

The SARS-COV-2 pandemic and the challenges of intellectual property rights

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SUMMARY

The COVID-19 virus pandemic had a drastic impact on the social lives of billions of people, hitting certain industries like a hurricane. What the answer will be to this and possible other occurrences of pandemics in the future will largely depend on the inventiveness of the researchers. Intellectual property is the first system to offer answers, opening patent bases to anyone developing new technologies to fight the COVID-19 pandemic. The need for the means of prevention, treatment, and care has caused thousands of different researches, which find inspiration and guidance for discovering new solutions in patents that already exist. Publication of scientific papers has never been so intense in any scientific field as in medicine since the fight against this virus began. The time since the beginning of the virus pandemic has shown that science and innovators are ready for such challenges, but the global health crisis has imposed a new challenge on the intellectual property system, which refers to the strict implementation of its rights at times when rapid and global effect is needed in order to avoid additional deterioration due to further circulation of the virus among the population, which inevitably leads to the emergence of new strains of the virus.

Keywords: pandemic; COVID-19; intellectual property; authorship; patents

INTRODUCTION

In the beginning of January 2020, the world started facing the biggest pandemic in the last 100 years. From the beginning of the SARS-CoV2 pandemic, the world has seen an unprecedented healthcare crisis.

From the moment when the patient zero believed to be an asymptomatic carrier was infected in the beginning of January in Wuhan, China, the impact of the outbreak of newly-identified coronavirus (COVID-19 virus SARS-COV-2) on the global population is unbelievable, and its consequences are being felt in all the industries [1, 2]. The world has faced an unprecedented crisis and medicine has been challenged with the task of helping all the sick and disadvantaged [3]. The virus, named by the World Health Organization as 2019-nCoV, has temporarily changed the manner of doing business, as well as the shape of global economy [4]. The coronavirus disease 2019 (COVID-19) pandemic has affected all aspects of public health, especially treatment processes that have never changed so quickly [5]. The objective of this paper is to point out the importance of research work through the prism of patents and copyrights in the fight against pandemic virus outbreaks.

COVID-19 PANDEMIC – AN ACCELERATOR OF INTELLECTUAL PROPERTY RIGHTS

Scientific work as a form of authorship holds great significance in such situations. Upon

facing some new form of an illness that was inexistent until the given time, doctors, virologists, immunologists and other professions started closely following scientific journals, in waiting of new scientific works that would confirm or negate the existing stances and lead them towards finding a manner for treating the infected. The COVID-19 pandemic confirmed this. More than 500 scientific works were published world-wide during the first three months of the COVID-19 pandemic (Figure 1).

Thanks to the scientific work titled “Genomic characterization and epidemiology of 2019 novel coronavirus: implications for virus origins and receptor binding,” published in the Lancet scientific journal, and which provided the characterization of the SARS-CoV-2 genome, the global effort for developing a vaccine for the prevention of COVID-19 has been greatly facilitated [6].

The significance of scientific work is also visible from the aspect of panic suppression, given that panic is being spread as a consequence of false or partly true information. According to data provided by the Sprinkle analytics platform as early as March 11, 2020, coronavirus had been mentioned on the Internet more than 19 million times. Such enormous interest is fertile ground for spreading different conspiracy theories, misinformation, and suspicious health recommendations [7].

The speed of publishing scientific work in such situations is very significant, but speed brings along mistakes. The results of laboratory and clinical trials are immediately published in

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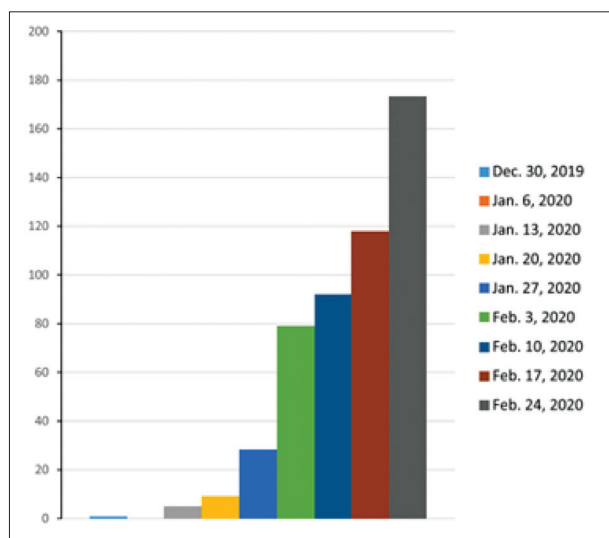


