the trend is certainly toward high craftsmanship in counterfeits"

5.1 GENERAL OVERVIEW OF COUNTERFEIT PHARMACEUTICALS IN RUSSIA

5.1.1 WHAT ARE COUNTERFEIT PHARMACEUTICALS?5.1.2 COUNTERFEIT PHARMACEUTICALS IN RUSSIA

The World Health Organization defines 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.

Falsified medicine "is medicine accompanied with false information on 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 define the case and classify the offending pharmaceutical will determine how the matter is handled by law enforcement agencies.[30]

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 medicine 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.[31] Since then counterfeit pharmaceuticals have been a growing concern.

According to the latest statistics released by Roszdravnadzor, approximately 12% of all medicines in Russia are counterfeit. According to this source, more than 2 million packages of counterfeit medicine were seized in 2015.[32] Roszdravnadzor recently reported that by the end of H1 of 2016 it had withdrawn 9 trade names and 15 series of counterfeit medicines (in comparison with 16 trade names and 33 series in 2015).[33] Based on these statistics the Russian Academy of Sciences concluded that the counterfeit pharmaceutical trade in Russia was valued at approximately 2.5 Billion USD.[34] 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.[35] 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.[36]

According to recent polls, 40 percent of Russians believe that they have been the victims of counterfeit medication.[37] Conversely, Spiegel, former deputy chairman 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.[38]

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 a 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.[39] In 2006 a private investigation conducted by Pfizer found that Russian counterfeits were "the finest counterfeits" they had seen.[40] As Gennandy 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."[41]

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.[42] 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.[43] 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.[44]

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.[45] In early 2009 a report indicated that approximately 62% of all counterfeit drugs in circulation in Russia were manufactured domestically.[46] However, other estimates have claimed that this number is much lower, and that 50% of counterfeits in Russia are domestically produced.[47] 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.[48] While most of Russia's counterfeit medicine is domestically produced, a study in 2012 revealed that as much as 31% were manufactured in South East Asia.[49] Other CIS countries (former Soviet Republics) account for 2% of Russia's counterfeit pharmaceuticals.[50] 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.[51]

5.1.3 CONSEQUENCES OF THE COUNTERFEIT TRADE OF PHARMACEUTICALS

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.[52] 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; conversely they may contain a dangerously high quantity of the active ingredient; or they may contain the wrong active ingredient.[53] 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.[54] Mislabelled drugs create the risk that patients will overdose on medication or be harmed from unintentional drug-to-drug interactions.[55] 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.[56] 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.[57]

As Ranjit Roychoudhurry, 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."[58]

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.[59] According to the World Health Organization, approximately one hundred thousand deaths a year occur in Africa as a result of counterfeit drugs.[60] However, some reports claim that this number can be as high as 450,000 deaths caused by counterfeit anti-malaria drugs alone.[61] 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.[62]

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 pharmacy[63]; 149 Americans died in 2007 and 2008 as a result of a contaminated counterfeit blood thinner.[64] In 2012 it was discovered that counterfeit vials with no active ingredient of the cancer medication AVASTIN had entered the U.S. market.[65]

"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.[66] Allied Market Research estimates that globe trade in counterfeit drugs will reach approximately 142.7 billion USD by the year 2020.[67] In 2006 it is estimated that counterfeit medicine cost the pharmaceutical industry 300 million USD in Russia alone.[68] Additionally, because customers are unable to differentiate between genuine and counterfeit pharmaceuticals, counterfeiting poses serious reputational risks to the pharmaceutical industry by decreasing product quality and safety.[69] 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.[70] Counterfeit pharmaceuticals also increase the burden on the government to enforce 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 as many as 7 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 Customs 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

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 wide specter of unfair competition, including:

- passing-off (art. 14.2);
- unfair competition aimed at acquiring and using of 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);
- unfair competition aimed at creating confusion (including illegal copying or imitation of a product's design that can cause confusion between consumers) (art. 14.6).

