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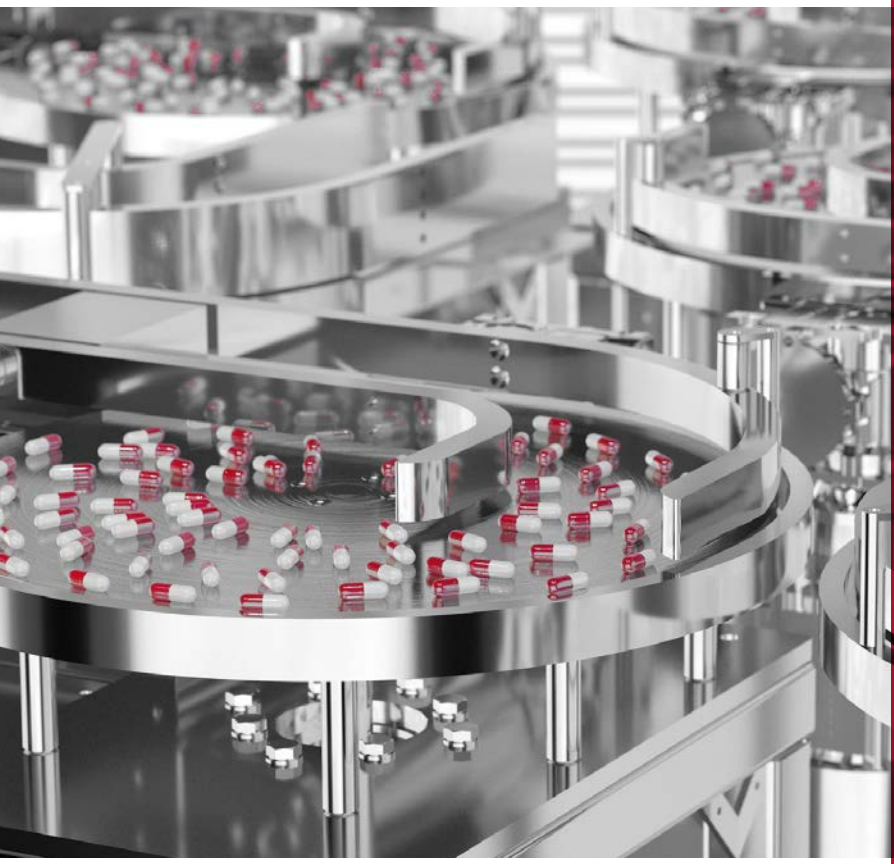

# PARALLEL IMPORTS OF MEDICAL GOODS IN RUSSIA: EFFECTIVE METHODS TO PREVENT THEM AND PRACTICAL RECOMMENDATIONS FOR RIGHTS HOLDERS IN THE FACE OF THE CRISIS

Parallel import remains one of the most relevant topics in trademark protection in Russia.

On the one hand, foreign rights holders that are the manufacturers of medical goods still retain almost complete control over the import of goods bearing their trademark into Russia, as well as the ability to preclude unauthorized shipments.

In general, in 2022, thanks to the joint work of rights holders and the Russian customs authorities, more than 7 million non-genuine goods were identified at the import stage, although in 2020 this number was over 13 million — almost twice as much.

The ability to control the import of trademarked medical goods allows rights holders to increase their sales, protect their distributors in the country, and also protect their brand's reputation.

However, the situation is changing rapidly. The partial legalization of parallel imports is affecting more and more sectors, and already calls are being heard for parallel imports of medical goods to be allowed as well, if rights holders reduce supplies to Russia or even suspend and withdraw their business from the country.

The antitrust risks that result from the fight against parallel imports and the restriction on the ability importers to bring authentic goods into Russia also add fuel to the flames.

In addition, the distribution of medical goods is a centre of contention: on the one hand, rights holders fight to ensure the quality of goods being delivered, but on the other hand the Russian antitrust authorities believe that under certain circumstances imports by parallel or "independent" importers can be a good thing.

In this brochure, we will talk about how to do business in turbulent conditions and how to maintain control over imports and avoid falling into antitrust traps.

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# I. Trademark as the key tool for fighting parallel imports of medical goods

## 1. Parallel imports and counterfeit goods: general characteristics and distinguishing features

As a first step in looking at the issue of fighting illegal imports, one should strictly distinguish between two concepts:

- parallel imported goods and
- counterfeit goods

*Parallel imported medical goods* are goods that are authentic and labelled with a trademark by the rights holder (or on its instructions), but which are imported into Russia without its consent by an unauthorized (i.e., parallel) importer.

The necessity of obtaining such consent is attributable to the fact that the import into Russia of goods labelled with a trademark is an independent form of use of this trademark, which in accordance with Clause 1 of Article 1229 of the Civil Code of the Russian Federation (the "**Civil Code**") is permitted only with the prior consent of the holder of the trademark.

As soon as this consent is received, the goods can then freely circulate on the Russian market, and each subsequent resale will not require the consent of the trademark holder. This is evidenced in particular by Article 1487 of the Civil Code, pursuant to which it is not an infringement of exclusive trademark rights for other entities to use the trademark in respect of goods that were put into circulation in Russia by the rights holder itself or with its consent.

In scholarly study, the model described above is traditionally named the national model for the exhaustion of trademark rights. However, there are other models for the exhaustion of trademark rights – the regional and the international. In the regional model, the trademark holder gives its consent to the import of goods into several countries at once, normally when these countries are members of a particular economic union (the EU or the EAEU, for example). Under the international model, the trademark holder's consent is required only for the initial labelling and first sale of the goods, after which they can freely circulate on the market of any country in the world.

At present the regional model has been implemented within the framework of the European Union and the Eurasian Economic Union[1]. Moreover, within the framework of the

[1] See Clause 16 of Annex No. 26 to the EAEU Treaty.

EAEU, there are plans[2] to assign the Eurasian Intergovernmental Council the authority to establish the international model of exhaustion of trademark rights in respect of certain categories of goods.

As a general rule, parallel import is a violation of the exclusive rights of the trademark holder, which is entitled to protect its violated rights by any means granted to it by civil legislation. However, in no case does parallel import create the *corpus delicti* of an administrative or criminal offense. This position was established in Russian court practice at the time of the well-known Judgment No. 10458/08 of the Presidium of the Supreme Commercial Court of the Russian Federation of 2009, in the case of the import of a genuine Porsche Cayenne S automobile into Russia.

Thus, the initiative to fight parallel imports lies entirely with the trademark holder, as the injured party in the infringement. The government can only provide assistance to the rights holder in its battle against parallel imports.

Parallel imports should be strictly distinguished from the circulation of counterfeit medical goods. These are non-authentic goods manufactured by entities unrelated to the rights holder and labelled with the trademark without the consent of the rights holder.

