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Government-Use License and Stem Cell-Based Pharmaceuticals Patent: Equitable Access to Covid-19 Medications

Licencia de uso gubernamental y patente de productos farmacéuticos basados en células madre: Acceso equitativo a los medicamentos Covid-19

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RESUMEN

En respuesta al brote de la pandemia Covid-19, algunas compañías farmacéuticas han patentado sus medicamentos para combatirlo, incluidos aquellos basados en células madre. Probablemente se plantearán preguntas sobre cómo acceder a dichos medicamentos porque la protección de la patente otorga un derecho exclusivo al titular de la misma, para evitar que otra persona pueda beneficiarse con un aumento de precio a gran escala. Luego, el documento revisará la regulación y la práctica del uso gubernamental en Indonesia y la posibilidad de dicho mecanismo para acceder a los medicamentos Covid-19.

Palabras clave: Covid-19, Indonesia, medicamentos, patente, uso gubernamental.

ABSTRACT

In response to the outbreak of the Covid-19 pandemic, some pharmaceutical companies have patented their drugs to combat it, including those based on stem cells. Questions about how to access such drugs will likely be raised because patent protection grants an exclusive right to the patent owner, to prevent someone else from benefiting from a large-scale price increase. The document will then review the regulation and practice of government use in Indonesia and the possibility of such a mechanism to access Covid-19 drugs.

Keywords: Covid-19, Indonesia, drugs, patent, government use.

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INTRODUCTION

Covid-19 is the name given by the World Health Organization (WHO) to the SARS-CoV-2 virus-associated disease (Golchin et al.: 2020, pp. 1-7). Covid-19 has emerged as the most deadly pandemic around the world since the new coronavirus strain firstly reported in Wuhan, China. This new coronavirus had elicited a pandemic of respiratory ailment since December 2019 and has now disseminated to multiple countries in the world, including in Indonesia after the first case reported on March 2, 2020, when two residents of West Java tested positive for the virus. The Covid-19 has plunged most countries, including Indonesia, into a global pandemic and the virus continues to cause massive disruptions in all facets of societies around the world. The World Health Organization has proclaimed this epidemic as a global public health emergency (BBC News: 2020).

Most countries have taken measures to slow down the spread of Covid-19 through lockdown, confinement and other social distancing measures. Even with painstaking global restraint and lock-down efforts, the prevalence of Covid-19 still continues to climb, with an increasing number of new cases and significant mortality worldwide. The virus has infected over 5,704,736 people globally and killed over 357.736 (WHO: 2020). In Indonesia, more than 25.216 cases have been confirmed as positive for Covid-19 with the number of fatalities is over 1.520, while the number of patients who have recovered is 6.492 (the Jakarta Post: 2020; AHK Indonesian: 2020). However, the actual number of Covid-19 deaths in Indonesia may be substantially higher than officially reported as several regions have recorded hundreds of fatalities among patients under surveillance.

Since the current measures are to slow the spread of the virus only, some believe that the effective way to actually prevent people from catching Covid-19 is with a vaccine, drugs, antiviral, or any effective medications. The battle against Covid-19 is not won until successful medications can be tested, manufactured, and distributed to the population at large around the globe.

However, it has become a big challenge to find an effective medications solution for this dangerous disease since scientists are still developing medications to treat its symptoms of Covid-19 as viral infection known to have the fastest frequency of recombination or replication. Although according to the World Health Organization (WHO) that there are more than 120 vaccines being developed worldwide and undergoing clinical trials, still no proven vaccines or antiviral drugs to treat Covid-19 and most patients only receive palliative care. Scientists around the world are still working on experimental treatments for Covid-19 and to combat Covid-19 virus with the concerted effort to rapidly innovate new diagnostic tools, treatments, medicines and vaccines for the virus.

Covid-19 has introduced a new global race to own patent rights to Covid-19 medications which countries were competing to be the first to find medications to this deadly pandemic and to ensure that their citizens will have access to any medications once available. This includes developing a vaccine to stop people from falling ill in the first place, testing kits and drugs to treat that infected Covid-19.

Most countries and big pharmaceutical companies are racing to respond as quickly as possible to stop the virus from spreading and save lives by innovating new medical products and technologies, including devices, save lives, reduce suffering and improve health in good quality, safe, effective, available, affordable, acceptable and properly used for Covid-19 response. Although there is currently no vaccine or drugs for Covid-19, several pharmaceutical companies in Europe, the United States, and China believe they are close to producing successful drugs for Covid-19.

The Covid-19 pandemic deserves consideration of all medications and experimental treatment choices. Severe respiratory consequences of the Covid-19 pandemic have prompted an urgent need for new and effective medications or therapies. The therapeutic options against this virus are under clinical evaluation such as antiviral drugs, steroids, traditional medicine, or serum from healed patients. The therapist believes stem cells could have been an alternative solution too and turned out to be a viable option for Covid-19. Although

the medication using stem cell is quite extraordinary and need a larger clinical trial for result validation, it may offer a promising improvement for treating Covid-19 patients by reducing the death rate from infections.

Once a Covid-19 stem cell-based drugs or medication have been approved and patented, a further set of challenges will present itself. The main challenge relates to production and supply since as soon as Covid-19 vaccine, or stem cell-based medication is approved, it's going to be needed in immense quantities and many of the companies in the Covid-19 drugs or vaccine do not likely have the necessary production capacity to meet the mass supply demand. Due to so few candidates in the pharmaceutical stem cell-based drugs or vaccine development and production facilities tend to be tailored to specific vaccines or drugs, the supply will be under threat, and the demand outweighs the production.

In addition, since patent gives to the patent holders an exclusivity period during which it may choose who, when, where, and how that invention is made, used, or sold, the patent holder can decide how medications are approved for use within their borders only, or to whom and when they may be exported internationally. Given the rate at which Covid-19 is spreading globally, it is likely the global demand for Covid-19 medication will exceed any supply. A similar situation happened when Australia became the first nation to develop a successful Swine Flu vaccine in 2009, the global demand for the vaccine exceeded Australia's ability to produce it, and Australia's government ordered that Australian citizens receive priority in obtaining the vaccine before any could be exported abroad (the National Law Review: 2020). The problem is making sure the vaccine gets to all those who need it. This is a challenge even within countries, and some have worked out guidelines. There will be a limited supply when a vaccine is successfully developed, at least initially. The healthcare workers who come into contact with Covid-19 patients would be prioritized to get the vaccine first, followed by the elderly people since the disease is most deadly in the older group. In the pandemic scenario, some countries would prioritize vaccinating healthcare and social care workers, along with those considered at highest medical risk with the overall goal of keeping sickness and death rates as low as possible.

