

## THE IMPACT OF COVID-19 ON INTELLECTUAL PROPERTY LEGAL SYSTEM RELATED TO PUBLIC HEALTH IN CONNECTION WITH TRIPS FLEXIBILITIES IN INDONESIA

**Andrieansjah**

Directorate General of Intellectual Property, Ministry of Law  
and Human Rights of the Republic of Indonesia  
Jalan H.R. Rasuna Said, Kav. 8-9, Kuningan, Jakarta Selatan, Indonesia  
E-mail: andriesoeparman2701@gmail.com

### Abstract

In early 2020, countries in the world was shocked by a new virus called Coronavirus Disease 2019 (COVID-19) including Indonesia. The COVID-19 pandemic gives impact to the legal system, including intellectual property (IP). Trade Related Aspects of Intellectual Property Rights (TRIPS) flexibilities on public health in developing countries: Transition Periods, Compulsory License, Government Use, Parallel Imports, Exceptions to Patent Rights, Exemptions from Patentability, Limits on Data Protection, and Implementation of the Paragraph 6 of the Doha Declaration. Research problems: (1) what are the conditions for implementing the flexibilities of TRIPS in facing COVID-19 pandemic in Indonesia and (2) what are the issues that should be anticipated for future IP legal system relating to public health as a lesson from this COVID-19 Pandemic. Government Use is most effective to be used for encounter COVID-19 Pandemic, and voluntary license is recommended to be promoted for future approach. The study is using a qualitative literature study.

**Keywords:** Compulsory License, Government Use, COVID-19, Intellectual Property, Public Health.

### A. Introduction

In early 2020, the world was shocked by the outbreak of a new virus; A new type of coronavirus (SARS-CoV-2) that caused a disease called Coronavirus disease 2019 (COVID-19). The origin of this virus is from Wuhan, China, and it was discovered at the end of December 2019. There were

more than 65 countries infected with the COVID-19 virus.<sup>1</sup> The WHO responded rapidly by coordinating diagnostics development, issuing guidance on patient monitoring, specimen collection, and treatment as well as providing up-to-date information on the outbreak.<sup>2</sup>

Pandemic COVID-19 hit parts of the

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<sup>1</sup> WHO Director-General's remarks at the media briefing on 2019-nCov on 11 February 2020. Cited Feb 13rd 2020. <https://www.who.int/dg/speeches/detail/who-director-generalsbriefing-on-2019-ncov-on-11-february-2020>. (accessed 11 May, 2020).

<sup>2</sup> Shrikrushna Subhash Unhale et al., "A Review on Corona Virus (COVID-19)", *World Journal of Pharmaceutical and*

world including Indonesia, with thousands declared positive.<sup>3</sup> This pandemic affects physical, mental-economic, socio-cultural and even religious health. In terms of regulation, the Indonesian government issued a package of rules in 2020 to overcome COVID-19.<sup>4</sup> There are Government Regulation in Lieu of Law (Perpu) No. 1 of 2020 on State Financial Policy and Financial System Stability for Handling the COVID-19 Pandemic and/or in order to Face Threats that Harm National Economy and/or Financial System Stability, Government Regulation (PP) No. 21 of 2020 on Large-Scale Social Limitation in the Framework of Accelerating COVID-19 Handling, and Presidential Decree (Keppres) No. 11 of 2020 on Determination of the COVID-19 Public Health Emergency. The COVID-19 pandemic also affected the intellectual property (IP) legal system. The government should be aware that in responding to the pandemic, they can take measures to rapidly overcome potential patent barriers in order to increase access to patented diagnostics, medicines including biologics, and vaccines, consistently with the Agreement on Trade Related Aspects of Intellectual Property Rights of the World Trade Organization (TRIPS).

IP pertains to any original creation of the human intellect such as artistic, literary,

technical, or scientific creation. Intellectual property rights (IPR) refer to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.<sup>5</sup> These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize his invention/creation for a given period of time. In Indonesian legal system, IP protection is regulated by (1) Law Number 28 of 2014 on Copyright and Related Rights; (2) Law Number 13 of 2016 on Patent; (3) Law Number 20 of 2016 on Trademark and Geographical Indication; (4) Law Number 31 of 2000 on Industrial Design; (5) Law Number 32 Year 2000 on IC Topography; (6) Law Number 30 Year 2000 on Trade Secret; and (7) Law Number 29 of 2000 on Plant Variety Protection.

The national emergency situation as the COVID-19 Pandemic can give an impact on the IP legal system. Refer to the TRIPS Agreement, there are flexibilities for public health purposes in developing countries. Those flexibilities are Transition Periods, Compulsory License, Government Use, Parallel Imports, Exceptions to Patent Rights, Exemptions from Patentability, Limits on Data Protection, and Implementation of the WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration.<sup>6</sup> As developing

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*Life Sciences WJPLS*, Vol. 6, Issue 4, 109-115 (2020), [www.wjpls.org](http://www.wjpls.org) (accessed 11 May, 2020).

<sup>3</sup> Indonesia statistics for COVID-19: Confirmed 22.271; Recovered 5.402; Deaths 1.372 (WHO: 24 May 2020).

<sup>4</sup> Pakuan University, "The Legal Side of Handling COVID-19", <https://bogor-kita.com/sisi-hukum-penanganan-COVID-19/> (Accessed 11 May, 2020).

<sup>5</sup> Singh R., *Law Relating to Intellectual Property: A Complete Comprehensive Material on Intellectual Property Covering Acts, Rules, Conventions, Treaties, Agreements, Case-Law and Much More*, (New Delhi: Universal Law Publishing Co. Pvt. Ltd., 2004).