This activity is both an infringement of the exclusive rights of the trademark holder and an administrative offense, or even (under certain circumstances) a criminal offense. In consequence, when counterfeit products are found to be in circulation, the trademark holder can count on the assistance of the competent state authorities, while retaining all the civil-law remedies for protecting its violated exclusive rights to the trademark.

Together, parallel imports and counterfeit medical goods are referred to as *non-genuine* goods.

## 2. The road to gradual legalization of parallel imports since 2018

The Constitutional Court of the Russian Federation, in its Ruling No. 8-P dated 13 February 2018, took a major step towards the legalization of parallel imports. The salient fact of this Judgment, which concerns a case on the parallel import of a medical good – thermal paper manufactured by Sony Corporation – was that in a case of the gradual legalization of parallel imports the Russian Constitutional Court has gone even further than the Supreme Commercial Court in the aforementioned case of the import of a Porsche automobile, and among other things it differentiated between the civil-law consequences of parallel imports and those of the import of counterfeit goods.

[2] See Directive No. 30 of the Collegium of the Eurasian Economic Commission dated 24 April 2017 “On the Draft Protocol on Amendments to the EAEU Treaty dated 29 May 2014”.

The Constitutional Court proceeded on the assumption that the import of counterfeit goods is more dangerous for the market and consumers than parallel imports and causes much greater losses to the rights holder.

As a result, the Judgment makes an interpretation of civil law pursuant to which the seizure and destruction of parallel imported medical goods is permitted only in exceptional situations, specifically: if the medical goods are low-quality, or for the purposes of ensuring safety, protecting the life and health of the public, or preserving nature and cultural valuables. Also, compensation for the violation of trademark rights through parallel imports should be less than the similar import of counterfeits.

Thus, although the Judgment did not legalize the parallel import of medical goods, it did create substantial barriers to trademark holders in defending their rights at that time.

However, as concerns medical goods the exceptions listed above to the overall ban on the seizure and destruction of parallel imports are fairly relevant and available in practice.

Indeed, different medical goods often have special storage and transportation requirements, have a limited shelf life, etc. Compliance with all of these requirements involves significant financial and organizational costs, which are not always within the reach of parallel importers. As a result, there is a significant risk that by attempting to contain costs parallel importers will resort to violations of these rules, which can lead to the spoilage of the corresponding medical goods and in turn may cause harm to the life and health of the public (for example, if we are talking about reagents for blood analysis, their use can cause the results of the analysis to be unreliable).

In the end, in the situation described above there is a good chance the medical goods in question will fall under the exception and be seized and destroyed by court order, notwithstanding the Constitutional Court's prohibition.

One should also not forget that Russian civil law offers rights holders other means of defending their trademark rights unrelated to the seizure and destruction of parallel imports of goods.

For example, a rights holder whose trademark has been infringed has the right to request in court that the infringement of its rights be terminated by banning the infringer from putting the parallel imports onto the market in Russia. As a result, the infringer, being unable to sell such goods, will be forced to either re-export them, or use them for its own consumption, or destroy them on its own initiative. Whichever of the foregoing options the infringer chooses, the main goal of fighting parallel imports – freeing the Russian market of goods brought in as parallel imports – will have been successfully achieved by the trademark holder.

## 3. Partial legalization of parallel imports in 2022–2023

The year 2022 has been a turning point in Russia in various respects. However, from the perspective of the intellectual property, the key event was the partial legalization of parallel imports. What seemed unbelievable has happened, and yesterday's infringers of the exclusive rights of rights holders have now become an alleged link between an isolated Russia and the foreign markets.

In early 2022, the Russian Government was given the right to determine a list of goods to which the provisions of the Civil Code of the Russian Federation protecting exclusive intellectual property rights embodied in such goods and the means of individualization with which such goods are marked will not apply.[3]

This right has also been extended for 2023.[4]

The Russian government, in turn, has authorised the Ministry of Industry and Trade to approve a list of goods to which Subclause 6 of Article 1359 and Article 1487 of the Civil Code of the Russian Federation do not apply. The complicated wording of the name of this list implies a simple meaning — it amounts to permission to approve a list of goods for parallel import, i.e. goods which may be imported into Russia without seeking the consent of the owner of the trademark with which they are marked.

However, Russian national legal regulation has de facto been prioritized over international regulation. Unfortunately, the courts have not yet provided their legal assessment of this situation, but the practice on the "legalized" parallel imports is still taking shape.

In any case, the Russian Ministry of Industry and Trade exercised its right and issued Order No. 1532 dated 19 April 2022, which approved a list of goods for parallel import (hereinafter the "**List**" or "**List of Goods for Parallel Import**").[5] This Order has already been revised several times, with the List being both expanded and shortened.

The List currently includes several dozen groups of goods, systematized according to the first two digits of the Foreign Economic Activity Commodity Nomenclature (TN VED). Within the groups, goods are specified by indicating their names, TN VED codes of different lengths, trademarks, and the corporate names of the manufacturers.

[3] Clause 13 of Article 18 of Federal Law No. 46-FZ dated 8 March 2022 "On Amendments to Certain Legislative Acts of the Russian Federation".

[4] Article 20 of Federal Law No. 519-FZ dated 19 December 2022 "On Amendments to Certain Legislative Acts of the Russian Federation and Suspension of the Effect of Certain Provisions of the Legislative Acts of the Russian Federation".

[5] Order No. 1532 of the Ministry of Industry and Trade of the Russian Federation dated 19 April 2022 "On Approval of the List of Goods (Groups of Goods) in Respect of Which the Provisions of Subclause 6 of Article 1359 and Article 1487 of the Civil Code of the Russian Federation Do Not Apply, Provided that Such Goods (Groups of Goods) Are Put into Circulation outside the Russian Federation by the Rights Holders (Patent Holders), As Well As with Their Consent".

If there is a clarification in the “Name of Goods...” column, one should rely upon the TN VED code and this clarification, as well as the trademarks belonging to the rights holders registered in so-called “unfriendly states”.

The list of goods has included pharmaceuticals, lubricants, chemicals, textiles, paper, shoes, glass, metals, tools, electrical machinery, audio recording equipment, vehicles, medical instruments, watches, furniture, games, etc.

The registered medical goods were not included in the list for parallel imports as a general rule.

However, among the closest to the category of medical goods are the goods of TN VED Group 90 “Instruments and Optical, Photographic, Cinematographic, Measuring, Control, Precision, Medical or Surgical Apparatus, Parts and Accessories (Except for Goods Registered as Medicines and Medical Goods)”, which include, for example, non-medical thermometers.