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

The Code of Administrative Offences provides administrative sanctions and procedures for trademark infringement in the Russian Federation.

Article 14.10 of the Code of Administrative Offences provides 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 the Article, any illegal use of a foreign trademark shall create an administrative fine for individuals of 5 to 10 thousand RUB (80 to 158 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 (158 to 790 USD) RUB for officials, and increases to 50 to 200 thousand RUB (790 to 3161 USD) for legal entities.

The manufacture for the purpose of the sale of goods bearing an illegal trademark creates a fine for individuals of double the value of goods with the confiscation of 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 CUSTOMS UNION

The Law on Customs Regulations in the Russian Federation, taken in concurrence with the Customs Code of the Eurasian Customs Union provides mechanisms to prevent illegal 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.

To implement routine customs inspections, the trademark owner must apply to record its registered marks with the Federal Customs Service of the Russian Federation. The customs officials may then suspend the circulation of counterfeit goods. To be included 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 initiate a legal proceeding 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.[71]

The law directly addresses the issue of counterfeit pharmaceuticals. Historically the Russian government and brand owners had to rely on safety violations, fraud and trademarks to criminally charge counterfeiters.[72] 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 whose 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 selling of counterfeit medicines or medical devices resulted in serious harm to heath to establish 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 RUR (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 RUR (15,806 and 47,000 USD).

2. Production, Circulation or Importation of 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 Rubs (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 3 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 Citizens Health 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.[73] For example, judicially, universal definitions allow more focused efforts for protecting against counterfeit medicine and determining an appropriate punishment.[74] Analytically, a universal definition will create consistency between sources and reduce distortions of statistical findings (both wilful and otherwise).[75]

5.3.2 ENFORCEMENT OF THE NEW LEGISLATION

Criminal cases under the new legislation are not substantial yet. In 2015 there have been 12 criminal cases investigated under Art. 238.1 of the Criminal Code and 4 of them were brought to trial. On August 27, 2015 the district court in the town Rostov-on-Don sentenced a person to 2 years of imprisonment (conditionally) for the sale of unregistered medicines (case No.1-600/2015).[76] The district court in the town of Samara sentenced a person to 3 years of imprisonment (conditionally) for the sale of unregistered medical devices on May 11, 2016 (case No.1-164/2016).[77]

Administrative cases based on art. 6.33 of the Code of Administrative Offences are more common: on April 28, 2016 the Arbitrage court of the Irkutsk Region held an individual entrepreneur liable for the sale of inferior medical devices and levied a fine of 50,000 rubles (800 USD) (case No.A19-3703/2016)[78] 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 rubles (1,600 USD) (case No. 5-366/2016).[79] The Arbitrage court of the North-Western Circuit held on September 27, 2016 that the 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).[80]

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 Article 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 2 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 all the regulation of domestic and imported medicines and medical devices.

Roszdravnadzor was established in 2004 by the decree of the President, No.314. Roszdravnadzor has a Central Office (with 8 divisions), 11 federal laboratory complexes and 80 regional offices.[81]

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

As regards counterfeit medications, Roszdravnadzor is responsible for:

- pharmaceutical licensing;
- the federal state supervision in the sphere of the circulation of medicines;
- 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.[82]

The regulatory practice associated with Roszdravadzor[83] may be illustrated graphically as follows in FIG 1 (pg 26) and FIG 2 (pg 27).