Figure 1. The number of scientific works referring to COVID-19 published over time (weeks) [7]

numerous scientific journals, so that their outcomes can be applied in clinical application as soon as possible [8]. As a response to the needs of the scientific community, many journals have sped up their publishing procedures, especially the ones dealing with COVID-19. Even though this is not the first time that an epidemic led to an increase in publishing authorship works, the change in practice and the lack of implementation of standards, have led towards the publication of papers that were not founded on valid clinical research [9]. In order to prevent a negative impact of false research results, certain journals, such as Royal Society Open Science, conducted study reviews before collecting data, with a special focus on methods and the analysis plan. In such a way, the authors were given an acceptance “in principle” – if they followed the previously determined research plan, their study would be accepted for publishing, no matter the results [10].

INTERFUNCTIONAL DEPENDENCE OF PATENTS AND MEDICINE

Coronaviruses were discovered in 1967, but only with the emergence of the new coronavirus SARS CoV in 2002 the new chapter in virology was opened, and the up-until-then “marginal” coronaviruses became a current topic worldwide. The SARS epidemic (which carries the same gene) also started in China and then spread to some 30 other countries, counting 8098 infected and 774 deceased individuals, and stirred up great interest world-wide, thus causing a need for the development of new diagnostic tests, vaccines, and anti-virus agents [11]. This resulted in current existence of dozens of different patents for diagnosing and treating coronavirus. A relatively small amount of infected has significantly impacted the fates of patents related to this virus. Inventing medicines, vaccines, and other pharmaceutical preparations demands vast material investments that are, for the time being, not cost-effective. Among registered patents related to the SARS virus, about 80% of them refer

to therapy development, 35% relate to vaccines, while 28% relate to diagnostic means and methods [12].

Given that intellectual property results from innovations based on the previously existing knowledge, a great number of inventions is actually the result of creatural improvements of previous work, or the result of new creative expressions of old ideas and constructs [13]. Due to this, the availability of information of the already existing solutions, the level of development of science and technique is of fundamental significance for researchers. In order to speed up the race and find the treatment modes and efficient therapeutic means and vaccines as soon as possible, the World Intellectual Property Organization (WIPO), within its already existing online platform PATENTSCOPE, set up a new functional search engine for examining information that could be of use to inventors. Given that this database includes 83 million patent documents, in order to facilitate easier overview of data to the interested innovators regarding the PATENTSCOPE WIPO COVID-19, the patents are grouped in accordance with the technical fields significant for detection, prevention and treatment of COVID-10 [14]. Patent lists are “a rich source of technological knowledge acquired by people throughout the centuries,” and thus they must be made available to the interested public. By providing an insight in information on the previously existing technologies, the innovators might be inspired towards a further development of the already existing technologies in order to ease the suffering of thousands of patients, bend the death curves, and improve the quality of life for the non-infected individuals.

For faster and easier search of the patent database, the Strasbourg Accord introduced in 1971 the International Patent Classification, according to which patent applications and patents are being classified in accordance with their technical characteristics. Such classification determined eight technical fields (that are further divided into subclasses, groups, and subgroups) [15].

In order to enable easier and more functional search, the WIPO, through the PATENTSCOPE base, offered the inventors who work on easing the consequence of COVID-19 an opportunity to conduct research according to the following criteria: CPR; diagnostics; disinfection; computer science; medical equipment; medical facilities and transport; medical treatment / prophylactics; medical treatment / therapeutic; and personal protective gear. It is intended not only for inventors, but for the wider public as well, from creators of public policies to engineers, in order to find the resources necessary for easing the symptoms, prevention of the disease, and treatment of individuals infected with this virus, through mutual efforts and previously existing solutions.

The invention of a vaccine against COVID-19 is still seen by a majority of the community (with an active protest of one of its parts) as a public social interest, but it also has a huge potential within the economic interest. Global loss caused by the pandemic is measured in hundreds of billions, and the money that a vaccine could bring to pharmaceutical companies represents an enormous profit

and prestige. In the global race for the development of a vaccine, there are currently more than 90 vaccines against COVID-19 in different phases of testing.