<sup>6</sup> Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities In TRIPS by Developing Countries: Can They Promote Ac-*

countries, Indonesia has become one of the member of WTO.<sup>7</sup> Accordingly, based on the TRIPS principle, Indonesia is permitted to implement those TRIPS flexibilities in its national IP legal system. TRIPS flexibilities can promote access to medicine in developing countries. Most developing countries have their laws and practices incorporated to one or more of the TRIPS flexibilities and there has been an increase in the usage of these flexibilities such as compulsory licensing for public health purposes. However, there are important loopholes both in terms of incorporation and usage of flexibilities, which need to be addressed if the TRIPS flexibilities are to be used effectively across the developing world.<sup>8</sup>

In this paper, the scope of writing will be limited to the impact of COVID-19 in connection with the IP legal system especially patent for the interest of public health in Indonesia. Furthermore, the research problems will be focused on (1) what are the conditions for implementing the flexibilities of TRIPS in Indonesia, and (2) which issues should be anticipated for IP legal system on public health as a lesson for the future from this COVID-19 Pandemic.

## B. Research Method

This study uses a normative legal

research method with a sociological approach.<sup>9</sup> This type of research uses normative juridical research, which focused on examining the application of norms in positive law.<sup>10</sup> The purpose of this approach method is to conduct research and study of secondary data in the form of various library materials consist of primary legal materials, secondary legal materials and tertiary legal materials related to issues regarding the impact of COVID-19 on intellectual property legal system related to the public health in connection with TRIPS flexibilities in Indonesia.

The specification or nature of this research is descriptive analytical, which describes the problems regarding the problem of the impact of COVID-19 on intellectual property legal system related to public health in connection with TRIPS flexibilities in Indonesia, and then analyzes these problems so that it can be concluded what are the conditions that must be met in implementing TRIPS flexibility in Indonesia, and the anticipation of the IP legal system to deal with a pandemic similar to COVID-19 in the future. This research is conducted using Library Research supported by library data consist of primary legal materials (for example legislation), secondary legal materials (for example books, journals,

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*cess to Medicines?*, (Geneva: South Centre, 2006).

<sup>7</sup> Indonesia has ratified the TRIPS Agreement through the Indonesian Law Number 7 Year 1994. edge - Managing an archipelagic state, Indonesian Update Series, RSPAS Australian National University, ISEAS, Singapore, p.28-48.

<sup>8</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>9</sup> Lili Rasjidi and Liza Sonia Rasjidi, *Monograf: Pengantar Metode Penelitian dan Penulisan Karya Ilmiah Hukum*, (Bahan Kuliah Fakultas Hukum Universitas Padjadjaran, 2005), p. 4.

<sup>10</sup> Johnny Ibrahim, *Teori dan Metodologi Penelitian Hukum Normatif*, (Jakarta: Penerbit Bayumedia Advertising, 2006), p. 294-295.

scientific works, magazines), and tertiary legal materials (for example dictionary). After the required data is obtained, then an analysis of the data is carried out using qualitative juridical analysis methods.<sup>11</sup> In this case all information sourced from literature and statutory regulations will be analyzed then will be set out in the form of argumentations or descriptions.

## C. Discussions

### 1. Implementation of TRIPS Flexibilities Related to Public Health Based on Indonesian IP Legal System to Face COVID-19 Pandemic

#### a. Transition Periods

The TRIPS Agreement provides three transition periods for the implementation of its minimum standards. **Firstly**, the end of the 1995-2000 transition period obliged developing countries to implement the TRIPS Agreement and to put into place patent legislation that complied with the minimum standards of intellectual property protection prescribed by the TRIPS Agreement.<sup>12</sup> In terms of patent protection, the critical requirements included the criteria for patentability, the minimum 20 year protection term and, protection for both products and processes in all fields of technology.<sup>13</sup> **Secondly**, the 2000-

2005 transition period could be used by those countries which had not provided patent protection for pharmaceuticals or agrochemical products at the entry into force of the Agreement.<sup>14</sup> They were allowed a further five years to put in place a product patent regime for pharmaceuticals and agro-chemicals. However, the use of this transition period was subject to certain conditions. Developing countries were required to accept patent applications as of 1995, to keep them in a patent queue "mailbox", and to start processing the applications in 2005.<sup>15</sup> **Thirdly**, the 1995-2006 transition period allowed least-developed countries 10 years to implement their obligations under the TRIPS Agreement, in view of their economic, financial and administrative constraints.<sup>16</sup>

Based on aforementioned explanation, therefore for this TRIPS flexibility, Indonesia has already implemented critical requirements including the criteria for patentability, the minimum 20 year protection term and, protection for both products and processes in all fields of technology. The criteria for patentability requirements (novelty, inventive steps, industrial applicable) was provided by the Law Number 6 of 1989 before TRIPS<sup>17</sup> and in the Law Number 14 of 2001 after

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<sup>11</sup> Lili Rasjidi dan Liza Sonia Rasjidi (2005), *Op. Cit.*, p. 4.

<sup>12</sup> Article 65.2 of the TRIPS Agreement.

<sup>13</sup> Articles 27 and 33 of the TRIPS Agreement.

<sup>14</sup> Article 65.4 of the TRIPS Agreement.

<sup>15</sup> Article 70.8 and 70.9 of TRIPS Agreement.

<sup>16</sup> Article 66.1 of the TRIPS Agreement.

<sup>17</sup> Article 2 (1) of the Indonesian Law Number 6 of 1989 on Patent as amended by the Indonesian Law Number 13 of 1997.

<sup>18</sup> Article 2 (1) of the Indonesian Law Number 14 of 2001 on Patent.