In a pandemic period, countries also have to compete with each other for medications. Due to pandemic tends to hit hardest those countries that have the most fragile and underfunded healthcare systems, there is an inherent imbalance between need and purchasing power when it comes to medications. During the 2009 Swine Flu pandemic, for example, vaccine supplies were snapped up by nations that could afford them, leaving poorer ones short. The same problem will also apply to any potential Covid-19 medications.

Along with problem on availability and supply, the access to the Covid-19 medications will present as another handicap. Some countries make a promise to assure that drugs, vaccines, or technologies for combating Covid-19 will be broadly licensed and will be available across the globe to ensure access for vulnerable populations. However, the access to prospective Covid-19 medication seems vulnerable when knowing the response of China and the United States to Covid-19 which show a strong nationalist sentiment that access to the drugs or vaccine could be used as political leverage against the others (the National Law Review: 2020).

In addition, with the exclusive right, the patent may allow the holder to be dominant in the market, and they may abuse its dominant position by refusing to issue a voluntary license to manufacture the Covid-19 medications and may set excessive prices of essential medicines out of the reach of most people who need them. The excessive prices of the drug show disproportionate to the economic value of the goods even when taking into account the cost of production, research and development (R&D) costs and an appropriate rate of profit.

Patent abuse such as excessive pricing or refusals to license based on a dominant position in the market or where a finding anticompetitive behaviour of the patent holder may undermine to availability and access to Covid-19 medications. This situation calls the need for the government-use license as one of the important remedies to ensure availability and access to Covid-19 medication. Government patent use will reduce excessive prices for essential patented medicines and will permit the government to procure generic versions of patented drugs in reasonable exchange compensation the patent holders. Generic version for patented drugs is necessary for the outbreak of pandemic since such generic drugs are a proven and reliable method

to realize lower prescription drug prices. On average, drugs with three generic manufacturers are priced at 60% of the brand name level, and five manufacturers are priced at less than half the brand price, and that prices of drugs with ten or more manufacturers are only about one-fifth of brand prices (Dave et al.: 2017).

In the pandemic situation, it is essential to ensure access to Covid-19 medications, including stem cell therapy or stem-cell-based medicines that could potentially treat Covid-19 symptoms in patients most in need of medical aid. The public health emergency permits the Indonesian government to use patented inventions on Covid-19 treatment and make regulations to address shortages of such medications.

As Indonesia has experienced to issue government-use previously to improve access to essential medicines particularly antiviral and retroviral drugs, the paper argues that government should take the same strategy by invoking the provision of government-use license in case Covid-19 pandemic, where there are significant social gains to be achieved to procure drugs or medications at the generic price. This approach will also allow the government to import drugs at the marginal cost of production, therein maximizing social benefit. To make this mechanism work to support innovation policy, the government must pay patent holders compensation adequate to protect R&D incentives. With the scheme, the social gains in the practice of government-use will likely far exceed the possible losses.

METHODS

This paper is legal research aimed at analyzing for medicines. To achieve the goal, this paper uses both the primary legal materials (all applicable legislation), and the secondary legal sources which are in the form of literature and related materials. The method of this research includes conceptual, and statute approaches in order to affirm the conclusion that to address public health on access to medications, Indonesia can override patents for public health purposes by issuing government-use that enable the generic manufacture of Covid-19 medication. The research recommends that government-use license will be a workable method to ensure access to essential Covid-19 medications for Indonesia because Indonesia has previously carried out this scheme for Hepatitis and HIV/AIDS antiretroviral drugs.

RESULTS

Stemcell medication for Covid-19

The Covid-19 pandemic, which is rapidly and continuously spreading globally, is a severe acute respiratory illness caused by a new coronavirus named severe acute respiratory syndrome coronavirus two called SARS-CoV-2. This virus can mostly result in serious significant respiratory morbidity and mortality called Acute Respiratory Distress Syndrome, although in some cases, Covid-19 patients are afflicted with not only Acute Respiratory Distress Syndrome but also other complications such as myocardial injury, arrhythmia, acute kidney injury, shock, and death from multiple organ dysfunction syndromes. Mortality in COVID-19-infected patients with the inflammatory lung condition is reported to approach 50% and is associated with older age, co-morbidities such as diabetes, higher disease severity, and elevated markers of inflammation (Sami: 2020).

Treating Covid-19 patients, particularly those afflicted with severe ARDS or lung inflammation (pneumonia), is challenging as no specific drugs or vaccines against Covid-19 are currently available. According to the International Society for Stem Cell Research (ISSCR), recently, there are no proven vaccines or antiviral drugs for the effective prevention and treatment of Covid-19 infection (Golchin et al.: 2020, pp. 1-7) and palliative care is the most current treatment for patients. This global respiratory infection has prompted an urgent need for novel therapies; therefore, identifying a safe and effective treatment for severely affected Covid-19 patients is critical for saving lives. Several experimental treatments against the virus are under

clinical evaluation such as antiviral drugs, steroids, traditional Chinese medicine, serum from healed patients, etc. Recently, some doctors have tried stem cells therapy approach for their patients and persist that stem cell has been a valuable solution too and has turned out to be a viable option for Covid-19 medication. Stem cells are defined as unspecialized cells with self-renewal and differentiation potentials that have the abilities to maintain stemness or differentiate into more specialized cells.

Since most Covid-19 patients commonly characterized by fever (82%), cough (81%), severe pneumonia and acute respiratory distress syndrome, stem cell-based approaches have demonstrated safety and possible efficacy in patients with the acute respiratory distress syndrome. It is known that stem cells rejuvenate and regenerate cells in the body through various processes involving reduction of inflammation, secretion of substances that protect cells, transfer of mitochondria, reduction of cell death, anti-oxidative effects and improvement of immune system function. These effects are likely to increase survival in patients infected with Coronavirus.

Stem cells combat viral attack by the expression of specific genes known as interferon-gamma stimulated genes which are expressed in stem cells before their differentiation (Wu et al.: 2018, 423-438). Stem cells are expected to survive when transplanted into a patient with a confirmed Covid-19 infection because the therapy, particularly using Mesenchymal Stromal Cells, oppose viral infection due to the presence of specific cytokines improved qualities in the intrinsic niche before their separation process happens. There is direct evidence of stem cell protection against viral infection such as in the case of H5N1 coronavirus, the acute lung injury effect was reduced by stem cell treatment using Mesenchymal Stromal Cells, and the treatment increased survival. The researchers explain that, once MSC is injected into the blood, these cells can travel to the lungs and secrete growth factor and other cytokines—anti-inflammatory substances that modulate the immune system, so it does not go into overdrive (Nordrum: 2020).

