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THREATS OF TRADE IN COUNTERFEIT PHARMACEUTICAL PRODUCTS[1]

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ABSTRACT

Many authors point out to severe negative implications that trade in counterfeit medical products may cause to a national economy. It does not only create negative implications from the illegal exploitation of intellectual property rights under the TRIPS Agreement, but also creates serious threats to the economic growth, life, health and safety of citizens and undermines good governance, the rule of law, as well as citizens' trust in government.

The outburst of the COVID-19 pandemic at the beginning of 2020 had a strong impact upon the increment of on-line trade in goods, as well asupon on-line trade in pharmaceutical products. Different criminal networks used the COVID-19 pandemic for widening the scope and the scale of their operations in on-line trade in unauthorized or fake pharmaceuticals for medical treatment of different medical conditions including COVID-19.

Having on mind the gravity of the problem of global trade in counterfeit pharmaceutical products, the authors of this paper pay due attention to the correct definition on falsified medical/pharmaceutical products; provide literature review and a brief review of actual international and multilateral

[1] original research paper

regulative on intellectual property rights relevant for pharmaceuticals and the exemptions thereof; make an analyses of actual global trends and greatest traders of falsified pharmaceutical products; and finally present concluding remarks.

KEY WORDS:counterfeit pharmaceutical products; trade in counterfeit pharmaceutical products;on-line trade; international regulative on intellectual property rights, TRIPS.

INTRODUCTION

Trade in counterfeit goods is as old as trade itself. Due to globalization trends and tendencies, counterfeit goods instead of being traded through informal markets,started to make their way through the legitimate distribution channels. Criminal networks increased the scope and the scale of their criminal activity through intensifying on-line trade used for supplying small consignments of counterfeit goods to individual purchasers. The creation ofa digital trading space brought additional challenges for monitoring of international markets and illegal trade activities, as purchasing does not take place on any known physical location or marketplace. Instead, small parcels are delivered directly to final consumers through legitimate supply chains, which make the delivery almost invisible for the customs and for other relevant authorities. Hence, detection of on-line counterfeit trade is especially complex considering the intense, continuous changes within thedigital spaceand disappearance of traditional ways of doing business and trade exchange of goods.

In the past, in most of the cases, all participants in a trade transaction - buyers, sellers and goods - werepresentat the time of the transaction in the same geographic space. Nowadays, the seller (as an on-line store) may be registered in one country; the products may be in a warehouse in another, whereas the buyers may be all around the world.As virtual space is devoid of national territorial borders, detection of counterfeit products becomes a global problem for which national regulation becomes ineffective. Each of the jurisdictions where the buyers, the sellers and the goods are located might have different laws on intellectual property rights, or some of them even do not have such laws at all. On-line shopping allows transactions to be executed without parties ever seeing with or even directly communicating to one another. This occurrence is facilitated by the evasive role of the internetand the increasing number of new apps and social media platforms,

thus creatingnew channels of which counterfeiters and pirates take advantage. Very often counterfeiters abuse the advantages of operational free trade zones, of multilateral trade facilitation measures, as well asof national economies where government standards are insufficient.

Trying to pay due attention to the gravity of the problems caused by global trade in counterfeit pharmaceutical products, this paper provides a brief literature review followed by an overview on international and multilateral regulative on intellectual property rights relevant for pharmaceuticals and exemptions thereof; refers to the correct definition on falsified medical/pharmaceutical products;analyzes actual global trends and provides a list of the greatest traders of counterfeit pharmaceutical products; and finally presents concluding remarks.

LITERATURE REVIEW

There is an abundant literature in trade of counterfeit pharmaceutical products and negative effects thereof. The papers published in this area could be divided in two large groups: those which deal with the public health consequences, and those which deal with the economic and social consequences of trade in counterfeit pharmaceuticals. Both groups of papers point out that the consequences of trade in counterfeit pharmaceuticals are more grave for law income countries due to the lack of legal and institutional capacities for combat with this illegal practice.(1)

Papers that deal with the public health consequencesstate that the usage of counterfeit pharmaceuticals may cause poisoning, treatment failure, untreated disease or early death.