TRIPS<sup>18</sup>, and finally, it is provided in the recent Patent Law Number 13 of 2016.<sup>19</sup> For the minimum 20 years protection term, it was provided after TRIPS in the Law Number 14 of 2001<sup>20</sup> and then it is provided in the recent patent Law Number 13 of 2016<sup>21</sup>, whereas before TRIPS, the Law Number 6 of 2016 on Patent provided 14 years protection term and could be extended for 2 years.<sup>22</sup> Next, regarding protection for both products and processes in all fields of technology, it was provided in the Law Number 6 of 1989 before TRIPS<sup>23</sup>, in the Law Number 14 of 2001 after TRIPS<sup>24</sup>, and recently it is provided in the Patent Law Number 13 of 2016.<sup>25</sup> In conclusion, Indonesia IP legal system has already adopted the transition period flexibility of TRIPS in the recent Patent Law. This provision limits the patent to be used to encounter COVID-19 pandemic. Since there is a monopoly of the right holder, there are other flexibilities that can be used to encounter COVID-19 such as compulsory license and government use.

## b. Compulsory License

A compulsory license is an authority granted by the national authority (government) to someone (a party), without permission or without conflict with the rights holder, to exploit patented objects or other IP.<sup>26</sup> "Compulsory license is a license issued by a state authority to a government agency, a company or other party to use a patent without the patent holder's consent" (Paris Convention, 1883). In simple words, "compulsory license is an action of a government forcing an exclusive holder of a right to grant the use of that right to other upon the terms decided by the government".<sup>28</sup> The government, however, pays a royalty to the patent holder in order to compensate them for the use of their patent without their consent.<sup>28</sup> In other words, "Compulsory license means a non-voluntary license issued by the state to a third party, without the authorization of the patent holder, on the condition that the licensee pays reasonable remuneration to the right holder in return".<sup>29</sup>

Developing countries are generally not ready or able to neutralize the impact of

<sup>19</sup> Article 3 (1) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>20</sup> Article 8 (1) of the Indonesian Law Number 14 of 2001 on Patent.

<sup>21</sup> Article 22 (1) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>22</sup> Article 9 (1) and 42 of the Indonesian Law Number 6 of 1989 on Patent as amended by the Indonesian Law Number 13 of 1997.

<sup>23</sup> Article 1 point 2 of the Indonesian Law Number 6 of 1989 on Patent as amended by the Indonesian Law Number 13 of 1997.

<sup>24</sup> Article 1 point 2 of the Indonesian Law Number 14 of 2001 on Patent.

<sup>25</sup> Article 3 (2) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>26</sup> Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, (Geneva: South Centre, 1999), p. 3.

<sup>27</sup> T. Jain, "Compulsory Licenses Under Trips and Its Obligations for Member Countries", *Journal of Intellectual Property Rights* (2009).

<sup>28</sup> E. Durojaye, "Compulsory Licensing And Access To Medicines In Post Doha Era: What Hope For Africa?" *Journal of Intellectual Property Law* (2011).

<sup>29</sup> J. Kuanpoth, *Intellectual Property and Access to Essential Medicines: Options for Developing Countries*, *Journal of Generic Medicines* (2004).

price increases caused by the existence or strengthening of IP rights that may affect access to protected products, especially by low-income populations. In this context, the possibility of using compulsory licenses as a tool to reduce the impact of IP rights exclusively. Especially in situation in some countries, where the price of drugs is not affordable for the majority of the population, and opposition by the United States government to compulsory licenses, has revived the debate over the use of compulsory licenses to achieve the public interest goal.<sup>30</sup> In order to ensure the widest possible use of compulsory licensing, developing countries should not only incorporate within their patent laws provisions to enable the granting of compulsory licenses, but they should also specify as many of the possible grounds for the issuing of licenses in order to avoid ambiguity or uncertainty.<sup>31</sup> The TRIPS Agreement does not explicitly mention the term compulsory license in the text, but Article 31 is implied to allow compulsory license and government use without authorization of the right holder.<sup>32</sup> Article 31 of the TRIPS Agreement states: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third

parties authorized by the government, there are some following provisions shall be respected", such as, Article 31 (a), (b), (f) and (j) of the TRIPS Agreement.<sup>33</sup>

There are certain common requirements on compulsory license: (a) the authorization of such use must be considered on its individual merits; (b) such use may be permitted only if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions, which efforts have not been successful within a reasonable time; (c) the scope and duration of such use must be limited to the purpose for which it was authorized, (d) such use must be non-exclusive; (e) such use must be non-assignable, except with that part of the enterprise or goodwill which enjoys such use; (f) any such use must be authorized predominantly for the supply of the domestic market of the Member authorizing such use; (g) authorization for such use must be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority must have the authority to review, upon motivated request, the continued existence of these circumstances; (h)

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<sup>30</sup> Carlos M. Correa (1999), *op. cit.*, p. 1.