With Covid-19, complications arise when the virus' spike protein binds to receptors (especially present in the lugs) on the surface of a healthy cell and when the cells fuse, the virus infects the healthy cell, followed by an aggressive immune response that, in turn, causes, irreparable cellular damage. Stem cell therapy which involves one of the methods of the injection of such Mesenchymal Stromal Cells is capable of modulating and normalizing the function of a body's immune system.

While many approaches are being investigated, Mesenchymal Stromal Cells are showing intriguing potential for Covid-19 treatment since Mesenchymal Stromal Cells may help counteract a cytokine storm, an uncontrolled rise of the immune response resulting in the increase of inflammation mediators (Shetty: 2020, pp. 462-464). During a cytokine storm, the immune system goes into overdrive, and the patient's tissues and organs can be fatally damaged with Acute respiratory distress syndrome is a common sign (Bioscience Institute: 2020). In Covid-19 patients, it corresponds to the severe oxygen deprivation that requires mechanical ventilation. The secretions from Mesenchymal Stromal Cells to be effective at treating inflammation, cytokine storms and potentially exert beneficial effects by improving the lung microenvironment, inhibiting immune system over-activation, promoting tissue repair, protecting lung alveoli epithelial cells, preventing pulmonary fibrosis, or improving lung function.

To treat Covid-19 patients who particularly afflicted with severe pneumonia, Stem cell therapy using Mesenchymal Stromal Cells offers a promising approach towards mitigating delirious effects of infection. The therapy may reduce the expression of pro-inflammatory cytokines and promoting endogenous repair of damaged tissues. Stem cell therapy using intravenous infusion of Mesenchymal Stromal Cells could reduce the over activation of the immune system and support repair by modulating the lung microenvironment after Covid-19 infection even in elderly patients (Shetty et al.: 2019, pp. 470-482). The intravenous infusion of Mesenchymal Stromal Cells has claimed a safe and efficient approach for treating patients with Covid-19 pneumonia, including in elderly individuals (Shetty: 2020, pp. 462-464). Mesenchymal Stromal Cells infusion would likely be particularly beneficial to elderly patients infected with Covid-19, both with and without co-morbidities, as this population is more susceptible to Covid-19 induced pneumonia, resulting in severe respiratory distress and death because of immune senescence (Shetty et al.: 2019, pp. 470-482). Intravenous

infusion of Mesenchymal Stromal Cells typically leads to their accumulation in the lungs, where they secrete multiple paracrine factors (Lee et al.: 2009, pp. 54-63). Such factors likely played a significant role in protecting or rejuvenating alveolar epithelial cells, counteracting fibrosis, and improving lung function.

There are numerous virologists, stem cell researchers and cell therapy companies are exploring potential approaches to the treatment and prevention of Covid-19. For instance, researchers in China administered Covid-19 patients with a mesenchymal stem cell therapy that demonstrated success at treating the illness by effectively boosting the immune system to fight Covid-19. Researchers have reported results from patients treated with stem cells at Beijing You'an Hospital by receiving a single infusion of Mesenchymal Stromal Cells. They claimed that virtually all symptoms disappeared in all patients and reported no apparent adverse effects. Chest CT imaging demonstrated that chest pneumonia infiltration was significantly subsided. Also, the majority of patients showed negative results for the virus nucleic acid test over a week or two after Mesenchymal Stromal Cells infusion. The overall improvement was quite extraordinary for an elderly patient in a critical condition after the infection.

In Australia, abased firm Mesoblast is evaluating stem cell therapy for use against Covid-19 by investigating allogeneic Mesenchymal Stem Cells candidate called remestemcel-L, in patients with Acute Respiratory Distress Syndrome. Remestemcel-L has potential for use in the treatment of Acute Respiratory Distress Syndrome, which is the principal cause of death in Covid-19 infection. Remestemcel-L comprises culture-expanded MSCs derived from the bone marrow of an unrelated donor and is administered in a series of intravenous infusions. Since the same inflammatory biomarkers are also elevated in Covid-19, remestemcel-L could be useful in the treatment of patients with acute respiratory distress syndrome due to Covid-19 because Remestemcel-L infusions were well-tolerated, significantly reduced inflammatory biomarkers, and significantly improved pulmonary function in those patients with elevated inflammatory biomarkers. This stem cell therapy is believed to have immune-modulatory properties to counteract the inflammatory processes that are implicated in several diseases by down-regulating the production of pro-inflammatory cytokines, increasing production of anti-inflammatory cytokines, and enabling recruitment of naturally occurring anti-inflammatory cells to involved tissues (Sami: 2020).

In the United States, some cell therapy companies patented stem cell inventions such as FibroGenesis, and a Texas-based regenerative medicine company focused on tissue regeneration and chronic disease reversal using Human Dermal Fibroblasts (HDFs) filled with United States Provisional Patent Number 63/002,134 titled, "Peptides and Adjuvants for Augmentation of Fibroblast Therapy for Coronavirus". The invention provides methods of preventing infection, propagation, and pathology caused by the Covid-19 virus. The claims in the patent include the utilization of fibroblast cells along with adjuvants such peptides and hydroxychloroquine which stimulates the production of natural interferon to suppress the viral infection and corresponding cytokine storm. Other US cell companies, Vitro Biopharma, developed patent-pending and proprietary line of umbilical cord-derived stem cells AlloRx(TM) Stem Cells now being used in offshore regenerative medicine clinical trials (Barons, 2020). In addition, BeyondSpring Inc, a New york biopharmaceutical company focused on the development of immuno-oncology cancer therapies, has submitted a provisional US patent application for BPI-002, for methods of treating viral infections, including Covid-19, when administered alone or in combination with a vaccine. BPI-002 is a novel orally administered small molecule agent that is a potent T-cell co-stimulator. Moreover, Novellus patented process applies exclusive non-immunogenic synthetic messenger ribonucleic acid (mRNA) molecules for the creation of induced pluripotent stem cells (iPSCs). The iPSCs are stem-cell therapy for acute respiratory distress syndrome associated with Covid-19 that usually will be used to create MSCs with advanced immune-modulatory properties (Drug Discovery: 2020). Along with Novellus, Citius Pharmaceuticals has also patented process uses non-immunogenic synthetic mRNA molecules to create iPSC-derived MSCs.

In India, Bengaluru-based R&D firm, Stempeutics Research has submitted to the Drug Controller of India (DCGI) over a license to begin trials on Covid-19 patients for Stempeucel. Stempeucel is a stem-cell-based

drug which is granted by a US process patent. Stempeutics makes stem cell-based drugs or regenerative medicine, which enables living, functional tissues to repair or replace tissue or organ function lost due to age, disease, damage or congenital defects (Abrar: 2015). In Israel, pharmaceutical outfit, Pluristem Therapeutics has revealed positive results having tested it on critically ill Covid-19 patients by using PLX cell product candidate for treating respiratory and inflammatory complications caused by the novel Coronavirus infection under a compassionate use program for the treatment of Covid-19, as approved by the Israeli Ministry of Health.