Poisoning from counterfeit pharmaceuticalsis a result of undeliberate or deliberate usage of unapproved ingredients in the production of medicaments and drugs that may cause serious injuries, even deaths, such as blue printer ink, amphetamines, arsenic, boric acid, brick dust, cement powder, floor polish, leaded road paint, nickel, shoe polish, etc.(2) A number of papers state the usage of diethylene glycolin pharmaceutic products (the active ingredient in antifreeze)which lead to hundreds of deaths of patients due to kidney failure from usage of such products. The most exploited examples of such kind of poisoning are the 84 cases of dead children in Nigeria from the usage of a teething syrup containing diethylene glycol (3); the 219 deaths from kidney failure in Panama, and an unknown number of deaths by selling

60,000 bottles of cough syrup produced with diethylene glycol sold to a European company as a pharmaceutical-grade glycerin by a Chinese manufacturer (4).Other negative experience with serious consequences from poisoning were detected by SFIDA in 254 separate cases of companiesthat were listed as sources of the chromium-tainted medicines (5)

The problem of medical treatment failure of chronical diseases and infections, as well as causing antimicrobial, antimalarial and other antiparasitic resistance by using counterfeit pharmaceutical products, however, is even more jeopardizing.(6) Such cases are very difficult to detect, as many of the counterfeit pharmaceuticals that cause treatment failure often contain benign ingredients, such as chalk, pollen, or flour, instead of medical chemicals.(7) Some of those products contain substances intended to mask the illness and feign treatment, such as paracetamol added to fake antimalarials to lower fever, thus causing deaths of patients who take ineffective drugs.(8) In most of the cases it is very difficult to revilewhether the patient died by natural causes, as the ineffective faked products are very difficult to identify.(9)

In regard of socio-economic consequences from trade in counterfeit pharmaceuticals, most of the researchers point out that treatment with substandard and falsified drugs significantly raises drug costs to patients and to the health system. In the case of law income countries, where the costs for medicaments comes second next to the costs for food in the household, there is a significant pressure on procurement agencies to provide for drug orders with lowest prices. There is abundant empirical evidence which confirms that opting for the lowest prices very often ends up with a loss of an entire budget on medicines on drugs with insufficient active ingredients.(10)This problem especially hits poor countries which carry the vast amount of high cost for drugs and their transportation, for example South Asian countries. However, rich countries are not risk free in this regard. (11)

Other negative effect registered under this criterion is additional increment of costs due to development of drug resistance by using counterfeit pharmaceuticals. This also applies to the oldest and cheapest anti-infective drugs which become useless as the drug resistance reduces their effective life. Therefore, development of new more complex drug molecules has to be financed, which creates additional costs for the economy. In 2003 a research study pointed out that the costs for drug development grew by 7.4% faster than the inflation at that time.(12)

Nevertheless, the loss of trust in contemporary medicaments and their effectiveness due to the trade in counterfeit pharmaceuticals, as well as the loss of faith in the public health system is even a much bigger socio-economic challenge. In many low income countries patients already doubt the competence and the clinical skills of the personnel, and the mistrust culminates with the proliferation of counterfeit medicines. (13)

UNODC reckons that only in West Africa the estimated worth of trafficked antimalarials alone is more than 400 millionAmerican dollars. At the same time the totalsale in falsified medicines may be worth as much as the billion-dollar oil and cocaine trafficking industries. Even more important is the fact that trade in counterfeit pharmaceuticals is organized by criminal cartels which run highly profitable and untaxed businesses. Such businesses become very rich and influential. Most of them are usually involved in financing of terrorist organizations, but also they are so powerful that are able to control authoritarian governments which create environment under weak rule of law. Thus, trade in counterfeit pharmaceuticals becomes a source of corruption, which is the final important negative socio-economic effect. (14)

INTERNATIONAL/MULTILATERAL REGULATIVE ON INTELLECTUAL PROPERTY RIGHTS IN THE PHARMACEUTICAL INDUSTRY

International/multilateral regulative on intellectual property rights is the fundamental instrument used in prevention of abuse of patents and licenses, as well as of combat with counterfeit goods, including counterfeit pharmaceutical products. Multilateral conventions on protection of industrial property and authors' rights enacted back in the second half of the 19th century have still been in force. Yet, the new global multilateral system enhanced the protection of intellectual property rights through the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO). These international organizations contribute to the harmonization of national laws and regulative withthe international and multilateral regulative on protection of intellectual property rights.