<sup>31</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>32</sup> Timothy Bazzle, "Pharmacy of the Developing World: Reconciling Intellectual Property Rights in India with The Right To Health: Trips, India's Patent System and Essential Medicines", *Georgetown Journal of International Law*, Vol. 42 (2011), p. 788

<sup>33</sup> Sri Wartini, "The Legal Implication of Compulsory License Pharmaceutical Products In The TRIPs Agreement to the Protection of the Right to Health in Developing Countries", *Jurnal Dinamika Hukum* Vol. 18 No. 1, (January 2018).

the right holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization; (i) the legal validity of any decision relating to the authorization of such use must be subject to judicial review, or other independent review by a distinct higher authority in that Member; and any decision relating to the remuneration provided in respect of such use must be subject to judicial review, or other independent review by a distinct higher authority in that Member.<sup>34</sup>

One of the most important restrictions is adopted in Article 31(f)-the use of commercial license should be "predominantly for the supply of the domestic market." The term "predominantly" in Article 31(f) implies that some exportation under compulsory license from the exporting nation could not be allowed to be exported to other countries which do not have the capacity to produce the medicine. Based on Article 31 (f), It is clearly ignites a problem in the implementation of compulsory license in developing countries which do not have the capability to produce medicine.<sup>35</sup>

Article 31 does not hamper the grounds on which compulsory licensing is allowable, and it becomes the authority of states to determine the balance of the protection of patent holders and the interest of the patients. Article 31(b) provides that this limitation may be waived by a Member

in the event of a national emergency. Unfortunately, there is no explanation what constitute "national emergency" in the TRIPs Agreement. The Contracting Parties of the TRIPs Agreement have a freedom to define what national emergency is. For example, the endemic of HIV/AIDS which occur in a developing country can be considered as national emergency.<sup>36</sup>

Most countries provide for the use of patented inventions without the consent of the patent holder in emergency situations, such as war, famine, natural catastrophe, and so on. In the case of compulsory licenses for emergencies, the requirement for prior negotiations for a voluntary license is also waived and it should also be reflected in the domestic law.<sup>37</sup> The COVID-19 pandemic can be also considered as national emergency. In Indonesia, the government issued Presidential Decree No. 11 of 2020 on Determination of the COVID-19 Public Health Emergency. Therefore, based on this Decree, the COVID-19 pandemic can be stated as national emergency situation in connection with public health in Indonesia. In this condition, the compulsory license on patent is possible to be implemented in Indonesia to overcome the COVID-19 pandemic situation.

In Indonesian IP legal system, the compulsory license of patent is provided in article 81 to 108 of the Law Number 13

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<sup>34</sup> Coenraad Visser, *Patent Exceptions and Limitations in the Health Context*, (Geneva: WIPO Standing Committee on Patent, SCP/15/3, 2010).

<sup>35</sup> Sri Wartini, ", *op. cit.*

<sup>36</sup> Sri Wartini, *ibid.*

<sup>37</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

of 2016 on Patent, and its implementing regulation is regulated by the Minister of Law and Human Rights Regulation Number 30 of 2019. Basically, compulsory license is a non-exclusive<sup>38</sup>, and is given through the Minister of Law and Human Rights' decision, based on reasons: (a) The Patent Holder does not carry out the obligation to make products or use the process in Indonesia within 36 (thirty-six) months after being granted a Patent; (b) Patents have been implemented by the Patent Holder or licensee in a form and manner that is detrimental to the interests of the public; or (c) Patents resulting from the development of patents that have been previously granted cannot be carried out without the use of other parties' patents that are still in protection.<sup>39</sup>

Eventually, the situation was difficult for implementing the compulsory license since there was still no vaccine or medicine for COVID-19 has been invented yet, even in Indonesia. However, there were some efforts from big pharmaceutical company such as Gilead in United States. Gilead was working with regulatory authorities worldwide to map out options to make access to investigational Remdesivir wider available through expedited regulatory processes globally, should it demonstrate the potential to be a safe and effective treatment option based on the results of preliminary clinical trials. In the United

States, the Food and Drug Administration (FDA) has authorized the emergency use of Remdesivir to treat hospitalized adult and pediatric patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. The FDA's Emergency Use Authorization will enable appropriate patients more ready access to Remdesivir at this time, due to the public health emergency. Remdesivir has not been approved by the FDA for any use, and the safety and efficacy of Remdesivir for the treatment of COVID-19 are not yet established.<sup>40</sup> Remdesivir is one of the more promising treatments for COVID-19 selected for the WHO Solidarity trial. It is an experimental antiviral medicine developed by Gilead Sciences with substantial public funding that has not been approved for any indication. Various clinical trials are ongoing to test for safety and efficacy for COVID-19. Clinical trial results from China are expected in mid-April 2020 and from the United States in May 2020. Gilead holds various patents for Remdesivir in multiple countries. This means that no other party would be able to develop or produce the medicine unless authorized through a license by Gilead.<sup>41</sup>

In Indonesia, the government through public R&D organization of the Ministry of Agriculture also has an effort to use Eucalyptus for medicine of COVID-19. Eucalyptus plants are known to have several

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<sup>38</sup> Article 81 of the Indonesian Law Number 13 of 2016 on Patent.

<sup>39</sup> Article 82 (1) a, b, dan c of the Indonesian Law Number 13 of 2016 on Patent.

<sup>40</sup> <https://www.gilead.com/purpose/advancing-global-health/COVID-19> (accessed 22 May, 2020).

<sup>41</sup> Viviana Muñoz Tellez, *The COVID-19 Pandemic: R&D and Intellectual Property Management for Access to Diagnostics, Medicines and Vaccines*, (Geneva: South Centre, POLICY BRIEF, No. 73, April 2020).