Also worth mentioning is TN VED Group 31 “Other Chemical Products (“Except for Goods Registered as Medical Goods”), where parallel imports are allowed for goods under TN VED code 3824 99 960, in particular those marked with the trademark Miltenyi Biotec (reagents and consumables for the equipment to treat oncohematological diseases).

As practice has shown, the manufacturers of medical goods are divided into two groups. The first group believes that it is unacceptable to allow the parallel import of medical goods, justifying its position by the need to comply with a large number of mandatory requirements for the transportation and storage of goods, which parallel importers often ignore. In contrast, the other group appeals to the Ministry of Industry and Trade to allow the parallel import of medical goods or parts thereof, as in their opinion it significantly affects domestic production which is not fully localized.

The first group is still on the defensive, and so far has been very successful. Apart from the above examples of paramedical goods, there are no direct medical goods on the List.

When forming and amending the list, the Ministry of Industry and Trade has been governed not only and not so much by requests from individual entrepreneurs, but has been pursuing the following objectives:

- Mitigating the risks of a shortage of socially and industrially important imported products on the Russian market;

- Preventing the expansion of parallel imports to the products of bona fide rights

holders who continue to produce goods in Russia (supply goods to Russia) in full;

- Mitigating the risks of establishing indiscriminate parallel imports;
- Preventing the abolition of other requirements provided for by the laws of the Eurasian Economic Union;
- Regular monitoring of parallel imports;
- Carrying out industry expert examinations;
- Analysis of production capacity in the Russian Federation.

The Ministry of Industry and Trade of Russia may add reagents, consumables and equipment for laboratory diagnostics to the list of goods for parallel imports if these products become in short supply on the market.[6]

Below we examine the state authorities and institutions that, in the current crisis situation, can support rights holders who are manufacturers of medical goods in the fight against parallel imports.

# II. The Customs register of intellectual property as a means of fighting the parallel import of medical goods

## 1. Operating principle of the customs register of intellectual property

In accordance with Chapter 57 of the Customs Law[7], the customs authorities take certain measures to protect intellectual property rights within their jurisdiction.

In accordance with Article 124 of the EAEU Customs Code[8], one such measure is to suspend the date for the release of goods containing items of intellectual property.

[6] https://www.vedomosti.ru/business/articles/2022/05/23/923174-reagenti-dlya-laboratorii?ysclid=lbwxr9picg245443660.

[7] Federal Law No. 289-FZ dated 3 August 2018 "On Customs Regulation in the Russian Federation and on Amendments to Certain Legislative Acts of the Russian Federation" (the "**Customs Law**").

[8] Customs Code of the Eurasian Economic Union (Annex No. 1 to the Treaty on the Customs Code of the Eurasian Economic Union) (the "**EAEU Customs Code**").

The following conditions must be met in order to apply this measure:

- goods containing intellectual property (for example, labelled with a trademark) have been submitted for customs procedures;

- the intellectual property has been entered in the Russian customs register of items of intellectual property ("**TROIS**" or the "**Customs Register**") or in the EAEU customs register of items of intellectual property ("**EAEU TROIS**");[9]

- the customs authorities have discovered signs of the infringement of intellectual property rights.

If all three criteria are met, the release of such goods is suspended by the customs authority for 10 business day to clarify the circumstances.

TROIS is not simply a database of trademarks and other intellectual property, but is a whole system that represents a protective barrier in the path of parallel imports and imports of counterfeit products into Russia.

When goods are imported into Russia, the customs authorities automatically compare data in TROIS against the information in the customs declaration for the goods. In the customs declaration (column 31) the customs declarant must indicate the trademark with which the goods are labelled, if any. If the trademark has been registered in TROIS, the customs authorities review whether the importer is authorized, i.e., whether information on the importer is listed in the Customs Register. If TROIS has no information on the importer, then the rights holder or its representative is notified as appropriate, and the release of the goods is suspended for 10 business days. The trademark holder may apply (giving reasons) for this date to be extended a further 10 business days, and as a result the total delay in releasing the goods will be approximately one calendar month.

However, if the goods are on the List of Goods for Parallel Import, then TROIS will be of no use. As the First Deputy Head of the Federal Customs Service Mr. Ruslan Davydov pointed out shortly before the legalization of parallel imports: "*Customs officers currently check whether the company that intends to import the goods is on the list of authorised persons of the rights holder; if it is, then they let it through, and if not, then they notify the rights holder, but when allowing parallel imports we will not do it.*" And they do not. For example, the Apple trademark is simultaneously in TROIS and on the List of Goods for Parallel Import. Therefore, if Apple goods bearing TN VED code 8544 are imported, the rights holder of this trademark should not expect a notification from the customs authority on suspending the release of goods imported by a parallel importer. The customs authorities's failure to notify the rights holder about the impor-

[9] Not in operation as of the start of 2021.

tation of goods marked with its trademark is justified by the fact that the rights holder cannot bring the parallel importer to civil liability if such goods are on the List of Goods for Parallel Import.

Unfortunately, the customs authorities neglect the fact that the rights holder plays a key role in detecting another type of non-genuine goods: counterfeit goods, liability for the import of which is provided for by the laws on administrative offences and criminal laws. This is probably the reason why the number of administrative cases related to intellectual property that were initiated by the customs authorities fell by almost half, from 888 in 2021 to 449 in 2022.

## 2. The principle of *ex-officio* – an alternative to TROIS?

There is an alternative to the Customs Register: the so-called *ex officio* principle. Guided by this principle, the customs authorities have the right to suspend the release of trademarked goods even if the trademark is not listed in TROIS.

This procedure is relevant only in the event that the trademark with which the goods being imported into Russia are labelled has been registered with the Federal Intellectual Property Service ("**Reparent**"), i.e., as a general rule international trademarks are not protected by this procedure.

In addition, the customs authorities take measures to suspend the date of release of goods under *ex officio* procedure only once, i.e., without the ability of the rights holder to apply to extend the suspension, as described above. The customs authorities keep automated records of such suspensions, in order to avoid situations of repeat suspensions.

However, the customs authorities are not very proactive in exercising the authorities derived from the aforementioned *ex officio* principle: according to the information of the customs authorities for the first half of 2020, only 5 per cent of suspensions of the date of release of goods were made in respect of trademarks not listed in TROIS (i.e., *ex officio*).[10]

These statistics can be explained as follows. The customs authorities are governed by the following principle of protecting intellectual property: if the rights holder believes that there is a risk that its rights will be infringed by imports into Russia, it has the right to use a tool such as TROIS. If the rights holder does not use this tool, then the government will not expend its resources.

[10] See the webinar of the Federal Customs Service of Russia from 10 August 2020, available at: https://www.youtube.com/watch?v=2am3aCjZ05E&t=16s.