According to Hidreth (2020), some stem cells for Covid-19 medications have been explored by some cell companies such as to the development of allogeneic, virus-specific T-cell therapies to combat SARS-CoV-2, the virus that causes Covid-19 has been developed by AlloVir collaborating with Baylor College of Medicine. Also, Celltex Therapeutics is evaluating autologous Mesenchymal Stem Cell against Covid-19 induced pneumonia and has previously facilitated over 9,000 Mesenchymal Stem Cell (MSC) therapies for various diseases without incurring any adverse events, including Acute Respiratory Distress Syndrome, inflammatory lung disease, influenza and viruses similar to Covid-19. In addition, Celularity has studied the capacity of its cryopreserved allogeneic, off-the-shelf NK cell therapy developed from placental hematopoietic stem cells (CYNK-001) for the treatment and prevention of Covid-19 infections Cynata Therapeutics is investigated The capacity of its Cymerus™ platform to manufacture iPSC-derived MSC for the treatment of Covid-19 patients with severe symptoms, including Acute Respiratory Distress Syndrome, sepsis and cytokine release syndrome. ImmunityBio which explore the use of bone marrow-derived allogeneic mesenchymal stem cells (BM-Allo-MSC) to mitigate the cytopathic storm for severe state patients in the severe state of Covid-19 disease has been developed by NantKwest.

While patented the stem cell-based medications for Covid-19, some researchers and pharmaceuticals companies have also increased activity in the clinical trial. The World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) reported a combined 29 trials exploring the potential of stem cells for treating Covid-19.

Patent and access to essential medications of Covid-19

A patent is an exclusive right granted by the state to inventors for their inventions in the field the technology for 20 years to carry out the invention or provide the approval to other parties to carry it out (Article 1.1 and Article 22 of the 2016 Patent Act). This exclusive right also includes the right to prevent third parties from "making, using, offering for sale, selling, or importing" the patented product or process without the patentee consent (Article 19 of the 2016 Patent Act). Patent owners shall also have the right to assign, or transfer by succession the patent (Article 74 of the 2016 Patent Act), and to conclude licensing contracts (Article 75 of the 2016 Patent Act).

According to TRIPS, patents shall be available for both products and processes, in all fields of technology, that new, involve an inventive step and are capable of industrial application (Article 27) with the duration of patent protection is 20 years (Article 33) with the bundles of rights in Article 28. These standards have been adopted in Article 2 of the 2016 Patent Act that includes new, inventive step and capable of industrial application for patentability. These standards apply to any inventions, including for stem cell-based drugs or vaccines or medications. Although stem cell-based inventions are extraordinary and sometimes controversial, the inventions shall be protected under the patent system as long as they meet the patentability requirements since patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology.

However, once a Covid-19 stem cell-based drugs or medications have been patented and approved to be used for Covid-19 treatment, there is a question of how to access to such medications. The problem of making sure the medication gets to all those who need, will emerge since the patent on medications may prevent patients from accessing to such medications. The patentees of stem cell-based medications are given by patens system an exclusivity right to choose who, when, where, and how that invention is made, used, or

sold. A patent secures to the inventor the exclusive property in the patented invention which cannot be appropriated or used without the license of the patentee. Patents suppress competition since during the period of patent protection it enables the patent holder to exclude the competitors from making the same products, which lead to limited supply and high prices for medication. At a health systems-level, high drug costs may lead to overstretched health budgets, rationing, and failure to provide the best possible care and access to essential medicine. At an individual level, these costs may lead to catastrophic expenditures, non-adherence to treatment (Huskamp et al.: 2003, pp. 2224-2231), sickness (Cohen: 2013, pp. 25-37) and even death. New medications are expensive not because they are expensive to manufacture but because they are protected by patents, which allow companies to bar competition and act as the sole supplier of new medicine.

Patents permit companies to charge profit-maximizing prices; they reduce the uptake of patented medicines, generating a social cost for people who need to access the medicines. Companies introducing new drugs enjoy a long period of market exclusivity. Such exclusivity has made pharmaceuticals one of the world's most profitable industries with profit margins for some companies reaching an estimated 42%. The grant of the monopoly allows the manufacturer to charge any price that is believed the market will bear. The average markup for patented drugs is nearly 400% (Baker: 2004). Introducing generic competition can cause prices to fall to as little as 6 % of the patent-protected price. However, in many instances, there are no close substitutes for a given drug; it is difficult for medicines to be true market substitutes for one another.

Experts have pointed out how the current patent system is not fit for purpose, with suppliers accused of turning a profit by denying access to life-saving medicine. Experts warned that multiple patents were still in force in most of the world for such treatments, threatening the affordability and supply of the new drugs. When a medication currently has been patented, and clinical trials have been acquired, the further question to ask is whether all countries have access to these medications at affordable rates since patent regimes that are prone to monopolizing innovations that people need access to. In the pandemic period, this situation will contradict the need for universal access to patented medicines, medical products, vaccines, health technologies, and any other treatments for Covid-19. If there is a clash between access to essential medicines and patent rights, the primacy of access should be promoted firstly. Given how strict access to patented drugs can be under existing norms, it calls a solution to find a way to enable wider access to some patented medications for Covid-19.

Covid-19 pandemic places sudden and intense demands on health systems, including access to essential medications to treat and to combat the virus. The morbidity and mortality of Covid-19 lead to the rapid response on Covid-19 medications, including access to such medications as the primary public health priority. The International Health Regulations 2005, which came into effect in 2007, imposes a binding legal obligation to strengthen alert and response capacity in the face of pandemics, public health risks and emergencies and to provide support to states in the development and maintenance of minimum core capacities for the detection and assessment of, and response to, those risks and emergencies which are attributable to communicable diseases. This obligation also applies to the pandemics of Covid-19.

In the pandemic situation, it is essential to ensure access to Covid-19 medications that could potentially treat Covid-19 in patients most in need of medical aid. Ensuring access to essential medications is one of the main obligations for fulfilling the right to health (United Nations Economic and Social Council: 2000). WHO has encouraged countries to amend their national legislation or constitutions to provide for this specific right. It is the policy of the state to protect public health and, when the public interest or circumstances of extreme urgency so require, it shall adopt appropriate measures to promote and ensure access to affordable quality drugs and medicines for all.