benefits including relief of the respiratory tract, eliminating mucus, repelling insects, disinfecting wounds, relieving pain, reducing nausea and preventing mouth disease. The main active ingredient is cineol-1,8 which acts as an antimicrobial and antiviral agent. The R&D organization of the Ministry of Agriculture has already done the research by using this plant. Testing of eucalyptus against influenza viruses, Beta and Gamma Corona viruses shows the ability to kill viruses by 80-100 percent. The invention has been tested on those who exposed to COVID-19 and the results are very good. But at that time, that is still had to wait from the relevant parties to be distributed.<sup>42</sup> This invention has been lodged for patent protection to the Directorate General of Intellectual Property (DGIP). The Indonesian Centre for Veterinary Research, the Centre for Agricultural Postharvest Research, and the Spice and Medicinal Research Institute have applied patents, including: (1) Eucalyptus Oil-Based Aromatic Formula Antivirus with application number P00202003578; (2) Eucalyptus-based Antivirus Inhaler and Manufacturing Process with patent application number P00202003574; and (3) Eucalyptus-based Nano-encapsulate Antibiotic Potion powder with patent application number P00202003580. Another invention, that

is *Eucalyptus citridora* essential oil as an antivirus against avian influenza virus subtype H5N1, gamma-corona virus, and beta virus. Based on Indonesian Patent Law, for granting of patent needs maximum 54 months to be processed at the DGIP.<sup>43</sup> Cooperation is carried out for the development of product innovation through a licensing cooperation mechanism, in this case with PT Eagle Indo Pharma as a R&D Organization of Ministry of Agriculture (*Balitbangtan*) licensing partner. Cooperation partners have an obligation to produce technology with supervision from the *Balitbangtan*.<sup>44</sup>

By this situation, the possibility for implementation of compulsory license will take time, while the pandemic keep spreading at that time. Therefore, it will be difficult to process the compulsory licensing in this emergency situation since the process to apply the compulsory license needs a certain procedure and it will take time. The period of time to process compulsory license, excluding the postponement period, is no later than 12 (twelve) months from the date of notification of the postponement by the Minister.<sup>45</sup> This is in line with the limit of compulsory license in practice: (1) the process of issuing such licenses is long, expensive and politically very sensitives; (2) even if significant reductions are obtained for the

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<sup>42</sup> <https://www.cnnindonesia.com/gaya-hidup/20200511080522-255-501912/pemerintah-kembangkan-eucalyptus-untuk-obat-antivirus-corona> (Accessed 23 May, 2020)

<sup>43</sup> The Indonesian Law Number 13 of 2016 on Patent.

<sup>44</sup> <https://www.kompas.com/tren/read/2020/05/19/164705565/ini-4-produk-anti-virus-corona-yang-dipatenkan-balitbangtan-kementan?page=all#page3> (Accessed 23 May, 2020).

<sup>45</sup> Article 88 (3) of the Indonesian Law Number 13 of 2016 on Patent.

drugs produced under compulsory license, the impact on the overall cost of treatment remains slight; lastly (3) the process is subject to dispute and legal challenge.<sup>46</sup>

### c. Government Use

A Government Use Authorization (or compulsory license for public non-commercial use) can be considered as a special case of compulsory licensing, i.e. it is a compulsory license that the government issues for its own purposes, for instance to ensure the availability of medicines in public health facilities. The TRIPS Agreement allows countries to issue compulsory licenses including government use authorizations, and leaves countries free to decide the grounds, or reasons, for issuing a compulsory license.<sup>47</sup> Government Use is a public or non-commercial use of Patents. The right of the state to use a patent without the consent of the patent holder for public health purposes is recognized to be an important public health safeguard by many countries. Although Article 31 of the TRIPS Agreement sets out the conditions governing both government use of patents and compulsory licenses, one important difference is that government use of patents may be "fast-tracked" because of the waiver of the requirement for prior negotiations with patent holders; in this regard, the

establishment of a straightforward and simple administrative system of inter-agency decision-making process, as in the case of compulsory licensing, is also paramount. As for compulsory licenses, it will also be important to formulate open and transparent decision-making processes and procedures, including the formulation of guidelines for determining adequate remuneration so that it is predictable and easy to administer. A single administrative system could serve the purpose of facilitating decision-making in relation to the granting of compulsory licenses and government use authorization.<sup>48</sup>

Indonesia IP legal system provides provisions on the Government Use for patent through the Indonesian Law Number 13 of 2016 on Patent; the Government Use on Patent is provided in Article 109 to 120 of the Law Number 13 of 2016 on Patent. The government can implement patents themselves in Indonesia based on considerations relating to national defense and security or urgent needs for the benefit of the public and be implemented on a limited basis, to meet domestic needs, and are non-commercial in nature.<sup>49</sup> The Government Use on patent including pharmaceutical and/or biotechnology products which are expensive and/or necessary to cope with diseases that can

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<sup>46</sup> Benjamin Coriat and Luigi Orsenigo, "IPRs, Public Health and the Pharmaceutical Industry: Issues in the Post-2005 TRIPS Agenda", in book: Mario Cimoli et.al, *Intellectual Property Rights: Legal and Economic Challenges for Development*, (UK: Oxford University Press, 2014), p. 219-241.

<sup>47</sup> UHC Technical Brief, "Public Health Protection in Patent Laws: Selected Provisions", (World Health Organization, 2017).

<sup>48</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>49</sup> Article 109 (1) dan (2) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>50</sup> Article 111 a of the Indonesian Law Number 13 of 2016 on Patent.

cause sudden death in large numbers, significant disabilities, and constitute a World-Worst Public Health Emergency.<sup>50</sup> In the case of the Government Use for urgent needs, it is in the public interest not to reduce the right of the patent holder to exercise his exclusive rights.<sup>51</sup>

In the event that the Government intends to use a Patent that is important to the most urgent needs of the public interest, the Government shall notify the Patent Holder in writing of such matter.<sup>52</sup> A copy of the Presidential Regulation on approval of the use of a Patent by the Government shall be sent by the Minister to the Patent Holder.<sup>53</sup> The Government Use of Patent is recorded in the general register of patents and announced through electronic and/or non-electronic media.<sup>54</sup> The Government's decision that a Patent is implemented solely by the Government is final and binding.<sup>55</sup> In the event that the Government cannot implement the Patents themselves, the Government may appoint a third party to implement.<sup>56</sup> These third parties must fulfil the following requirements: (a) have facilities and are capable of implementing patents; (b) does not transfer the use of the Patent concerned to another party; and (c) have a good method of production, circulation,

and supervision in accordance with statutory provisions.<sup>57</sup> The awarding on behalf of the Government is carried out by a designated third party.<sup>58</sup> The procedure for the Government Use of patents by the Government shall be regulated by a Presidential Regulation.<sup>59</sup>