You can check online whether a specific trademark has been entered in TROIS on the relevant page of the official website of the Federal Customs Service ("**FCS**").[11]

## 3. How effective is TROIS?

In total, over 7 million non-genuine goods were detected at the import stage in 2022 thanks to the cooperation of rights holders with the Russian customs authorities, although in 2020 the amount was over 13 million – almost twice as much. Despite a significant decrease in the number of detected non-genuine goods, today TROIS remains one of the most effective tools to fight against the illegal import of medical goods into Russia, in a situation where medical goods still may not be imported into Russia without the permission of the rights holder.

## 4. Listing a trademark in TROIS: required documents

Thus, despite all the challenges, TROIS is an effective tool in fighting both parallel imports and imports of counterfeit goods related to medical goods. How does the trademark holder get its trademark listed in TROIS?

One should first check the current List of Goods for Parallel Import. If your medical product is still not on this list, you can get down to business.

FCS representatives agree that at the moment the procedure for entering trademarks in the system is fairly cumbersome. The package of documents that have to be submitted to the customs authorities can run to several thousand pages.[12] For this reason the FCS is considering revisions to optimize the procedure, but for now the list of documents does in fact remain quite broad.

In addition to the application itself, specific documents coming from the rights holder must be provided to the FCS. First and foremost, these include documents establishing title, the company's charter/articles of association, and a power of attorney.

It should be noted that if the rights holder is located outside of Russia, then the power of attorney should be notarised and the notary's signature should bear an apostille. Even though a *power of attorney* issued by a legal entity does not generally need to be notarized and bear an apostille, the customs authorities still make this a requirement.

Particular care should be taken to ensure that the person who signs the power of attorney is authorised to perform these actions on behalf of the company holding the rights to the trademark entered in the TROIS. For example, as a general rule, a manager can act on behalf of a legal entity in Germany, however there may sometimes be several

[11] https://customs.gov.ru/registers/objects-intellectual-property.

[12] http://customs-academy.net/?p=7052.

managers in a company or, in addition to the managers, attorneys-in-fact may be appointed in a company. All of these circumstances can usually only be established through a careful study of the excerpt from trade register and the charter of the relevant company.

It should also be noted that this power of attorney must contain a range of special authorities related to listing the trademark in the TROIS. Most of these authorities are determined by the corresponding provisions of the Administrative Policy[13], which governs the inclusion of trademarks in the TROIS.

Once the issue of the power of attorney is settled, all the other documents may be signed by a representative of the rights holder in Russia using the power of attorney.

To enter the trademark in the TROIS, the rights holder must conclude a *liability insurance contract to cover any material damage caused to persons in connection with the suspension of the release of goods*. Standard liability insurance agreements do not generally cover this situation. Liability insurance is required in those cases when the customs authorities mistakenly suspend the release of goods that are, in fact, being imported legally or when the rights holder does not take any actions to prevent an infringement due to the insignificance of the lot of goods being imported.

In this case, the importer may incur certain expenses (for example, on storing the goods at a bonded warehouse), which, if charged to the rights holder, should be covered by the insurance company.

Experience shows that the rights holder's biggest difficulty when entering a trademark in the TROIS is the collection of evidence confirming the *fact of illegal import of goods* marked with its trademarks.

In the Administrative Policy, the requirement to provide this evidence is worded as follows: "information on goods that violate the rights holder's right to trademarks during the period of customs clearance and on the persons responsible for their circulation".

Thus, according to the Administrative Policy only those trademarks that have been directly infringed upon through the import of goods marked with these trademarks can be included in the TROIS.

The Administrative Policy stipulates that a "rights holder *having sufficient grounds to believe* that its rights may be violated through the import of the goods can include the trademark in the customs register". The customs authorities are rigid in their interpre-

[13] Administrative Policy of the FCS on the Provision of State Services on Maintaining the Customs Intellectual Property Register, approved by Order No. 131 of the FTS of Russia dated 28 January 2019 ("**Administrative Policy**").

tation of this provision: the FCS must be provided with evidence of an infringement of the rights of the rights holder to the trademark identified upon the import of the goods.

## 5. The case of OOO TRIVIUM-XXI vs. the FCS

However, one Russian rights holder (OOO TRIVIUM-XXI) did not agree with the position of the customs authorities described above.

This company applied to the FCS to have its Russian trademark No. 465837 TRIVIUM included in the Customs Register, but in the opinion of the customs authorities did not provide sufficient evidence of an infringement of its rights. As a result, the customs authority refused to include the trademark in the TROIS.

The company appealed this refusal all the way to the Russian Supreme Court,[14] which disagreed with the FTS and indicated the following in February 2020:

> "*The interpretation that the Administrative Policy dictates the provision of information on previously committed infringements is incorrect. This defeats the purpose of the TROIS as a means to facilitate the identification and prompt prevention of infringements and to protect the rights of rights holders*".[15]

In other words, the Russian Supreme Court took the side of the rights holder and noted that no evidence of previously committed infringements needs to be provided when including trademarks in the TROIS.

Consequently, the Russian Supreme Court sent the case for reconsideration to the Commercial Court of the City of Moscow, which issued a decision in September 2020 declaring unlawful the FCS's decision to return without consideration the application of OOO Trivium-XXI to include the trademark TRIVIUM in the Customs Register and obliged the FCS to eliminate the committed infringement of the rights and lawful interests of the applicant. The FCS did not appeal the Decision of the Commercial Court.

Did the practices of the FCS change as a result?

To date, no. From the responses to the official requests of ADVANT Beiten to the FCS and the Ministry of Finance of the Russian Federation[16] it follows that the rights holder's inability to provide evidence that its trademark is being infringed by unauthorised importers makes it impossible to list the trademark in the Customs Register.

[14] Case No. A40-241863/2018.

[15] https://kad.arbitr.ru/Document/Pdf/6cdbc393-9f75-47c4-bacc-6e529ea61170/8c2fb6b5-05b3-4b1b-be31-b79a89a28bfa/A40-241863-2018_20200122_Opredelenie.pdf?isAddStamp=True.

[16] ADVANT Beiten is in possession of Letter No. 14-35/T-2692 of the FCS of Russia dated 14 April 2020 and Letter No. 27-01-23/47070 of the Ministry of Finance dated 2 June 2020.

However, we are hopeful that the aforementioned (and clearly progressive) opinion of the Russian Supreme Court will be reflected in future application of the law by the FCS.

## 6. After the trademark is listed in the TROIS

A trademark may be included in the TROIS for a period of up to three years; this period can be extended an unlimited number of times.

However, a trademark may be deleted from the TROIS if the rights holder fails to notify of a change in the information included in the TROIS (the deadline for sending this notice is five business days after this information changes).

It must also be remembered that, even after a trademark is entered in the TROIS, the customs authorities will not independently combat parallel import. The most they are willing to do is to inform the rights holder of the unlawful import of goods marked with a trademark included in the TROIS and to automatically suspend the release of these goods for 10 business days.