In order to ensure access to essential medicines, Indonesia has established a national drugs policy. WHO has released comprehensive guidance on creating these policies, which should address access to, and the quality and rational use of, medicines. The WHO Model List of Essential Medicines can help to guide drug selection, although the development of a national list should take account of national priorities and disease

challenges. A national drug policy, including a list of essential medicines and standard treatment guidelines, can increase the use of generics, improve prescribing practices and protect against drug resistance. The policy has the main objective to secure the right to universal access to essential medicines by committing the government to: a) ensure the availability and accessibility of essential medicines to all citizens; b) ensure the safety, efficacy and quality of drugs; c) ensure good prescribing and dispensing practices; d) promote the rational use of drugs by prescribers, dispensers and patients through the provision of the necessary training, education and information; and e) promote the concept of individual responsibility for health, preventive care and informed decision-making. To achieve the aim of such national drugs policy, Indonesia can implement TRIPS flexibility to meet the goal of access to essential medications for Covid-19 under the government-use license scheme.

Government-use: The concept and international legal basis

TRIPS Agreement lays down the minimum substantive standards of patent protection provided by WTO Members, which main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection. The patent is an exchange between the inventor and national government in which the inventor discloses to the public exactly how to recreate drug invention and is in return given an exclusivity period during which it may choose who, when, where, and how that invention is made, used, or sold.

Accordingly, the patent is an exclusive right that enables the holder to exclude competing suppliers during the period of patent protection. In the case of the patent on pharmaceuticals, when patent regimes work well, they ensure a return on investment for the patent holder who to discover, develop and deliver a new drug to market, while ensuring the continued availability of generic medicines after the patent has expired. However, patents may fail to achieve their objective as instruments of innovation on new drugs in the market since both governments and patients, particularly in low-income countries, lack the purchasing power to new medicines. The number of new essential drugs under patent protection will increase, but the drugs will remain out of reach to people, particularly in developing countries because of excessive price.

Since patents eliminate competition, they can also lead to limited supply and high prices for medicines during the term of patent protection. High prices, as well as the scale of need for Covid-19 drugs, may combine to defeat the goal of providing universal access to a national list of essential medicines, especially in poor countries. The patent may prevent the widespread availability of patented medicines, medical products, vaccines, health technologies, assured health quality for the treatment of Covid-19.

To respond these public health problems, the Doha Declaration on TRIPS and Public Health adopted by Trade Ministers at the Doha Ministerial Meeting in November 2001 (the Doha Declaration on TRIPS and Public Health) has recognized the complexity of the impact of patents as incentives for drug discovery, access to medicine and the effect of patents on generic medicines need in the market. When the period of patent protection has expired, generic versions of the drug may be manufactured and imported without infringing any patent rights. However, in the period of patent protection, national government and private suppliers need to negotiate with the patent holder for the price at which the medicine can be imported into that country, or alternatively negotiate for a license to manufacture the medicine within the country in the case that equal generic medicines are not available.

Since patent protection for a particular medicine may affect price and availability, TRIPS includes a number of flexibilities that can be used to reduce the prices of essential medicines and to meet the goal of universal access. The flexibilities are given as the options for countries' decisions and choices when the implementation of the patent standard in the TRIPS is undertaken according to their national policy. The flexibilities could be distinguished into (i) subject matter which qualifies for protection; (ii) scope of the protection; (iii) modes of IP enforcement; and (iv) matters of administration.

The flexibilities allow WTO members to customize their patent laws in accordance with their unique legal systems, public-health situations and development needs. In particular, members were given the ability to

adopt certain measures that neutralize the impact of exclusive rights, promote competition and facilitate access to medicines. Despite their obligation to implement laws granting and enforcing patents on pharmaceutical products, WTO Members retain considerable scope to adjust their patent laws in order to achieve public health objectives.

Under the flexibilities, TRIPS does not prevent national governments from issuing government-use as part of compulsory license in order to meet national health objectives. The Doha Declaration on TRIPS and Public Health affirms that each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted (Doha Declaration: 2001). Government-use license to manufacture or import a patented drug without the authorization of the right holder are allowed but are made subject to conditions ruled in Article 31 of TRIPS in order to protect the legitimate interests of the right holders. Article 31 of TRIPS acknowledges that national patent laws may authorize public, non-commercial uses of patents by or on behalf of the government, where the conditions set out in Article 31 are satisfied. The conditions include the obligation to have prior negotiations with the patent holder to acquire a voluntary license - although prior attempts to obtain access to the patented drug on commercial terms are not required in the case of a national emergency, or in cases of extreme emergency, or in other circumstances of public, non-commercial use by the government in order to achieve the government's policy of providing universal access to medicines, diagnostics, vaccines or medical devices (Doha Declaration: 2001). However, these conditions should be read together with Article 27.1 of TRIPS, which require that patent rights shall be enjoyable without discrimination as to the field of technology, and whether products are imported or locally produced.

The Covid-19 pandemic crisis has brought the international community together in formulating a response to facilitate access to diagnostics, patented medicines and other tools needed for prevention, treatment, and care for people. Concerns had been growing that patent on Covid-19 medication might restrict access to essential medicines for populations in Indonesia in the efforts to control diseases of public health importance. The country might face obstacles when seeking to implement measures to promote access to Covid-19 medication in the interest of public health. To respond the obstacles, Indonesia may authorize the use of a patent without the permission of the patent holder, due to the scale of the health threat caused by a disaster, pandemic or security threat of Covid-19, including the interruption of supplies at affordable prices.

A government-use license is a compulsory license granted in favour of a government entity to use the patented invention. A compulsory license is an authorization granted by a government to a party other than the holder of a patent to use a patented invention without the consent of the patent holder (UNTAD, 2005). Government-use enables a competent national authority to license the use of a patented invention to a third party or government agency without the consent of the patent-holder.

Government-use license gives the government the right to use patented inventions without permission as long as paying the patent holder a reasonable compensation. Government-use is a march-in right to respond to the soaring cost of pharmaceuticals by relying on the rights to use generics for drugs that are excessively priced against benchmarks set. The government-use provision is a kind of government immunity from patent claims and immunity from patent infringements. It means that although in pharmaceuticals area, a patent actually gives the right to prevent others from making, selling, using, or importing a covered medicine, patent holders cannot stop the government from procuring the generic version of their patented medicine or prevent other generic manufacturers from producing or importing the medicine in certain circumstances and conditions, with entitled to reasonable compensation. Although government-use is issued without the permission of the patentee, the application of government-use will not infringe their patent right when all requirements and the conditions are satisfied, and reasonable royalty is provided. The availability of compensation in this scheme shows that the provisions of government-use try to create health policy when they mandate comprehensive drug coverage on the one hand, and simultaneously demand strong exclusive rights for pharmaceutical innovators on the other.