The TRIPs Agreement actually regulates three choices that can be made by the government to get cheap AIDS drugs, namely: collaborative drug research, parallel imports, and the implementation of patents by the government. The Indonesian government ultimately sought to show its concern for the people who needed affordable AIDS medicines. Out of the three choices, the Government of Indonesia finally chooses the third option for the administration of patents by the government; without Government Use procedures, patents of a drug product can only be accessed if it has been 15-20 years. Regarding the policy of implementing patents by the government for the production of antiretroviral (ARV) drugs, the Government of Indonesia has issued three Presidential Regulations. First Presidential Decree of the Republic of Indonesia Number 83 of 2004 on the Implementation of Patents by the Government on Anti-Retroviral

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<sup>51</sup> Article 112 (2) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>52</sup> Article 114 (1) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>53</sup> Article 114 (2) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>54</sup> Article 114 (3) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>55</sup> Article 114 (4) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>56</sup> Article 116 (1) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>57</sup> Article 116 (2) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>58</sup> Article 116 (3) of the Indonesian Law Number 13 of 2016 on Patent.

<sup>59</sup> Article 116 (3) of the Indonesian Law Number 13 of 2016 on Patent.

Medicines, Presidential Decree of the Republic of Indonesia Number 6 of 2007, and Regarding Amendments to the Presidential Decree Number 83 of 2004 on the Implementation of Patents by the Government on Anti-Medicines Retroviral, and most recently on 3 September 2012, issued Presidential Regulation of the Republic of Indonesia Number 76 of 2012 on the Use of Patents by the Government on Antiviral and Antiretroviral Drugs.<sup>60</sup>

In 2004, the Minister of Health also issued a Decree, Decree of the Minister of Health of the Republic of Indonesia Number 1190/MENKES/SK/X/2004 on Provision of Anti-Tuberculosis Drugs and Anti-Retroviral Drugs for HIV/AIDS. In addition, the Minister of Health also gave Decree to Kimia Farma with Decree of the Minister of Health of the Republic of Indonesia Number 1237/Menkes/SK/VI/2004 on the Appointment of PT. Kimia Farma (PERSERO) TBK to carry out patents of ARV drugs on behalf of the Government. Since the decree been issued, PT. Kimia Farma began producing local ARV drugs, AZT, 3TC and nevirapine. The three products have been tested for bioavailability and bioequivalent at the Faculty of Pharmacy ITB. With the results of BA & BE both products have been registered at the BPOM. The government finally issued a presidential decree (Keppres) which said that Indonesian

people needed more affordable ARV drugs. Therefore, the Indonesian government has officially implemented government use. The 2004 Presidential Decree also stated that the Indonesian government would pay 0.5% of the royalty to the patent owner.<sup>61</sup>

If the drug, vaccine or medical device fulfills the patent criteria, which is new, contains inventive steps and can be applied in the industry then the product can be granted a patent, even though the drug is generally needed by the world community in dealing with this pandemic. Furthermore, in order for the drug to be massively available in an emergency, the solution available in the patent system is through a compulsory licensing mechanism and/or the use of patents by the government (government use). Based on the provisions of the Article 31 TRIPS, it is possible for a State to apply for a compulsory license or government use, especially in emergency situations. In this situation, it is possible to implement a patent without permission from the patent owner. In Patent Law No. 13 of 2016, the compulsory license and implementation of patents by the Government, as mentioned in the regulation, provided that the Government can carry out patents without permission from the patent holder in urgent situations including producing expensive products and/or needed to cope with diseases that can result in sudden death

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<sup>60</sup> <https://www.kebijakanidsindonesia.net/id/artikel/artikel-kontribusi/470-kebijakan-pelaksanaan-paten-obat-arv-oleh-pemerintah-indonesia> (accessed 24 May, 2020)

<sup>61</sup> <https://www.kebijakanidsindonesia.net/id/artikel/artikel-kontribusi/470-kebijakan-pelaksanaan-paten-obat-arv-oleh-pemerintah-indonesia> (accessed 24 May, 2020)

in large quantities. Thus, the inventor of drugs can get economic rights and their creations protected. Basically, the COVID-19 pandemic situation meets the requirements for the Government to take steps to provide the drugs needed for the treatment needed through the government use mechanism.<sup>62</sup>

Therefore, for Indonesia, the most effective and faster procedure to overcome the COVID-19 pandemic is by implementing the Government Use. In this approach, the Government has initiative to implement the patent based on the presidential regulation with the principle of non-voluntary and non-exclusive license. The possibility to implement this Government Use in Indonesia is to use patent for Remdisivir and other medicine or vaccine which have already invented for being used in COVID-19 pandemic.