WIPO was established as a self-funded agency of the United Nations in 1967. Its establishment was enacted by adoption of a convention (a WIPO Convention), currently supportedby 193 member-states. WIPO is a global forum on intellectual property services, policy, information, and cooperation

which administers the following international conventions and treaties on protection of industrial property and copy rights: (15)

- The Paris Convention for the Protection of Industrial Property from 1883;
- The Berne Convention for the Protection of Literary and Artistic Works from 1886;
- The Madrid System for International Registration of Marks from 1989;
- The Trademark Law Treaty (TLT) adopted in 1994;
- The Nice Agreement, the Vienna Agreement, and the Nairobi Treaty, all of which regulate specific aspects of trademarks or specific symbols, but provide no provisions related to counterfeits or prevention of illicit practices;
- The Hague Agreement Concerning the International Registration of Industrial Designs adopted in 1925; and
- The WIPO Copyright Treaty (WCT) from 1996.

Looking at international conventions and copy rights administered by WIPO, it is obvious that the agency deals with legal instruments that are used as legal tools on protection of intellectual property rights. Yet, it lacks regulation on situations when it comes to an infringement of the protected rights.

The World Trade Organization (WTO) adopted the so-called Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is the most comprehensive multilateral legal document related to intellectual property rights up to date. The TRIPS Agreement covers: copyright and related rights; trademarks and service marks; geographical indications and origin appellations; industrial designs; patents; layout-designs of integrated circuits; and undisclosed information including trade secrets and test data. According to TRIPS,the innovator, by registering a patent, gains exclusivity for its usage and exploitation of benefits thereof, and has the right to prevent third parties to produce, to use, to offer for sales or to export patented products without his/her consent.(16)

Unlike the WIPO, TRIPScontains provisions referring explicitly to counterfeit products. In its preamble it acknowledges the negative impact of counterfeit products in international trade, and recognizes the need of a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods.(17) Each member-state of the WTO has an obligation to adopt measures on any act of infringement of

intellectual property rights, including remedies on infringement prevention, as well as remedies which can serve as deterrent to further infringements. Member-states must ensure enforcement and protection of intellectual property rights in civil, administrative, and even criminal procedures. They also must grant national courts power to order provisional or interim measures in situation of threats of imminent irreparable harm and authorize customs authorities to exercise border measures to sanction infringements.(18)Member-states are expected to cooperate with each other to eliminate international trade in goods infringing intellectual property rights. (19)

The TRIPS Agreement guarantees exclusivity of usage and exploitation, as well as of benefits of protected intellectual property rights. Regarding protection patents, this agreement provides three exemptions. Article 27 of TRIPS stipulates that exempted from patent protection are:(20)

- Inventions banned for commercial usage in order to protect ethics and public order which covers inventions that might endanger life and health of humans, animals and plants, or could jeopardize the leaving environment;
- Diagnostic, therapeutic and surgery treatment methods used for healing humans or animals;
- Production of plants and animals, except of microorganisms and biological procedures for plant and animal production, i.e., non-biological and microbiological procedures.

TRIPS also defines provisions on so-called compulsory licensing, when the government decides to use a patent without a consent of the patent owner which usually happens in the pharmaceutical industry, i.e. in production of medicines in specified untypical circumstances in the global economy. The provisions were brought under *The Declaration on TRIPS Agreement and Public Health* proposed at the Doha Ministerial Conference in 2001, amended at the Ministerial Conference in Cancun and enforced in 2017 when it was accepted by 2/3 of the WTO member-states.(21)The amendment perceives that pharmaceutical products produced under compulsory licensing should be offered for sales not only on domestic markets, but also for exports and sales abroad. It alsoaims to facilitate distribution of pharmaceutical products and drugs in the least developed countries and to support their health systems. Since, these provisions have been used only once in the case of Ruanda for importation of triavir from the Canadian Apotheks.(22) Evidence confirms that compulsory licensing is a time consuming and very expensive procedure, in which implementation costs

overcome the benefits thereof for developing countries. Therefore, this has been the one and only practical example of its implementation up to date.