By the ability to procure low cost of the generic version of patented Covid-19 medication, government-use offers a panacea for patented medications which is not made available to the public on reasonable terms, and become a legal remedy for the social cost of negative excess of patent exclusive right since patents permit their holders to extract as much revenue as possible, setting prices without regard to the real cost of R & D or pharmaceutical manufacturing. Government patent use should be used to remedy the national crisis surrounding access to Covid-19 medications.

Government-use in Indonesia

Indonesian government policies on access to medicines are driven by the goal of universal health care which is underpinned by the 2004 Social Security Law. Indonesian health authorities have also often stressed the need for self-reliance to meet pressing public health about ensuring access to medicines, including for Covid-19. Some efforts have been taken to make medicines and vaccines more widely available to the population. Health authorities encourage firms to set up local pharmaceutical factories, develop local vaccine production capacity and have exerted the government-use licenses.

The government has issued some decrees that override the patents on some essential drugs (hepatitis and HIV-AIDS) and opens the way for cheap generic versions, in what is being described as a precedent under government-use license. The government has regulated government-use license firstly in the Patent Act No 6 in 1989 (Article 104-108). The further standard and procedure of government-use were set up under Government Regulation No. 27 in 2004. In the new patent act (the 2016 Patent Act), provisions of government-use are included in Article 109-120 which adopts the procedural requirements for government-use in Article 31 of the TRIPS Agreement. Although it does not appear that any articles on the provisions contradict the TRIPS Agreement, it is still needed to design better leverage existing TRIPS flexibilities in the government-use to ensure access to medications for Covid-19.

According to the 2016 Patent Act, the government-use license is issued under the critical reasons that the patents are very important for national security and defence (Article 109.1.a), and very urgent for the public interest (Article 109.1.b). For security and defence, government-use is allowed to use of the patent in the fields of firearms, ammo, military explosives, chemical weapons, biological weapons, nuclear weapons, military equipment (Article 110). For public interest emergency reason, government-use will be also allowed to manufacture patented drugs under the reason that the patents are very urgent for the public interest (Article 109.1.b) which covers the use of patent in the fields of: pharmaceutical products needed to deal with widespread infectious diseases; chemical products related to agriculture; or animal medication needed to cope with pests and/or animal diseases that are widely infected; processes and/or products to deal with natural disasters and/or environmental disasters (Article 111). In relation to Covid-19, Indonesian authority can issue government-use license for patented medication (drugs, vaccines, test used for Covid-19 pandemic) under the rational background that the patent are very urgent for the public interest, including patent on stem cell based pharmaceutical products needed to combat widespread infectious deadly diseases of Covid-19.

Along with those critical reasons, it is necessary actually to add other reasons in the sub paragraph of the patent provisions which allow the possibility of issuing a government-use license upon a finding of anticompetitive behavior of patent holder. This is essential since patent may allow the holder have dominant position in market by providing set of exclusive rights, that make them abuse its dominance by refusing to issue a voluntary license to procure the Covid-19 medications. Patent abuse by refusals to license based on a dominant position in the market or other finding anticompetitive behaviors of the patent holder may insecure to access to Covid-19 medications.

When government manufactures and procures the generic version of patented Covid-19 medications under government-use, the 2016 Patent Act ensures that government will provide appropriate compensation to the patent holders (Article 115). Standard of compensation in the case of pharmaceuticals has set under on Article 31(h) of the TRIPS Agreement and the 30 August 2003 Decision of the implementation of Paragraph

6 of the Doha Declaration on the TRIPS Agreement and Public Health which states that remuneration should be "adequate", taking into account the economic value of the authorization in the country. Although no specific compensation rates are specified in the 2016 Patent Law, in practice, the rate became the subject of further regulations that are announced with the issuance of government-use license such as the Presidential Decree No. 83 of 2004 on exploitation of patent by the Government on Anti Retroviral (ARV), Presidential Decree No. 6 of 2007 on the amendment of the Presidential Decree No. 83 of 2004, and Presidential Decree No. 7 of 2012 on exploitation of patent by the Government on Antiviral and Anti Retroviral. In these Presidential Decrees, compensation to the patent holders was given at 0.5% of the generic net sales value. Although there is no real global precedent on the issue of remuneration, the specific rate cited in the Indonesian government-use licenses of 2004, 2007, 2012 could be considered "adequate" since in relation to licenses, the rates have differed widely from as low as 0.01% (in the United States) to as high as 45% (United Kingdom) of net sales (UNTAD, 2011). However, it should be reasonably explained how government set at 0.5 % compensation rate and how to respond when the rate is challenged by patent holders.

Not only ensuring compensation, the 2016 Patent Act also ascertains that the implementation of government-use license on Covid-19 medication will not eliminate the right of the patent holders to exercise their patent rights (Article 112.2). In addition, the Act also obliges that patent exploitation by the government shall be limited, to meet domestic needs, and are non-commercial (Article 109.2). In previous practice of government-use for Hepatitis and HIV-AIDS drugs, the Indonesia health authority has issued government-use specifically for local production to fulfil the domestic demand on patented drugs and the license is aimed for non-commercial purpose of patients treatment only.

The first government-use license issued in 2004 under Presidential Decree No. 83 in 2004 as legal basis for a government-use license over two anti retrovirals (Nevirapine patented by Boehringer Ingelheim, and Lamivudine patented by GlaxoSmithKline) for the HIV-AIDS medication by commanding the state-owned enterprise (Kimia Farma) to manufacture them. In 2007, under Presidential Decree No. 6 in 2007, government issued the second government-use license to manufacture the generic version of Efavirenz (patented by Merck). The basis reason of both government-use licenses relied on the price differential between the patented drug and the cost of producing a generic equivalent as the rationale for issuing the government-use license. Compensation to the patent holders was established under the Decrees at 0.5% of the generic net sales value. Summary of Indonesia's government-use based on Presidential Degree No 83 od 2004 and Presidential Decree No. 6 in 2007 can be seen in the table below :

No	Type	Patent Holders	Patent Number	Commence Year	Valid Until	Compensation
1	Nevirapin	Boehringer Ingelheim (BI)	ID 0001338	2004	Oct 31, 2011	0.5% of the net sales value
2	Lamivudin	Biochem Pharma INC	ID 0002473	2004	Jan 28, 2012	0.5% of the net sales value
3	Efavirenz	Merck & Co, INC	ID 0 005 812	2007	August 7, 2013	0.5% of the net sales value