Accordingly, if the rights holder does not actively seek to challenge the infringer within this period, the customs authorities will be forced to release the parallel imports onto the Russian market.

To stop this from happening, the rights holder should react promptly: a claim should be filed against the infringer (parallel importer) in court as soon as possible after receiving the notice from the customs authority, together with a request for injunction in the form of the arrest of the corresponding goods. If the court takes injunctive measures and arrests the goods, the customs authority cannot release them onto the Russian market until the court has taken a final decision on the case.

As part of the court proceedings, the rights holder may file the following claims against the infringer (parallel importer):

- to refrain from infringing upon the rights to the trademark (for example, by banning the release of goods marked with the trademark into circulation or by forcing the infringer to reexport these goods);

- to recover losses or to pay compensation (in a reduced amount; for more information on this see point 2 of section I of this brochure);

- to seize and destroy the parallel imports (only in certain extraordinary circumstances; for more information on this see point 2 of section I of this brochure).

If the first and/or second of the claims listed above is satisfied, the main goal of the fight with parallel import will have been achieved – the corresponding goods will not be released into circulation on the territory of Russia.

## 7. The common Eurasian market and EAEU TROIS

At the same time, the rights holder should keep in mind that the Russian market is not an isolated market. It is part of the common economic area of the member countries of the EAEU, which in addition to Russia includes Belarus, Kazakhstan, Armenia and Kyrgyzstan.

In accordance with Clause 3 of Article 28 of the Treaty on the Eurasian Economic Union dated 29 May 2014, among other things, non-tariff regulatory measures, which include the aforementioned procedure for suspending the release of goods under the TROIS or the *ex officio* principle, are not used in mutual trade in the goods of the member states of the EAEU as part of the functioning of the internal market.

In other words, goods imported into the territory of one member state of the EAEU can be freely imported into any other member state of the EAEU without the customs authorities performing the control procedures designed to protect the rights of the trademark holders.

Therefore, the "border" of protection of rights to trademarks is expanded from the Russian borders to the borders of the entire EAEU.

This problem has found expression in the legislation of the EAEU. For example, two new institutions are in the final stages of being introduced within the framework the EAEU: the unified EAEU TROIS and the EAEU trademark.

Decision No. 35 of the Board of the Eurasian Economic Commission dated 6 March 2018 "On the Introduction of a Unified TROIS of the Member States of the EAEU" approved the Regulations on the Introduction of a Unified TROS of the Member States of the EAEU. The key conditions for including a trademark in the EAEU TROIS are as follows:

- the trademark is protected in all five member states of the EAEU: Russia, Belarus, Kazakhstan, Kyrgyzstan, and Armenia;

- the rights holder identified an infringement of the trademark during the import of goods into at least one member state of the EAEU;

- period of inclusion – up to two years (instead of the three years stipulated by the Russian TROIS).

So, the main difference between the EAEU TROIS and the Russian TROIS is the fact that the EAEU TROIS can only include those trademarks that are protected not only in Russia but also in the other member states of the EAEU.

At present, this condition can be met either by expanding the registration of an international trademark to all EAEU member states or by registering national trademarks in each of the five countries. The first of these options is clearly preferable for foreign rights holders.

In the near future another method for expanding the legal protection of a trademark to the entire territory of the EAEU might become available – registration of a common EAEU trademark. This was made possible when the member states of the EAEU adopted the Agreement on Trademarks, Service Marks and Appellations of Origin of Goods of the EAEU (signed in Moscow on 2 February 2020) that went into effect on 26 April 2021. Russia has already ratified this Agreement as part of Federal Law No. 360-FZ dated 9 November 2020, but the Agreement will only enter into force after it is ratified by all member states of the EAEU.

Therefore, rights holders interested in the Eurasian market will have a new tool that simplifies the procedure for expanding the legal protection of their trademarks throughout the EAEU. That being said, it is assumed that if a rights holder has registered international trademarks, international registration will still be the preferred tool for further expanding the legal protection of trademarks.

## 8. Conclusions and recommendations for rights holders

In view of the foregoing, we are ready to offer rights holders the following practical recommendations that may help them to organise the fight with parallel import of medical products:

- monitor applications for the inclusion of medical goods in the List of Goods for Parallel Import and promptly justify your position that these rules should not be extended to medical goods;

- register your trademarks (one way or another) in all five member states of the EAEU: Russia, Belarus, Kazakhstan, Kyrgyzstan and Armenia;

- include your trademarks in the Russian TROIS or in the common EAEU customs register (once it begins to function);

- promptly cooperate with the customs authorities regarding each identified instance of trademark infringement;

- document relations with official dealers by concluding trademark licensing agreements with them.

# III. Participation of Roszdravnadzor in the fight with parallel import of medical goods

## 1. Non-genuine, inferior and counterfeit medical goods

The Law on the Foundations of Protection of the Health of Citizens in the Russian Federation[17] splits medical goods, the circulation of which violates the provisions of this law, into three main categories:

- non-genuine;
- inferior;
- counterfeit.

In this regard, this law[18] understands non-genuine medical goods to be medical goods in circulation in violation of civil legislation. In other words, non-genuine medical goods include both fake goods and authentic goods imported into Russia through parallel import.

We talked in detail about non-genuine medical goods and their division into fake goods and goods imported through parallel import in section I.1 of this brochure.

*Inferior medical goods* include medical goods that do not meet the requirements of the product specifications, technical or operating documents of the manufacturer (producer) or, in their absence, other regulatory documentation.

For example, medical goods transported without complying with the temperature controls established by the manufacturer may be recognised as inferior medical goods.[19]

Counterfeit medical goods are medical goods that are accompanied by false information on their characteristics or the manufacturer (producer).

[17] Federal Law No. 323-FZ dated 21 November 2011 "On the Foundations of Protection of the Health of Citizens in the Russian Federation".

[18] Clause 14 of Article 38 of the Law.

[19] Judgment No. F05-22218/2018 of the Moscow District Commercial Court dated 27 December 2018 in case No. A40-227185/17.

Here we are usually talking about the actual chemical composition, for example, a reagent that does not correspond to the data indicated on the packaging.[20]

The Law on the Foundations of Protection of the Health of Citizens in the Russian Federation prohibits the import into the territory of the Russian Federation and sale of non-genuine, inferior and counterfeit medical goods.

For this reason, non-genuine and inferior medical goods are subject to seizure and subsequent destruction or export from the Russian Federation, and counterfeit goods – to seizure and subsequent destruction.