The right to health is a fundamental human right; however it is often threatened by the high cost of treatment, cure, and prevention. The new medicines are the result of many years of clinical trials that require extremely high investments. From initial *in vitro* laboratory research, with sometimes *in silico* molecular modeling, through drug development with various phases of clinical trials, to approval by regulatory bodies, pharmaceutical companies invest huge funds, which condition the price of drugs [16]. Due to the high prices of medicines, especially when speaking of populations of the developing countries, the issue of generic medicine and compulsory licenses is often raised [17]. Legal protection by a patent implies a relation in which the protected innovation might be used, produced, sold or in any other form put on the market, with the approval of the carrier of the patent rights [12].

With regard to pandemic occurrences, the medicines used for treating or easing the impact of the virus must be on the list of fundamental medicines, whose availability and accessibility must be ensured for everyone. One study shows that, even though a patent lasts 20 years, an effective patent protection of pharmaceutical products in the European Union lasts only eight years, and the gamut of pharmaceutical preparations used in prevention and cure of SARS and MERS showed to be, on the off-chance of the humanity, unprofitable for the pharmaceutical industry, due to the small number of infected persons [18].

A justified question arises: if the progress in all fields, from culture to technology, is based on creations and innovations whose inventiveness is awarded by implementation of monopoly rights over a patent (patent protection), does this reduce the incentive for further improvement of the previously existing creations? It is hard to find the balance. Due to the crisis caused by AIDS and HIV virus, the Government of the Republic of South Africa passed a law that determined a reduction of prices of medicines used for the treatment of this illness in order to make them more accessible. Even though this action caused dissatisfaction among pharmaceutical companies and legal procedures, such restrictions in cases of pandemics seem like an adequate compromising solution [19].

A pandemic, unfortunately, causes a feeling of panic among numerous people when, due to a reduced ratio, numerous consumers become more prone to procuring counterfeit medicine. In accordance with the Law on Medicine and Medical Needs [Official Gazette of the RS, no. 30/2010, 107/2012, 113/2017 – State Law and 105/2017 – State Law], a counterfeit medicine is a medicine produced and/or placed on the market with an intent of deceiving the individuals that consume it, characterized by fake identification information (about the producer, place of production, etc.), or containing right or wrong contents in comparison to the declared content and/or does not contain or contains insufficient amounts of the active substance in question. In the times of the flu pandemic caused by the A (H1N1) virus, also known as the swine

flu, the Internet was crowded with offers such as, “antivirus herbal product for the flu; natural prevention of swine/bird flu,” “strong natural direction in the fight against swine flu and other viruses,” etc., and numerous seizures of counterfeit medicine Tamiflu were conducted in the USA and in Europe (in the Netherlands and the UK) [20]. Deceiving sick people, as well as harmful consequences that counterfeit medicines can have on the health of individuals that consume it as a preventive measure, have unforeseeable consequences.

Even though vaccines and respirators are currently in the center of interest not only of scientific communities, but also the wider public, given that there is not a clearly determined model that would calculate the exact time of the end of this pandemic, numerous mathematicians are giving their contribution by attempting to find new models upon which it would be possible to foresee the end of the pandemic, as well as a possible new wave. Some have turned to the Gauss curve, while others search for the fundamentals in other theories.

In addition to pharmaceutical workers and mathematicians, thousands of new inventors give their contribution to the global fight against COVID-19 through innovations that refer to the means of personal protection, diagnostics, medical equipment and its transportation, respirators and medical preparations, bioinformatics and information technology in medicine.

ECONOMIC CONSEQUENCES OF PATENT REGISTRATION AND THEIR IMPACT ON HUMAN HEALTH IN A PANDEMIC

The pandemic has reduced economic activity in many economic sectors, reducing the incomes of citizens and the economy. As a response, many countries have provided financial assistance to citizens and the economy by increasing the public debt. In such a situation, the health sector is particularly burdened in less developed countries that find it difficult to meet the health needs of their citizens. The system of intellectual property that provides exclusive monopoly rights to patent holders further increases the cost of health care, which in extreme situations, such as a pandemic, raises the justified question of international exhaustion of patent rights [21].