Table 1. The government-use license for Antiretroviral in 2004-2013

In 2012, under the Government Regulation No.76 of 2012 government exploits patents for seven HIV/AIDS and hepatitis B medicines to ensure the availability of good quality, safe and effective generic versions of anti-retroviral and anti-viral drugs. This decree may represent the broadest single use of government-use license for pharmaceutical and renews the previous government-use by adds seven more drugs in the list that includes Evavirenz and Nevirapine (for anti retroviral), Lamivudine (for Hepatitis B). These drugs can be now licensed by the Ministry of Health to pharmaceutical companies to exploit patents on behalf of the government, effective until the end of term of each patent, with a 0.5% compensation paid to the

patent holders. Indonesia's government-use based on Presidential Degree No 76 of 2012 is summarized below:

No	Type	Patent Holders	Patent Number	Commence Year	Valid Until	Compensation
1.	Efavirenz	Merck & Co, INC	ID 0 005 812	2007	August 7, 2013	0.5% of the net sales value
2	Abacavir	Glaxo Group Limited	ID 0 011 367	2012	May 14, 2018	0.5% of the net sales value
3	Didanosin	Bristol Myers Squibb Company	ID 0 010 163	2012	August 6 August, 2018	0.5% of the net sales value
4	Lopinavir & Ritonavir	Abbot Laboratories	ID P 0023461	2012	August 23, 2018	0.5% of the net sales value
5	Tenofovir & Emtrisitabin	Gilead Sciences, Inc	ID 0 007 658	2012	July 23, 2018	0.5% of the net sales value
6	Tenofovir, Emtrisitabin & Evafirenz	Gilead Sciences, Inc	ID P0029476	2012	November 3, 2024	0.5% of the net sales value

Table 2. The government-use license for Antiretroviral in 2012-2024

DISCUSSION

The benefit of government-use

By issuing government-use in 2004, 2007 and 2017, Indonesia has set an important precedent about how to solve patent problem on access to drugs by initiating to produce low-price of generic drugs. Indonesia's action sets a critical precedent for global public health and shows powerful example for other countries. Indonesia has shown that countries can take action to enable the production of low-price versions of essential life-saving medicines for the citizens. It is a tremendous triumph for Indonesia when issuing government-use that allows government to access generic versions of patented medicines at much cheaper prices. Indonesia stands at the head of the pack of countries that have stood up to big pharmaceutical corporation power and to the trade and diplomatic pressure exerted by US and EU powers that consistently advance the patent monopoly rights of pharmaceutical corporations (Baker: 2012).

It is very substantial benefits of government patent use as a strategy to lower drug costs and improve access to medicines, particularly where communicable and life-threatening diseases such as Covid-19 are concerned. From a public health emergency viewpoint, the scheme offers the benefit for the best form of patient care or the best approach to managing Covid-19 outbreak by ensuring access to essential Covid-19 medications. In the case of facing difficult access to patented Covid-19 medication, government-use will be a strategic solution which allow patients to be treated appropriately with inexpensive generic medications for Covid-19 according to clinical need and far less money will be spent in the situation of financial distress during the outbreak.

From the financial standpoint, given major new drug approvals result in debilitating costs to public health care budgets, acting government-use decisively in the case of Covid-19 can save the national budget in expenditures on other new medicines in the future. Asserting government-use may encourage government agency or companies to establish lower launch prices and escape from drug-pricing trap by procuring the generic version. The substantial benefit would be a reduction in the opportunity for patentee to extract monopoly profits that far exceed their R &D costs. Used wisely, power of authority to issue government-use

license could help diminish the inefficiencies and health impact of the current pricing trap paradigm or patented drug monopoly, at least for current government health programs in combating Covid-19 pandemic.

To access drugs on Covid-19 medication, the government-use might the strategic options chosen by health authority although the TRIPS Agreement provides other similar patent flexibilities such as a compulsory license. The reason why Indonesia may opt to issue government-use over Covid-19 medications because government-use is more feasible than compulsory license as the compulsory license has tighter requirements such as the need to demonstrate prior negotiations with the patent owner for the unsuccessful voluntary license, to address a national emergency or other circumstances of extreme urgency, non-working patent or harmful implementation of the patent in local territory (Article 31 of TRIPs and Article 82.1 of 2016 Patent Act).

There are some certain benefits of issuing government-use licenses over compulsory licensing. Procedurally, the ability to proceed with the government-use is easier because it can be issued in the absence of failed prior negotiations with the patent holder, and therefore easier to issue in the medical emergency such as a break of pandemic Covid-19. Indonesian government might procure patented Covid-19 medications under the reason that the patents are very urgent for the public interest (Article 109.1.b of the 2016 Patent Act) which covers the use of the patented pharmaceutical products needed to deal with widespread infectious deadly disease of Covid-19. The authority also issues government-use license rather than compulsory license because it is not limited to cases of non-working under the current Patent Law.

Furthermore, government-use will restrict the choice of firms who could import or manufacture using that license to government ministries and state-owned enterprises, of which there are currently only four (Bio Farma, Kimia Farma, Indofarma, and Phapros). The authority prefers to issue the government-use license to importation since the drug importation has set the stricter requirements. Importation is permitted for drugs destined for public health programs or new drugs and drugs that cannot be manufactured locally, with the requirement that a foreign manufacturer must sign a written consent to transfer technology to the local manufacture drug within 5 years (Health Ministry Decree No. 1010 in 2008, Articles 9 and 10).

The potential opportunity

According to Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, it instituted an elaborate system whereby government-use are encouraged as one method for providing medicines to countries with little or no manufacturing capacity and providing authority to exporting and importing drugs needed. With a strong local generic industry and with previous experience in procuring generic version of patented drugs, Indonesia will not only be able to procure generics of the patented medications for domestic consumption, but also can potentially serve as a candidate exporting country of Covid-19 medications by using government-use.

This opportunity widely opens because of the important position of Indonesia on regional cooperation. In Association of Southeast Asian Nations (ASEAN), Indonesia is often regarded as the natural leader has generally been recognized by the other ASEAN members as first among equals in the sense of its geographical dimensions, large population, strategic position and natural resources. With some members of ASEAN are less developed countries (LDCs) which are supposed not to have capacity in manufacturing pharmaceuticals, there is opportunity to manufacture and export the Covid-19 medication to them. Therefore, Indonesia needs to incorporate the Paragraph 6 of the Doha Declaration into patent law in order to have notification mechanism which request local pharmaceutical industries to act as a regional exporter for Covid-19 medications under the system instituted by Paragraph 6 of the Doha Declaration.