## 2. Seizure and destruction of non-genuine, inferior and counterfeit medical goods

New rules on the withdrawal from circulation and destruction of non-genuine medical goods, inferior medical goods and counterfeit medical goods came into effect in Russia from 1 January 2021 (hereinafter the "**Rules**").[21]

The Rules establish a different procedure for the withdrawal from circulation and destruction of non-genuine, inferior and counterfeit medical goods.

### 2.1 DESTRUCTION OF INFERIOR AND COUNTERFEIT MEDICAL GOODS

Seized counterfeit and inferior medical goods may be destroyed:

- by court order;
- based on a decision of the Federal Service for Surveillance in Healthcare ("**Roszdravnadzor**"), adopted based on the results of state control over the circulation of medical goods (according to the general rules).

Roszdravnadzor is responsible for state control over the circulation of medical goods through the performance of controlled buys to check compliance with the prohibition on the sale of non-genuine, inferior and counterfeit medical goods.

To exercise these functions, Roszdravnadzor has been granted broad authorities in this area, in particular:

- to receive documents and information on the circulation of medical goods from legal entities and individual entrepreneurs;

[20] Compare Judgment No. 08AP-946/2016 of the Eighth Commercial Court of Appeals dated 29 March 2016 in case No. A46-12947/2015.

[21] Approved by Resolution No. 145 of the Government of the Russian Federation dated 10 February 2022.

- to visit the buildings and territories used by entrepreneurs;
- to collect samples of medical goods;
- to issue mandatory, binding instructions;
- to draft protocols on administrative offences;
- to file claims and notices of infringement of legislation in court.

If there is evidence that a medical product is substandard or counterfeit, the owner of the medical product in question must, without the instructions of Roszdravnadzor or a court judgement, take an independent decision to withdraw it from circulation and destroy it and then immediately notify the manufacturer or its authorized representative and Roszdravnadzor of the decision taken.

## 2.2 DESTRUCTION OF NON-GENUINE MEDICAL GOODS

The Rules do not specify a special procedure for non-genuine medical goods. Non-genuine medical goods are subject to withdrawal from circulation in the territory of the Russian Federation and subsequent destruction by court order.

Accordingly, if non-genuine medical goods were seized during administrative proceedings and is evidence in a case, these non-genuine medical goods are to be destroyed according to the procedure stipulated by the Code of Administrative Offences of the Russian Federation ("**CoAO of Russia**"), i.e., according to the general rules.

It should be noted in this respect that the Constitutional Court of the Russian Federation, in its Judgment No. 8-P dated 13 February 2018, indicated that non-genuine goods imported into the territory of Russia through parallel import may be seized from circulation and destroyed only if their inferior quality has been established and/or to ensure the safety, health and life of the public and to protect the environment and items of cultural value.[22]

The following arguments can be used, based on the circumstances of the specific situation, to prove that medical goods pose a danger to the life and health of people:

- the lack of information on the origin of the goods;
- the medical goods did not pass through mandatory state registration;
- the medical goods did not have the mandatory markings and labels;

[22] We considered the specifics of application of this judgment of the Russian Constitutional Court in more detail in section I.2 of this brochure.

- the special conditions on storage were not observed;
- the special conditions for transportation, etc. were not observed.

## 3. Administrative liability for the circulation of non-genuine, inferior or counterfeit medical goods

The CoAO of Russia stipulates liability for a whole range of infringements of the legislation on the circulation of medical goods.

In its most general form, liability is stipulated for violations of established rules regarding the distribution[23] of medical goods.[24] An administration fine of RUB 30,000 to RUB 50,000 may be imposed on a legal entity for such a violation.

More specific norms of liability are also enshrined in legislation.

Part 1 of Article 6.33 of the CoAO of Russia stipulates liability for the distribution of counterfeit, non-genuine, inferior and unregistered medicines, medical goods and turnover in non-genuine nutritional supplements.

A court will consider this category of cases, while the customs authorities, Roszdravnadzor or Rospotrebnadzor may draft a protocol on the offence.[25]

The liability of legal entities may reach RUB 6 million in the case of an administrative fine or administrative suspension of activity for up to 90 days if the violation was committed online, for example.

However, it is worth noting that in actual fact Roszdravnadzor does not proactively seek to impose liability on parties distributing non-genuine goods.

In the opinion of Roszdravnadzor,[26] as medical products are declared non-genuine further to a decision of the judicial authorities in accordance with the civil legislation of the Russian Federation, then this process should be initiated by the party whose intellectual property rights were infringed.

[23] The circulation of medical goods includes technical tests, toxicology studies, clinical trials, the expert evaluation of the quality, effectiveness and safety of medical products, their state registration, production, manufacturing, import into the Russian Federation, export from the Russian Federation, confirmation of compliance, state control, storage, transportation, sale, installation, configuration, application, operation, including the technical maintenance stipulated by the regulatory, technical and/or operating documentation of the manufacturer (producer), and also repairs, disposal or destruction (see Clause 3 of Article 38 of Federal Law No. 323-FZ dated 21 November 2011 "On the Fundamentals of Healthcare for Citizens in the Russian Federation").

[24] Article 6.28 of the RF Code of Administrative Offences.

[25] Parts 1 and 3, Article 23.1, Sub-Clauses 12, 18 and 63, Part 1 of Article 28.3 of the RF Code of Administrative Offences.

[26] ADVANT Beiten is in possession of Letter No. 090-35290/2 of Roszdravnadzor dated 5 November 2020.

Consequently, initially the rights holder must independently file a motion in court on declaring a specific medical good non-genuine, and subsequently apply to Roszravnadzor to commence a case on the administrative offence stipulated by Article 6.33 the CoAO of Russia.

In general, the administrative liability stipulated by the CoAO of Russia for the distribution of non-genuine, inferior and counterfeit medical goods looks as follows:

| | Counterfeit medical goods | Inferior medical goods | Non-genuine medical goods |
|---|---|---|---|
| **Punishable act** | Production, import or sale | Import or sale | Import or sale |
| **Liability** | Fine of up to RUB 5 million or suspension of activity for up to 90 days | Fine of up to RUB 5 million or suspension of activity for up to 90 days | Fine of up to RUB 5 million or suspension of activity for up to 90 days |

Furthermore, if any of the aforementioned categories of medical goods are sold online or through the mass media, the fine could rise up to RUB 6 million.

## 4. Conclusions and recommendations for rights holders

Proceeding from the material in this section above, the following recommendations to rights holders on how to fight non-genuine, inferior and counterfeit medical goods, would appear most apposite and logical.

Firstly, formalise relations with distributors so that all non-genuine medical goods supplied to the Russian market can be reclassified as inferior products. It should be noted here that the requirements of the regulatory, technical and operating documentation of the manufacturer are as a rule fairly detailed, while infringers importing medical goods as parallel imports are highly reluctant to comply with all the respective requirements, for example, regarding temperature settings, rules on storage and carriage. Non-compliance with these requirements provides grounds for classifying such goods as inferior, resulting in all the consequences previously mentioned.