#### **d. Parallel Imports**

Parallel importation refers to importation, without the consent of the patent holder, of a patented product that is marketed in any other country. In other words, parallel importation allows for importation of the patented product from a third country where it is sold at a lower price. Parallel importation works most effectively when countries adopt an "international exhaustion" regime, thus

allowing the imports of patented products marketed anywhere in the world. Like a "Bolar" provision, parallel importation is usually incorporated in the section of the law that deals with exceptions to the rights conferred by a patent.<sup>63</sup>

Parallel import is the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent. A patent holder may have the exclusive right to manufacture his product and to put it on the market. However, once the product is placed on the market, the principle of exhaustion means that the patent holder has no further right over the product. Thus, a patent holder cannot prevent the subsequent resale of that product since their rights over the product have been exhausted by the act of selling it.<sup>64</sup>

Parallel importation is allowed under the TRIPS Agreement. Article 6 of the TRIPS Agreement provides that matters relating to exhaustion of rights shall not be subject to dispute settlement. They have three main options:<sup>65</sup> (1) Members may adopt the principle of international exhaustion of patent rights. Adoption of this principle in the national patent law would allow any party to import into the

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<sup>62</sup> <https://ekonomi.bisnis.com/read/20200419/257/1229318/obat-COVID-19-dibutuhkan-masyarakat-peneliti-bisa-daftarkan-paten> (accessed 24 May, 2020)

<sup>63</sup> UHC Technical Brief, "Public Health Protection in Patent Laws: Selected Provisions", (World Health Organization, 2017).

<sup>64</sup> Velasquez G. and P. Boulet, *Globalisation and Access to Drugs: Perspectives on the WTO/TRIPS Agreement*, (Geneva: Health Economics and Drugs Series, EDM Series No. 7, WHO, 1999)

<sup>65</sup> Sisule F. Musungu and Cecilia Oh, *The Use of Flexibilities In TRIPS by Developing Countries: Can They Promote Access to Medicines?*, (Geneva: South Centre, 2006).

national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party; (2) Members may adopt regional exhaustion of rights, where adoption of this principle would allow the possibility of importing into the national territory a patented product originating from any other member state of a regional trade agreement; and (3) The third option is that of national exhaustion of rights. This principle limits the circulation of products covered by patents in one country to only those put on the market by the patent owner or its authorized agents in that same country. In this case, there can be no parallel importation.

Developing countries should therefore avail themselves of the widest scope in terms of parallel imports and incorporate explicit provisions to put into effect the international exhaustion regime. It is important to note in this context that while this "flexibility", allowed in the TRIPS Agreement and confirmed by the Doha Declaration, does not automatically translate into the national regimes, it will be necessary for specific legal provisions to be enacted in national laws.<sup>66</sup>

In Indonesian Patent Law, the parallel import for especially pharmaceutical products is regulated in the Article 167 a of the Indonesian Law Number 13 of 2016 on Paten, stated that the import of

a pharmaceutical product that is protected by a patent in Indonesia and the said pharmaceutical product has been legally marketed in a country provided that the pharmaceutical product is imported in accordance with statutory provisions cannot be declared as patent infringement. Discussions about access to drugs for the prevention and treatment of COVID-19 are becoming increasingly important. The increasing number of positive sufferers of COVID-19 has encouraged the government to provide several drugs that are suspected of being potential in treating diseases caused by the Corona Virus. If later the most effective COVID-19 drug is found, the challenges will increase because all countries will compete with each other over the drug. Based on the International Clinical Trials Registry Platform of the WHO, until now there have been at least 536 clinical studies of potential drugs for COVID-19. WHO also developed the Solidarity Trial. The drugs being tested are almost all patents originating from abroad.<sup>67</sup> Therefore, the use of parallel import to get vaccines and medicines for COVID-19 is needed for the Government of Indonesia to overcome the COVID-19 outbreak in Indonesia. This approach can be used if there is no capability of pharmaceutical industries in Indonesia to produce vaccines and medicines for preventing and healing COVID-19.

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<sup>66</sup> Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement*, (Geneva: South Centre and WHO, 2002).

<sup>67</sup> <https://kumparan.com/erik-mangajaya-simatupang/akses-pada-obat-COVID-19-1tJqe1Xgqwt/full> (accessed 24 May, 2020)

<sup>68</sup> Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, (Geneva: South

### e. Exceptions to Patent Rights

Virtually all patent laws provide for exceptions to the exclusive rights granted by a patent, although the scope and content of these provisions vary from country to country.<sup>68</sup> Exceptions to Patents Rights are based on the premise that the rights conferred by patents are not absolute and, in certain circumstances use of a patented invention by third parties is justified, in order to achieve public policy objectives of facilitating the dissemination of knowledge, encouraging innovation, promoting education and protecting other public interests.<sup>69</sup>

The TRIPS Agreement allows for "limited exceptions" to the exclusive rights conferred by a patent. The Agreement does not define the nature and extent of these exceptions but, it provides a general test to be used to determine their admissibility. Article 30 of the TRIPS Agreement requires a three-fold test to be satisfied; that the exception does 1) not unreasonably conflict with the normal exploitation of the patent; 2) not unreasonably prejudice the legitimate interests of the patent owner, and 3) take into account the legitimate interests of third parties. Each condition must be satisfied as a separate and independent condition. In addition, the

conditions must also be interpreted in relation to each other.<sup>70</sup>

While it is obvious that Article 30 does not permit unreasonable interference with the patent rights, its wording suggests that some impact on patent rights is envisaged.<sup>71</sup> The early working exception for example, has a significant impact on patent rights by speeding up the approval of generic competition by as much as three years. This exception also generally known as the "Bolar exception" after the United States case on the use of this exception was introduced in the United States Drug Price Competition and Patent Term Restoration Act (1984), to permit the testing of a medicine for establishing the bio-equivalency of generic products before the expiration of the relevant patent. The TRIPS-compliant nature of this exception was confirmed by a WTO panel decision in 2000, which addressed the legality of the Canadian provision on early working.<sup>72</sup>

The patent law review indicated that most countries incorporated either one of two exceptions to patent rights. The first is the research exception or the exception for experimental use of patents. In nearly all of the country legislation reviewed, an explicit exception has been provided for use of patents for research purposes or the

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Centre, 2000)

<sup>69</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>70</sup> The WTO Panel in the Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R (17 March 2000).