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

- The Pharmaceutical Inspection Co-Operation Scheme (PIC/S)
- Working Group of Enforcement Officers of the Head of Medicines Agencies (HMA WGEO)
- Organization of the Black Sea Economic Cooperation (BSEC)
- International Medical Device Regulation Forum (IMDRF)
- The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)[84]

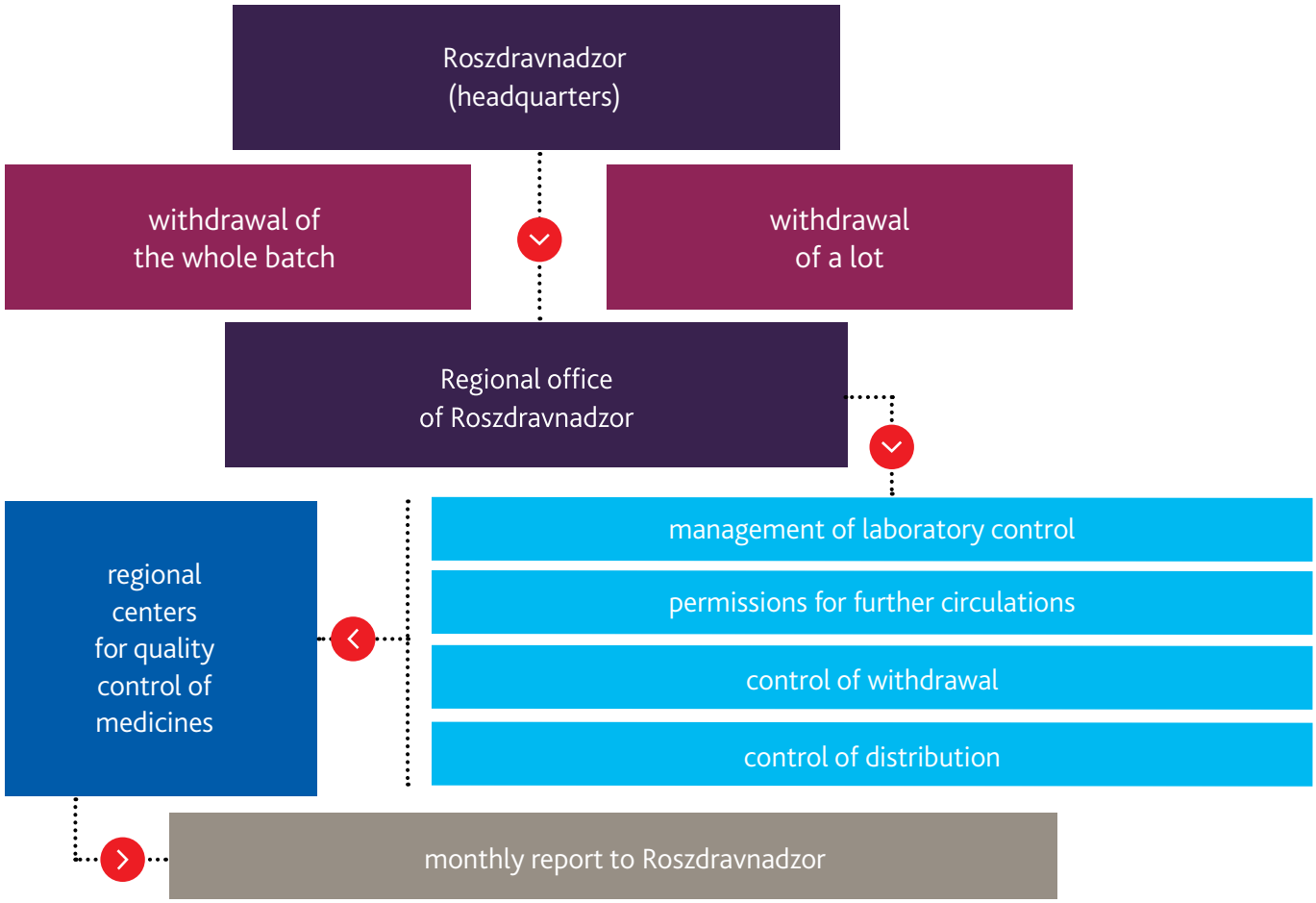
Additionally, Roszdravnadzor works with the regulatory agencies of other countries including the China Food and Drug Administration (CFDA), The National Institutes for Food and Drugs Control, China (NIFDC), and the United States Food and Drug Administration (US FDA).[85]

5.5 THE COMMON BARRIERS TO ANTI-COUNTERFEITING ENFORCEMENT IN RUSSIA

There are several barriers in Russia that pose serious limitations on the effectiveness of anti-counterfeiting laws:

- 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.