Secondly, apply to Roszdravnadzor to commence a case on administrative offences each time you identify counterfeit, inferior or non-genuine medical goods. It should be recalled here that administrative liability may be imposed on the actual corporate infringer and also its director (for example, the general director).

Thirdly, we recommend that you proactively cooperate with Roszdravnadzor in the court proceedings on imposing administrative liability on infringers, as practice shows that the involvement of the rights holder makes it far more likely that the infringer will be held administratively liable.

# IV. Chestny ZNAK marking system and its role in the fight against parallel imports of medical goods

## 1. Background information

The system for marking goods with the Chestny ZNAK ["Honest Mark"] system, whose phased implementation in Russia started back in 2018–2019[27], had been extensively covered in the mass media and different professional communities due to its extension to all new categories of goods by 2023. These days a variety of goods must be marked with the Chestny ZNAK – clothing, shoes, tobacco, medical goods and many other product categories. A full list of these categories can be found on the system's official website.[28] A voluntary labelling experiment is being carried out on medical goods from 15 February 2022 to 28 February 2023.[29]

The following medical goods are to be labelled as part of the experiment:[30]

[27] See: Federal Law No. 487-FZ dated 31 December 2017; Federal Law No. 488-FZ dated 25 December 2018; Instruction No. 792-r of the Government of the Russian Federation dated 28 April 2018.

[28] https://честныйзнак.рф.

[29] Resolution No. 137 of the Government of the Russian Federation dated 9 February 2022 "On Conducting an Experiment on Labelling Certain Types of Medical Goods with Means of Identification in the Territory of the Russian Federation".

[30] For the purposes of application of this list, in addition to the above EEA TN VED codes and OKPD 2, one should also be guided by the name of the type of medical goods and the code of the type of the medical product in accordance with the nomenclature classification of medical goods approved by the Ministry of Health of the Russian Federation.

| EEA TN VED Code | Code of the Russian National Classifier of Products by Type of Economic Activity 2 (OKPD 2) | Name of the type of medical goods | Code of the type of the medical product |
|---|---|---|---|
| 8421 39 200 8<br>8421 39 800 6<br>8539 49 000 0<br>9018 20 000 0 | 28.25.14.110<br>32.50.50.190 | Air disinfection purifiers (including the equipment, bactericidal systems and recirculators used for in-door air filtration and purification) | 131980<br>152690<br>152700<br>182750<br>209360<br>292620<br>336330 |
| 9021 10 100 0 | 32.50.22.150<br>32.50.22.151<br>32.50.22.152<br>32.50.22.153<br>32.50.22.154<br>32.50.22.155<br>32.50.22.156<br>32.50.22.157 | Orthopaedic footwear and corrective inserts for orthopaedic footwear (including insoles, half insoles) | 250220<br>250230<br>250250<br>250260<br>320560<br>343610 |
| 9021 40 000 0 | 26.60.14.120 | Hearing aids, other than parts and accessories | 113850<br>173110<br>202800<br>202810<br>204370<br>210000<br>228560<br>302870 |

| EEA TN VED Code | Code of the Russian National Classifier of Products by Type of Economic Activity 2 (OKPD 2) | Name of the type of medical goods | Code of the type of the medical product |
|---|---|---|---|
| 9021 90 900 1 | 32.50.22.190<br>32.50.22.195 | Coronary stents | 135820<br>155760<br>155800<br>155820<br>218190<br>273880<br>343410<br>343540 |
| 9022 12 000 0<br>9022 13 000 0<br>9022 14 000 0<br>9022 19 000 0 | 26.60.11.111<br>26.60.11.113<br>26.60.11.119 | Computer tomographs | 135190<br>142570<br>280730<br>282030 |
| 9619 00 890 | 17.22.12.130 | Sanitary products used to treat incontinence | 233730<br>233900<br>280360<br>320550<br>331320<br>331330<br>331830<br>356150 |

There are 4,704 companies participating in the medical goods labelling experiment.

Authorised to expand the list of labelled goods, the Government of the Russian Federation plans to apply the Chestny ZNAK system to all categories of goods traded on the Russian market by 2024.

## 2. Operating principles of the Chestny ZNAK system

The stated key objective of the Chestny ZNAK system is to tackle trade in non-genuine products on the Russian market. To attain this goal, each unit (packaging) of goods produced or imported into Russia must be marked with a unique code; any trading in goods without the indicated code is prohibited. When parties conclude each subsequent transaction with the goods, including sale to the end consumer, they must scan the code, and the information on the transaction is automatically transferred to the Chestny ZNAK system's database. As a result, by scanning the code on the good using a smartphone app, the end consumer will be able to obtain specific information on the goods (in particular, on the manufacturer, the date and place of manufacturing, the shelf life and storage terms, and a detailed description). Moreover, the competent authorities will have access to the entire transaction history of the goods, including information on the transacting parties.

## 3. Fight against trade in non-genuine products

The trademark, the corresponding rights holder and the state executive authorities monitoring compliance with the rights of the rights holder represent one of the key tools in the fight against trade in non-genuine products.

At the same time, the Government of the Russian Federation instructed[31] a private commercial legal entity – OOO Operator TsRPT (the "**Operator**") instead of a state agency to issue the marking codes and assume responsibility for overall coordination of the functions of the Chestny ZNAK system.

At the same time, the indicated system has potential to combat non-genuine goods which have already entered the Russian market and are proactively sold by the infringer. After performing a controlled buy of such goods, the competent authorities will be able to identify the entire chain of suppliers-infringers through the marking code and then impose the administrative liability stipulated by Part 2 of Article 14.10 of the CoAO of Russia on all of them. However, without the marking code as a rule it takes a significant amount of time to collect the indicated information and can necessitate material investments from the rights holder.

It is also worth noting here that acquiring marking codes from the Operator and implementing the Chestny ZNAK system for the production (import) of goods will entail certain financial and operating costs for all the parties interested in trading the respective goods on the Russian market (both rights holders and their official dealers, and infringers). However, whereas the rights holder as a bigger business will often manage to handle the indicated costs, an infringer, usually a small business, will find that they

[31] See: Instruction No. 620-r of the Government of the Russian Federation dated 3 April 2019.

render its illegal activity unprofitable, and consequently will be compelled to exit the respective market.

### 4. Conclusions and recommendations to rights holders

At present the Chestny ZNAK system represents a fairly contradictory way of combatting trade in non-genuine products. While definitely inferior to customs registers in this respect, the system could still prove useful as a way of obtaining information on non-genuine goods resale networks and the persons making such sales.