DEFINITION OF FALSIFIED MEDICAL/PHARMACEUTICAL PRODUCTS

The World Health Organization (WHO) is one of the international organizations and agencies actively involved in the combat with falsified medical/pharmaceutical products. For this purpose, it has established a WHO Member State Mechanism as a global platform where member-states can convene, coordinate, decide and organize actions to address substandard and falsified medical products. Back in 2013 the WHO launched a Global Surveillance and Monitoring System aimed to provide countries a tool for reporting incidents of substandard and falsified medical products. (23)

To help member-states to properly report on incidents on substandard and falsified products, the WHO defines three categories of medical products subject to international trade exchange that should be paid special attention, i.e. *substandard, unregistered/unlicensed* and *falsified medical/pharmaceuticalproducts*. (24)

SUBSTANDARD	**UNREGISTERED/UNLICENSED**	**FALSIFIED**
Also called "out of the specification", these are all medical products that fail to meet either their quality standards, or their specifications or both.	Medical products that have not undergone evaluation and/or approval by the NRRA* for the market which they are marketed/distributed or used, subject to permitted condition under national or regional regulation and legislation.	Medical products that deliberately/fraudulently misrepresent their identity, composition, or source.

Figure 1: Classification of medical products used in the context of the World Health Organization Global Surveillance and Monitoring System and the Member States Mechanism (25)

WHO warns all member-states and final consumers that substandard and falsified medical/pharmaceutical products can be found among all main therapeutic categories such as medicines, vaccines and in vitro diagnostics, although the most reported substandard and falsified medical products happen to be anti-malarias and antibiotics. They contribute to antimicrobial resistance and drug resistance infections. Generic and innovative

medicines/pharmaceutical, regardless of their price, may be falsified and this applies both to very expensive products for cancer, as well as to inexpensive products such as pain killers.(26)

Falsified pharmaceuticals are usually produced in very poor and unhygienic conditions with usage of unqualified personnel. They may contain unknown impurities, and due to disrespect of good producing practices of the pharmaceutical industry, may be contaminated with bacteria. Such pharmaceutical products may contain no active ingredient or the wrong amount of the correct active ingredient. Usually they contain corn or potato starch or chalk instead.(27) However, they very often contain dangerous ingredients that may cause serious injuries, even deaths, as described in our literature review. (28)

Definition presented in Figure 1 states that falsified products are medical products that deliberately/fraudulently misrepresent their identity, composition, or source. Such products are often very difficult to be identified, as they appear to be identical to the genuine product, although they do not produce the same effect in disease treatment which in certain cases may lead to lethal outcome. Consumers in all countries in the world are at serious risk to be victimized by being involved in purchases of counterfeit medical/pharmaceutical products without even being aware of it. Yet, the WHO states that low- and middle-income countries, areas with conflicts and civil unrest, as well countries with weak health systems, happen to be at biggest risk in regard of counterfeit medical/pharmaceutical products. WHO recommends not only to pay attention to the correct look and color of the purchased medicine, but also to check its smell, its packaging, the present spelling mistakes and grammatical errors, the manufacturing and expiry dates, and whether data presented on the outer packaging match those in the inner packaging.(29)

Another international agency involved in combat of counterfeit medical/pharmaceutical products is the United Nations Office on Drugs and Crime (UNDOC). In May 2019, the UNDOC issued a Guide to Good Legislative Practice - Combating Falsified Medical Product – Related Crime. This is a very useful tool for all interested in general provisions and definitions of counterfeit medical products; recommendations on preventions for the supply chain of counterfeit medicalproducts, as well as a relevant data basis for research, exchange and analysis; classifications of offences in the area and definitions of liability of legal person; definition of prosecution

of offences; information on national and international cooperation; and protection of and assistance to witnesses and victims. (30)