Immunization in a number of developed countries progresses well, but there is great uncertainty about how developing countries and especially underdeveloped countries will overcome economic difficulties, not only in terms of vaccination, but also the necessary diagnostic testing, personal protective equipment, necessary logistics systems for vaccination and reporting on adverse events after vaccination. The development of medical and pharmaceutical inventions is also characterized by the fact that their development requires more time and money. Therefore, the monopoly right to an invention obtained through patent protection is especially important for this industry, in order to financially encourage further research. However, in situations such as a pandemic, the issue of social benefit

takes on another dimension, the social interest in advancing medicine and pharmacy is suppressed by ethical challenges. Intellectual property rights are limited temporally (20 years) and geographically. In order for vaccines to be available in a timely fashion in all countries, due to the huge demand, this can only be achieved by assigning rights to registered patents through licensing [22]. Although many important facts are still unknown regarding this virus (transmission, period of incubation, full clinical presentation, radiography, laboratory findings, immune response and specific treatment), the SARS-CoV-2 genome is fully sequenced and it is a cause for concern that the longer the virus circulates among the population, the number of mutations will increase and new pathogen variants will appear [23, 24]. That is why it is important to achieve global immunization as soon as possible.

Although some authors believe that Article 31 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) can be interpreted as enabling the production of affordable vital pharmaceutical products in situations of global health crisis without violating the international intellectual property rights regime, India and South Africa, together with 57 member countries of the World Trade Organization, have launched an initiative to exempt certain provisions of TRIPS, due to the need for a temporary global waiver of patent protection for COVID-19 vaccines [25, 26]. This would enable the production of cheap generic vaccines, which would help enable more efficient vaccination of the population in poor countries. Local production of medicines is a far more affordable variant, because the prices of facilities used for their production are significantly lower with lower wages of workers, thus enabling a price that is acceptable for the markets of underdeveloped countries.

The alternative is the instrument of compulsory license issued in cases when the patent right holder refuses to assign to other persons the right of economic exploitation of the protected invention or imposes unjustified conditions

for such an assignment. In such cases, a legislation such as ours stipulates that the state administration body responsible for affairs in the field in which the invention is to be applied may, at the request of the interested person, issue a compulsory license. The scope and duration of the compulsory license is limited by the purpose for which it was granted, and the holder of the compulsory license is obliged to pay the right holder a fee determined by both parties or determined by the competent court (in cases when no agreement on the amount and manner of payment was made).

CONCLUSION

COVID-19 has caused numerous changes in a very short period of time. Whether they are permanent or simply one-time changes will depend on numerous factors, but their effect has, without a doubt, a destructive impact on numerous economic branches and the society. Wishing to reach the solution for easing the consequences of the virus, researchers have sped up their studies by publishing a colossal amount of data, which led to certain wrong interpretations and explications. The activity of inventors who attempt to devise as efficient prevention, treatment and combat measures as possible, is extremely live. In order to provide researchers with access to already existing solutions and knowledge, access to many patent bases is eased. Whether the resulting changes are emergent will, to the greatest extent, depend on the virus itself, the length of its lifespan, its possible mutations, and the speed the science will need to combat it. The next step in that fight is the fair management of the system of intellectual property rights, especially in the part of assigning patent rights to states whose inhabitants are not able to pay for expensive medicines.

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Пандемија САРС-КОВ-2 и изазови права интелектуалне својине

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САЖЕТАК

Пандемија вируса корона драстично је утицала на друштвени живот милијарди људи, погађајући ураганском јачином поједине индустрије. Који ће одговор бити на ову и могуће друге појаве пандемија у будућности у великој мери ће зависити од инвентивности истраживача. Интелектуална својина је први систем који је понудио одговоре, отварајући патентне базе свима који развијају нове технологије за борбу против пандемије ковида 19. Потреба за средствима превенције, третманима и лечењем узроковала је на хиљаде истраживања која у већ постојећим патентима налазе инспирацију и пут ка новим решењима. Објављивање научних радова ни у једној научној области никада није било

тако интензивно као што је у медицини од када је почела борба против овог вируса. Време од почетка пандемије вируса показало је да су наука и иноватори спремни за такве изазове, али глобална здравствена криза је пред систем интелектуалне својине наметнула нови изазов, који се односи на стриктно спровођење њених права у тренутку када је неопходан брз и глобалан ефекат, како не би дошло до даљих погоршања услед даљег циркулисања вируса међу становништвом, што неизоставно доводи до појаве нових сојева вируса.

Кључне речи: пандемија; ковид 19; интелектуална својина; ауторска права; патенти