The challenges

Although countries had a right to override patents by issuing government-use in certain limited circumstances, government-use license is criticized to undermine medical innovation since systematic issuance of such licenses sets a negative precedent and can reduce the incentive to invest in the R&D of new

medicines that address medical need, including in the case of Covid-19. Therefore, patent holders argued that government-use should be issued as a last resort since. They recommend that negotiated approaches, such as tiered pricing, or voluntary licensing or social responsibility have been also recently supported and promoted by the World Health Organization/WHO (Beyer: 2012, pp. 9-12).

Innovator of Covid-19 would likely complain that government-use interferes with their incentives to invest in innovation. However, such incentives would remain robust if the government compensation were sufficient to compensate the companies for research and development costs, adjusted for risk of failure and margins of error in calculations made government agency or court. Other adjustments might also be appropriate—for example, to reflect the share of R & D costs attributable to the market or to provide a bounty for particularly important innovations.

CONCLUSION

The number of people which are infected by coronavirus in Indonesia appears at alarming level since the country has intense population with nearly 250 million people. One of the major reasons to decrease Covid-19 mortality rates is the provision of have effective treatment and access to effective medications which mostly patented by the inventors. If Indonesia cannot afford the Covid-19 treatment, the mortality rate will exceed at very dangerous levels.

To stop the virus from spreading and save lives as the struggles to deal with the Covid-19 pandemic, stem cell based medications may reduce death rates and cure the critically ill patients. Although stem cell-based inventions are extraordinary and sometimes controversial, but as inventions they shall be protected under patent system as long as they satisfy the patentability requirements. Hence, when patent on Covid-19 stem cell based drugs or medications are approved, there is problem of making sure the medication gets to all those who need since patent may prevent patients to access to such medications due to the exercise of patent's exclusive rights which may cause high cost, lower output and limited supply of medications in market. The patent on Covid-19 medications might turn a innovation miracle into a social tragedy by stifling public health on access to essential medicines.

To address such public health on access to medications, under TRIPS flexibility, Indonesia can override patents for public health purposes by issuing government-use that enable the generic manufacture of patented drugs or vaccines or other medications for Covid-19. Government-use license requires some course of action to procure generic equivalents of the patents for Covid-19 medications, as urgent need to control the disease. In relation to the fact that implementation of the government-use depends on the capability or readiness of the local pharmaceutical industries to manufacture, the government-use license will be feasible way to ensure access to essential medications for Indonesia because Indonesia has previously implemented this scheme for Hepatitis and HIV/AIDS antiretroviral drugs.

BIBLIOGRAPHY

ABRAR, P (2020). "Indian biotech firm stempeutics research gets us process patent for its novel stem cell drug. The Economic Time. March 4."

AHK INDONESIEN. (2020). "Covid-19 development in Indonesia. April 30".

BAKER B (2012). "Indonesian Compulsory Licenses Show Values of Pro-Access TRIPS-Flexibility Terms in Voluntary Licenses. InfoJustice." Oct 30. http://infojustice.org/archives/27620.

BAKER, D (2004). "Financing drug research: what are the issues?. Ctr. For Econ". Res. Sept 22 https://www.cepr.net/documents/publications/intellectual_property_2004_09.htm

BBC NEWS (2020). "Coronavirus declared global health emergency by WHO". January 31. https://www.bbc.com/news/world-51318246

BEYER, P (2012). "Socially responsible licensing policies in the medical sector". WTO Worshop on IP & public health. pp. 9-12.

BIOSCIENCE INSTITUTE (2020). "Covid-19, Stem cells among most promising treatments". April 16. https://bioinst.com/en/covid-19-stem-cells-among-most-promising-treatments/

COHEN, RA, KIRZINGER, WK & GINDI, RM (2013). "Strategies used by adults to reduce their prescription drug costs". NCHS Data Brief, 119, pp. 25-37.

DOHA DECLARATION (2001). "Doha Wto Ministerial 2001: Declaration on the TRIPS agreement and public health". WT/MIN(01)/DEC/2, 20 November.

DRUG DISCOVERY (2020). "Citius, Novellus collaborate on novel stem-cell therapy for ARDS associated with Covid-19". April 2, https://pharmaceutical-business-review.com/news/citius-novellus-covid-19/

GOLCHIN, A, SEYEDJAFARI, E & ARDESHIRYLAJIMI, A (2020). "Mesenchymal stem cell therapy for covid-19: present or future". Stem Cell Rev Rep. 13, pp. 1–7.

HUSKAMP, HA, DEVERKA, PA, EPSTEIN, AM, EPSTEIN, RS, MCGUIGAN, KA & FRANK, RG (2003). "The effect of incentive-based formularies on prescription-drug utilization and spending". NEw ENG. J. MED. 341, pp. 2224-2231.

LEE, RH, PULIN, AA, SEO, MJ, KOTA, DJ, YLOSTALO, J, LARSON, BL, ... & PROCKOP, DJ (2009). "Intravenous MSCs improve myocardial infarction in mice because cells embolized in lung are activated to secrete the anti-inflammatory protein TSG-6. Cell Stem Cell". 5(1), pp. 54-63.

NORDRUM, A (2020). "Scientists use stem cells to treat Covid-19 patients in China, IEE spectrum", 26 March 2020, https://spectrum.ieee.org/the-human-os/biomedical/devices/stem-cells-covid19-china

SAMI, T (2020). "Australia's Mesoblast plans to evaluate its stem cell therapy in patients infected with Covid-19 Coronavirus-lungs-test-tube. Big World". March 11,

SHETTY, AK (2020). "Mesenchymal stem cell infusion shows promise for combating coronavirus (Covid-19) Induced Pneumonia. Aging and Disease". 11(2), pp. 462-464.

SHETTY, AK, UPADHYA, R, MADHU, LN, & KODALI, M (2019). "Novel insights on systemic and brain aging, stroke, amyotrophic lateral sclerosis, and alzheimer's disease". Aging and Disease. 10, pp. 470-482.

THE JAKARTA POST (2020). "Indonesia's latest official COVID-19 figures". May 29. https://www.thejakartapost.com/news/2020/03/23/indonesias-latest-covid-19-figures.html

THE NATIONAL LAW REVIEW (2020). "The global patent race for a Covid-19 vaccine". April 22. https://www.natlawreview.com/article/global-patent-race-covid-19-vaccine

UNITED NATIONS ECONOMIC AND SOCIAL COUNCIL (2000). "The right to the highest attainable standard of health". General Comment No 14. United Nations document E/C.12/2000/4. August 11. para. 43(d).

WHO. 2020. "Coronavirus disease (COVID-19) pandemic".

WU, X, THI, VLD, HUANG, Y, BILLERBECK, E, SAHA, D, HOFFMANN, H H, ... & ANDRUS, L (2018). "Intrinsic immunity shapes viral resistance of stem cells". Cell, 172(3), pp. 423-438.

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