TRADE IN COUNTERFEITPHARMACEUTICAL PRODUCTS

Recently the Organization for Economic Cooperation and Development (OECD) and the EU Intellectual Property Office (EUIPO)started to jointly prepare and publish series of analytical studies on global trends in tradein counterfeit and fake goods to provide solid empirical evidencefor policy makers. Their most important reports on this serious global threat are the following: Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact (2016); Mapping the real Routs of Trade in Fake Goods (2017); Trade in Counterfeit Goods and Free Trade Zones: Evidence from Recent Trends (2018); Why do Countries Export Fakes (2018); Misuse of Small Parcels for Trade in Counterfeit Goods (2018) and Trends in Trade in Counterfeit and Pirated Goods (2019). According to these sources, at the end of 2016, 3.3% of world trade and up to 6.8% of the EU import from third countries were trade in counterfeit and pirated goods. The latest report released in 2021 claims that in the period from 2017-2019 more than 50% of the detentions of counterfeit goods in the EU were related to on-line transactions, while over 90% of detention cases related to e-commerce were shipped to the EU by mail/post. (31)

In their joint reports, the OECD and EUIPO emphasize that this kind of trade seriously damages economic growth and jeopardizes benefits of internationally protected intellectual property rights, The problem of trade in counterfeit pharmaceutical products, however, is even greater having on mind that it is a direct threat to human health and life, as well as to consumers' safety.They also provide proves how trade in counterfeit pharmaceutical products undermines the good governance, the rule of law and citizen's trust in government, and may ultimately threaten political stability. (32) Therefore, OECD and EUIPO pay special attention to collection of data on trade in counterfeit pharmaceuticals and published a special report entitled: Trade in Counterfeit Pharmaceutical Products (2019). Data used in this report were collected from customs administrations, the World Customs Organization, the European Commission, and the United States DHS. They were also extracted from enforcement actions carried out not only by customs authorities, but also by the police, the health inspection services, the enforcement agencies, etc. Additional data were obtained from

cases of fraudulent manufacturing, mislabeling of drugs and fraudulent packaging all over the world.(33)

According to this report, in 2016 the total amount of counterfeit pharmaceutical products reached 4.4 billion American dollars, thus becoming the 10th most traded counterfeit type of products in the world. It is believed that such intensity of counterfeit trade in pharmaceuticals results from the high innovativeness and use of intellectual property within the pharmaceutical industry, on the one hand, and by the strong, often inelastic demand from patients and consumers, on the other hand.(34)In the period from 2014-2016 among the most traded counterfeit pharmaceutical products were medicaments for malaria, HIV/AIDS and cancer, while antibiotics, lifestyle drugs and pain killers were among the most targeted products by counterfeiters. The main source of counterfeit pharmaceuticals was recorded to be India, with almost 33% of global trade, followed immediately by China and Hong Kong (China) with about 26% of total globaltrade in these goods. Singapore participated with almost 20%, Germany with about 7%, Switzerland with 5%, and Australia with about 3% in the total globaltrade in counterfeit pharmaceuticals. Nevertheless, India, China and Hong Kong were the absolute leaders with almost 90% of the total seized value of counterfeit pharmaceuticals worldwide. (35)

Table 1: Top ten countries by number of arrested individuals engaged in counterfeit pharmaceuticals manufacturing in 2018

Country	**Number of arrests**
China	233
Spain	52
USA	48
India	38
Pakistan	10
Indonesia	10
Canada	7
Colombia	6
Egypt	1

Source: OECD & EUIPO, Trade in counterfeit pharmaceutical products, OECD & EUIPO, Geneva, p. 11, 2019

Data in Table 1 confirm that the majority cases of arrested individuals because of smuggling in counterfeit pharmaceuticals were registered in Asia

and Eurasia. At the same time, companies that originate from the USA and the OECD countries, such as Germany, Switzerland, and France, aresuffering greatest losses of sales and profits, as well as losses of protected brands and damaged reputation. Criminal activities in this area victimize individuals who use counterfeit pharmaceuticals and threaten their health and life, but they also represent a threat to the environment security, economic prosperity, jobs, foreign investment, as well as governments and entire economies. (36)