FIG 1



- 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 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 – Russians 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 5000 and 8000 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 recently enacted legislation making it a criminal offence to produce, circulate or storage 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 online health education, outreach disease surveillance, collaboration and communication between patients and providers, and support of clinical decision making.[96] According to the Internet market research organization eMarketer, the online pharmacy trade is a global $1 billion a year market.[97] However, with these benefits, the Internet also provides new opportunities for criminal organizations and other illicit actors to sell counterfeit pharmaceuticals by means of online pharmacies.

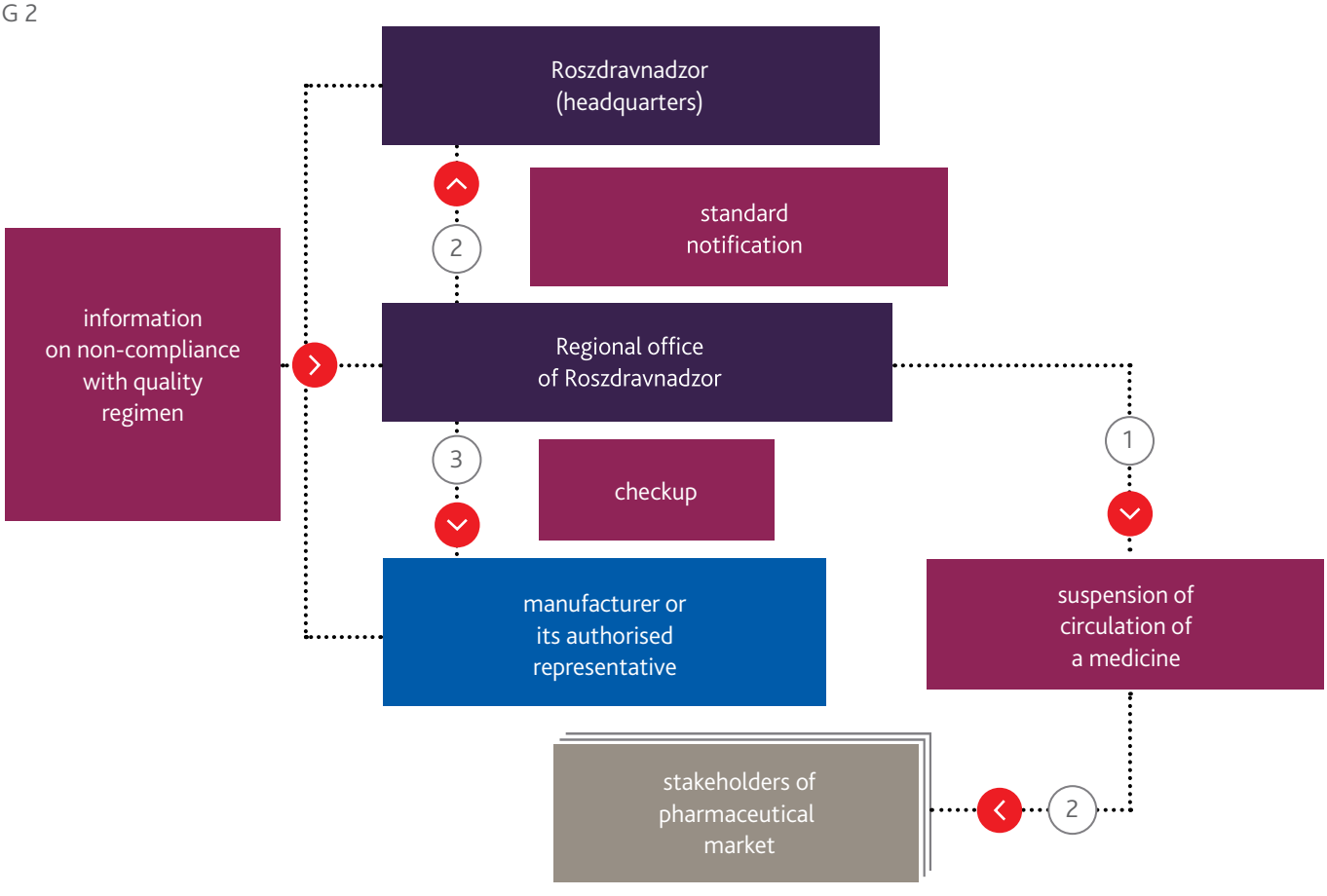
In the online pharmaceutical industry, more than 80% of the pharmacies that advertise are in some way illegal, mostly in regards to selling counterfeit drugs.[98] As previously discussed, fake drugs pose a serious global health risk over and above the economic challenges to innovative pharmaceutical 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 service – 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;**
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.[99]**