At the same time, at present the Chestny ZNAK system is still in the early stages of its development in respect of medical goods. After enhancements to the system, the fight against trade in non-genuine products on the Russian market could be elevated to a qualitatively new level.

## V. Antitrust risks of the fight against parallel imports of medical goods

### 1. General provisions

Even though the fight against parallel imports represents from a legal perspective the protection of the exclusive trademark rights of the rights holder, it could be fraught with specific risks for the latter. The main problem here is the position of the different Russian state authorities pushing for the gradual legalization of parallel imports.[32]

The Federal Antimonopoly Service (FAS) is also playing a proactive role as the country moves towards the legalisation of parallel imports, as illustrated by two precedent decisions of the service[33]. While the cases concern the automotive component market, it is highly likely that FAC will be able to apply the same arguments to medical goods.

In corresponding cases FAS established that antitrust legislation had been violated, specifically Article 14.8 of the Competition Law, by the actions of the companies Daimler AG and KYB Corporation and issued orders to the companies to eliminate the identified violations. As both of the cited cases are similar in terms of the facts and arguments

[32] One can cite the aforementioned Judgment No. 10458/08 of the Presidium of the RF Supreme Commercial Court dated 3 February 2009 and Judgment No. 8-P of the RF Constitutional Court dated 13 February 2018 as specific examples of the manifestation of such a policy.

[33] This concerns the decisions of the Federal Antimonopoly Service of the Russian Federation dated 18 September 2020 in case No. 1-14-163/00-08-18 (https://br.fas.gov.ru/ca/upravlenie-kontrolya-reklamy-i-nedobrosovestnoy-konkurentsii/8cfea32a-5dc8-49bc-b13a-19b4c8db9701/) and dated 18 September 2020 in case No. 1-14-164/00-08018 (https://br.fas.gov.ru/ca/upravlenie-kontrolya-reklamy-i-nedobrosovestnoy-konkurentsii/4b7249a3-2cf7-4f70-9b7e-defb0b0c453b/).

of the parties, we present below briefly only one of them (the Daimler AG case), which makes it possible to gain an insight into the position of FAS on such cases.

## 2. Daimler AG case

In this case the applicants applied to FAS, citing unfair competition on the part of Daimler AG, alleging that the company only issued permits to import authentic goods to the Russian Federation to its official dealers, denying this right to other companies. The applicants held that such competitive practices by Daimler AG unjustifiably restricted competition on the Russian market of spare parts manufactured by Daimler.

In response to the application, in summer 2017 FAS issued a warning to Daimler AG to terminate actions which attest to violations of antitrust legislation. As it did not receive information on compliance by the company, at the end of 2018 FAS commenced a case against Daimler AG on violation of antitrust legislation, specifically, Article 14.8 of the Competition Law ("Ban on other forms of unfair competition").

We propose briefly considering the arguments of the parties in the table below.

| Daimler AG | FAS |
|---|---|
| Effective legislation does not require the rights holder to consider the appeals of third parties for the receipt of a permission to import goods or issue respective permits. | In this case Daimler AG abused its exclusive right to a trademark defined by the Constitutional Court of the Russian Federation as a situation where the rights holder exceeds the reasonable limits of protection of its economic interest, the exercise of subjective rights, contrary to their designation or public goals, which results in the refusal to protect its rights (Sub-clauses 1-2 of Article 10 of the RF Civil Code). |
| | Daimler AG had not established a procedure (regulation) for considering the applications of independent importers for permits to import authentic goods into the Russian Federation, had not established the criteria for assessing such applications and grounds for issuing respective permits. |

| Daimler AG | FAS |
|---|---|
| Daimler AG attributes its decision not to issue a permit to the need to prevent adverse consequences for consumers and the market in the long term, as there is no guarantee that the applicants will adhere to good practices when doing business.<br><br>The applicants were repeatedly held administratively liable for different violations of legislation when importing goods into the Russian Federation. | Daimler AG's arguments that the applicants would perform their obligations improperly and in bad faith are mere assumptions and contravene the presumption of the good faith of participants in civil commerce (Clause 5 of Article 10 of the RF Civil Code).<br><br>The existence of an import permit would have eliminated the legal risks which might have been reason for the actions of the applicants in the indicated instances which had been qualified by judges as the infringement of exclusive rights. |
| Daimler AG and its Russian official dealers do not overstate prices for goods. | FAS was not assessing specific pricing decisions, but rather the competitive tactics applied by Daimler AG to the detriment of market participants and competition as a whole. |
| Daimler AG is ready to supply all its goods through official dealers in Russia. | FAS took account of the interest of consumers in acquiring specific goods from the applicants, which demonstrates either that Daimler AG is unable to satisfy such demand through official dealer channels or that consumers disagree with its terms.<br><br>Daimler AG's arguments do not confirm that specific goods were available at the time when a specific consumer contacted the company. |
| The applicants assume no brand reputation costs, accordingly the issue of a permit to them to import corresponding goods would offer them an unsubstantiated benefit, compared to the official dealers of Daimler AG in Russia. | Daimler AG's arguments on the adverse impact of investments by its official dealers in Russia to support brand reputation are irrelevant in this dispute, as the indicated dealers are parties to the dispute. |

As can be seen from the table above, FAS provided rebuttals to all of Daimler AG's arguments. In our opinion, in some instances the rebuttals of FAS were more convincing (for example, the reference to the presumption of the good faith of economic agents), in other instances – less convincing (for example, the assertion that Daimler AG was abusing its trademark right).

In any case, as noted above, after due consideration of the case, FAS concluded that the actions of Daimler AG included a violation of antitrust legislation.

At the time of the writing of this brochure, Daimler AG was appealing against the indicated decision of FAS in court[34]. However, to date, the initial unfavourable court decision was never successfully appealed —in the judgement dated 27 September 2022, the judge of the Supreme Court of the Russian Federation declined to refer the case to the Supreme Court's Judicial Panel for Economic Disputes.

## 3. Conclusions and recommendations to rights holders

To all intents and purposes, the position of FAS set out in the above table boils down to the fact that foreign rights holders may not without reason refuse to issue permits to independent importers to import authentic products into the Russian Federation bearing the trademarks of such rights holders.

Given the indicated position of the antirust agency, we recommend that rights holders take the following actions:

- adopt as an internal policy a regulation on considering the applications of independent importers for a permit to import the company's authentic goods into the Russian Federation;

- where possible, answer all the applications of independent importers, attribute the refusal to issue permits to the non-compliance of the applicants with the specific provisions of the adopted regulation (for example, the temperature settings, storage or transportation of the medical goods);

- where possible, organise the distribution of its goods into the Russian Federation through several official dealers, and not through one dealer.

[34] https://kad.arbitr.ru/Card/b2a701bd-c53e-4e4c-9b4c-497316bff7f8.

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