Until 2013 the main transport mode for counterfeit medicines and pharmaceuticals was the sea transport. Since, it has been replaced by road transport. However, in 2016 a new trend in counterfeit trade in pharmaceuticals emerged, created by a significant increment of using mail and postal services. The usage of small parcels expedited by express and postal services became extremely popular because of the rice of e-commerce. Criminals started to misrepresent products and to hide their identity, selling counterfeit pharmaceuticals through the dark web and the freely accessible surface web. (37)

The outburst of the COVID-19 pandemic increased the pressure and created new challenges for authorities to deal with the rising number of smuggled medicines and pharmaceuticals (as well as with COVID-19 vaccines) through dark web channels and small parcels post expeditions. The Europol led and coordinated a global effort to target trafficking of counterfeit and misused medicines and doping substances under the so-called Shield II Operation. The operation took place in the period from the 1st of April until the 15th of October 2021 and was treated as a project on intellectual property rights protectionco-funded by the EUIPO. Besides the French Gendarmerie, the Finish Customs, the Hellenic Police/ Financial Police Division, and the Italian Carabinieri Corps, the operation was supported by law enforcement authorities from 20 EU member-states and 7 third-party countries, the European Anti-Fraud Office – OLAF and the World Anti-Doping Agency. The operation enabled seizure of more than 25 million units of medicines and doping substances of worth of nearly 63 million euros.Shield II Operation helped to shut down 283 websites, while 1,029 have still been monitored. Also,544 individuals were arrested from a total of 634 individuals reported to the authorities. In Shield II Operation, as authorities from third-party countries,the law enforcement authorities from Macedoniaparticipated as well. (38)

CONCLUSION

For over a century and a half economic literature elaborates the harmful effects of misuse of intellectual property and trade in counterfeit goods upon new investments, creation of new jobs and economic growth. Yet, the introduction of new internet technologiesglobally opened the door for rather new,harmful ways of smuggling and increased criminal activities through on-line trade in counterfeit goods. These new, untraditional smuggling practices draw the attention of researchers and specialized institutions who try to create good quality data base necessary for government bodies and authorities to create policies and adequate measures in the combat with counterfeiters and smugglers.

The new global trends affect medical/pharmaceutical products as well. Trade in counterfeit pharmaceuticals, besides the well-known effects of misuse of intellectual property, have additional, extremely harmful effects, as they may cause serious health and life damage, thus threatening security of patients and consumers. The harmful effects of counterfeit pharmaceuticals might lead to mistrust in government and political unrest. Therefore, a number of international organizations put additional effort in this area for full implementation of international regulation on intellectual property protection and its transposition in national laws. The World Health Organization (WHO) specifies that not only falsified, butsubstandard and unregistered/unlicensed medical/pharmaceutical products are equally harmful. WHO provides precise definition of each of these categories of products for policy creators as a basis for combat with those involved in their trafficking. In 2019 the Organization for Economic Cooperation and Development (OECD) and the EU Intellectual Property Office (EUIPO) jointly prepared and publishedan analytical study on global trends in trade in counterfeit pharmaceuticals, thus providing solid empirical evidence on this serious issue. Last spring, Europol organized and led an international operation on combat with trade in counterfeit pharmaceuticals together with law enforcement authorities from 20 EU member-states and 7 third-party countries, the European Anti-Fraud Office – OLAF and the World Anti-Doping Agency.

The task of effective and efficient combat with counterfeit trade in pharmaceuticals is rather complex and difficult, having on mind the

increment of on-line trade, creation and usage of different deep webs for ordering pharmaceutical products, as well as diversion of trade flows of counterfeit pharmaceuticals from the usual ways of transportation to expediting small parcels through post/mail ordered through them. Police forensics points out to the challenges of discovering and controlling deep-web users as they constantly change domains. At the same time, most of the small parcels sent by post/mail are "invisible" for customs and other relevant authorities.

Nevertheless, there is an essential need to increase all efforts in combat of counterfeit trade of pharmaceuticals in order to protect not only the owners of intellectual property, but also consumers and citizens who might be misled, abused and by usage of such products be threaten with their health and life.

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