FIG 2



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.[100]

The use of online pharmacies in Russia is not uncommon. Russia ranked 4th globally in visitors to websites connected to illicit pharmaceutical spam, composing 6.5% of the total traffic.[104] The online sale of pharmaceuticals accounts for approximately 1% of the total pharmaceutical market in Russia.[102] 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.[103]

"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.[104] The United States was by far the number one visitor to websites associated with pharmaceutical spam, composing 54% of total traffic; followed by China and the United Kingdom who generated 26.5 and 8.9% respectively.[105]

The products offered are mostly lifestyle pharmaceuticals, diet pills, growth hormones, melatonin and products promising to help to quit smoking.[106]

Online pharmacies pose substantial challenges for agencies entrusted with 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.[107] This is particularly challenging by reason of the large volume of illegal online pharmacies.[108] 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.[109]

One example of this is illegal pharmaceutical website "medicshoperx" 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".[110] 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.[111]

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.[112] GeRa, an affiliate of SpamIt, was connected to a spambot that was capable of generating 18 billion emails per day.[113] 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[114] In total GlavMed had slightly fewer than 1,800 affiliate websites used to promote and sell online pharmaceuticals[115] 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 minor drop in spam emails for illegal online pharmacies after the charges were laid, the numbers bounced back to their previous high shortly afterwards.[116]

5.6.2 THE LEGALITY OF ONLINE PHARMACIES IN RUSSIA

Online pharmacies in Russia are illegal, however, there is ambiguity about what is 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 is 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 and 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) is prohibited.

There are 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 pharmacy.

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"

Online pharmacies employ 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.[117] 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.[118]

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.[119]

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.

The Russian Ministry of Healthcare and Social Development recently introduced an initiative to legalize distance sales of medicines. It is proposed that only licensed pharmacies would be allowed to sell medicines via the Internet. The bill has not been introduced into the Parliament yet, however, the Russian minister of Health, Veronika Skvortsova, expects that the bill will be considered by parliament soon.[120]

The Expert Council under the Government of the Russian Federation has developed the "roadmap" on the development of telemedicine technologies in Russia. The realization of the "roadmap" includes replacement of paper prescriptions with electronic ones. The "roadmap" provides that before electronic recipes will be available, the register of e-recipes should be created.[121]

The project will be tested in the four regions of Russia before 2017.[122]

VI.
THE PARALLEL IMPORTATION OF PHARMACEUTICALS IN RUSSIA

6.1 BACKGROUND

6.1.1 WHAT IS PARALLEL IMPORTATION?

As almost everyone is aware, 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.[123]

In his paper *The Parallel Importation of Unauthorized Genuine Goods*, Richard M. Andrade identified three reasons why gray markets may emerge[124]:

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;
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."[125]

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. 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 intellectually property emerged as a result of the "need to include the results of intellectual efforts in economic turnover".[126] 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 property law intellectual 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.[127]

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 Russia, Brazil and Turkey.

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 (EEC).

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 the 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.[128] 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.[129] 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.[130]

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 worth of direct savings in 2002 passed on to consumers. In the United Kingdom, there was direct savings of approximately €228 million for the purchase of parallel distributed pharmaceuticals. In Sweden, there were direct savings to the Swedish reimbursement system and patients of €46.7 million in 2002; 78% of which were savings by the government.[131] 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.[132] 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%.[133]

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.[134]

Proponents of parallel importation argue that the prohibition on parallel importation allows organizations to behave in an anti-competitive manner. [135] It is argued that regional exhaustion would allow 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.[136] Additionally, the threat of accessing parallel imported medicine provides health care providers with some negotiating leverage with manufacturers thereby assisting price control programs[137]

American legal academic 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".[138] 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."[139] 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 more valuable than their negative trade-restricting effect.[140]

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 a 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 the 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.[141] Some pharmaceutical products need to be stored under special conditions such as temperature or exposure to light; parallel importation by 3rd 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 substandard quantities of 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.[146]

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[147]

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

As discussed earlier, intellectual property rights are for the most part covered within Part IV of the Civil Code, which was introduced in 2008 and codified the fundamental rules for intellectual property.

Under Para 1 of Article 1484, a right holder has the exclusive right to use a registered trademark in Russia. This includes the right to use a trademark on goods that are imported into Russia. As regards imported goods, pursuant to Article 1487, only those goods that have been imported by or with the consent of the registered trademark owner are to be excluded from infringement. Therefore parallel importation is effectively a form of trademark infringement

6.3.1.2 THE COMPETITION LAW OF THE RUSSIAN FEDERATION

Prohibition of unfair competition aimed at creating confusion in 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 solid case law on this issue.

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 rights 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 RUR (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 RUR (160 to 800 USD) for officials, and increases to 50 to 200 thousand RUR (800 to 3125 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 thousand rubles (1,500 to 4,800 USD) or imprisonment for up to 2 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 but implicitly 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 Russia Federation. However, the import and sale of products that have been obtained by 3rd parties outside of the country are considered to be a violation of the trademark owner's exclusive right of importation.

6.3.3 RUSSIAN CASE LAW ON PARALLEL IMPORTATION

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 CASE[138]

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

The most instructive parallel importation decision is the landmark 2009 case from the Supreme Arbitration Court dealing with the importation of a Porsche Cayenne S (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 favor 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 Offenses, 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 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

The 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[149] 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 favor 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 *Nissan*[150] and *Nestle* trademark151 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.[152] 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 RUR (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.

6.3.4 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.[153]

Early on in 2017 the Eurasian Commission is believed to have drafted specific amendments to the Union Agreement that will serve to exclude pharmaceuticals and, likely, some categories of medical devices from the regional exhaustion of rights provisions.

6.4 THE CHANGING LEGAL ENVIRONMENT FOR "GRAY MARKETS" IN RUSSIA

The leaders of the Russian Federation, along with the Eurasian Economic Commission, are currently 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) since 2009. 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.[154]

On October 21, 2013 Russian First Deputy Prime Minister Igor Shuvalov claimed that if parallel importation is introduced into Russia, the process will be slow and will not begin before 2018.[155] Recent reports indicate that the FAS plans on fully legalizing parallel importation by 2020.[156]

6.5 THE REGIONAL COMMON ECONOMIC SPACE TRADEMARK

On February 2, 2017 Russia announced that it will 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 will co-exist alongside national registers which will 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 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, for example Russia, can elect to convert the pending application into a CES application by giving notice and paying the requisite fees2. 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.

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

http://www.eurasiancommission.org/ky/act/finpol/dobd/intelsobs/Documents/AGREEMENT 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 win 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 ratification of the draft agreement is in its final stages and it is hoped that all member-states will ratify the draft agreement by the end of 2017 with implementation perhaps as early as 2018.

Please see our comments in 6.3.4. as regards short term initiatives in the form of industry exceptions.

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