<sup>71</sup> UNCTAD and ICTSD, *Resource Book on TRIPS and Development*, (Cambridge: Cambridge University Press, 2005)

<sup>72</sup> *Ibid.* The complaint was brought by the EU against Canada under the WTO dispute settlement mechanism, in which the EU questioned the legality of a Canadian provision allowing not only the testing of medicines prior to patent expiry, but also production and stock-piling of the generic product for immediate release upon patent expiry. The Panel confirmed the early working provision was TRIPS-consistent but, the production and stockpiling was not.

experimental use of patents. National laws reviewed in Latin American and Caribbean countries all contained provisions relating to the research or experimental use exception; in Asia, 85% of the national laws reviewed provided for this exception, although the figure is lower in Africa at 59%.<sup>73</sup>

Indonesia provides the provisions on exceptions to patent rights, in Article 167 of the Indonesian Patent Law Number 13 of 2016 on Patent. In this article, it is regulated that the exceptions to patent rights in connection with Bolar Provision, which says that the production of the pharmaceutical products whereby it is protected by patent in Indonesia, in the period time 5 (five) years before the end of patent protection, with the objective to process marketing authorization, then it can be marketed after the patent has been expired.

#### **f. Exemptions from Patentability**

The TRIPS Agreement only requires that patents be granted to products and processes which are new, involve an inventive step and are industrially applicable. The Agreement does not require the patenting of new uses of known products including pharmaceuticals, and permits countries to deny protection for such uses for lack of novelty, inventive step or industrial applicability. Protection of new uses, particularly second medical

indications, is often used for anti-competitive purposes mainly for extending patent protection periods and blocking generic entry. Therefore, it is prudent for developing countries to exclude new uses of known products or processes from patentability, in order to promote access to medicines. This is the approach recommended by the IPR Commission, which stated that "most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products".<sup>74</sup>

Prior to the TRIPS Agreement, under the Paris Convention for the Protection of Industrial Property (1883), countries were able to exclude certain areas from patentability and to make special rules for certain types of invention. There are numerous examples of how domestic laws defined and applied the patentability criteria, according to the prevailing technology levels and public policy priorities.<sup>75</sup> At the start of negotiations on the TRIPS Agreement, some 50 countries did not provide patent protection for pharmaceutical products at all, and some also excluded pharmaceutical processes from protection.<sup>76</sup> These general exclusions from patentability of pharmaceutical products, once common in national patent laws, will no longer be permitted when countries are obliged to

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<sup>73</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>74</sup> *Ibid.*

<sup>75</sup> *Ibid.* Such as the exclusion of pharmaceutical and food products, chemical processes, and agricultural methods.

<sup>76</sup> UNCTAD, *The TRIPS Agreement and Developing Countries*, (New York and Geneva: UNCTAD, 1996)

<sup>77</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*



implement the TRIPS Agreement in full.<sup>77</sup> Article 27.1 of the TRIPS Agreement now makes it obligatory for WTO Members to make available patent protection to all inventions, in all fields of technology. The Article also sets out the criteria of novelty, inventive step and industrial applicability, which an invention must meet to qualify for a patent. Although there appears to be a general principle of eligibility to be patented where these criteria are satisfied, there is still some degree of flexibility for countries in their national implementation. Since the TRIPS Agreement does not define the terms "novelty, inventiveness and industrial applicability", WTO Members may determine how these criteria should be interpreted and applied, and hence, the scope of patentability of pharmaceutical inventions.<sup>78</sup>

From a public health perspective, where patentability standards are too lax, the terms "novelty" and "inventive step" are too loosely defined then too many secondary patents may be granted on the various forms of the new chemical entity, such as the formulation, and new combinations and uses, which will have implications for access to medicines. The innovation claimed in pharmaceutical patents range from major "discoveries" to minor modifications of existing medications. New

molecules or new innovative medicines are now rare, yet pharmaceutical patents number in the thousands each year. This raises a number of questions as to the number of patents that may be granted for minor modifications.<sup>79</sup> A related concern is that of the quality of patents granted, given that a number of studies have given rise to a general opinion that the patent offices have been lax in granting certain types of patents, including pharmaceutical patents.<sup>80</sup>

In the Indonesian Patent Law, there are several inventions cannot be protected by the patent, namely aesthetics creations, schemes, rules and methods to do something (involve mental activities, games, business), rules and methods which only contain computer programs, presentation on information, and discovery (new use of existing or known products and/or new forms of existing compounds which do not result in a significant increase in efficacy and known chemical structure differences are known from the compounds).<sup>81</sup> Therefore, Indonesia does not protect a "secondary patents" refer to the provision regarding discovery which not includes subject to be protected by the patent as it is provided in Article 4 f of the Law Number 13 of 2016 on Patent.

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<sup>78</sup> Ibid.

<sup>79</sup> The National Institute of Health Care Management Research and Educational Foundation (NIHCM) showed that during the 12 year period 1988-2000, only 35% of the 1,035 drugs approved by the FDA contained a new active ingredient (NIHCM 2002). Highly innovative drugs are increasingly rare.

<sup>80</sup> Carlos Correa, *Trends in Drug Patenting: Case Studies*, (Buenos Aires: Corregidor, 2001).

<sup>81</sup> Article 4 of the Indonesian Law Number 13 of 2016 on Patent.

<sup>82</sup> High-Level Panel on Access to Health Technologies, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicine: Promoting Innovation and Access to Health Technologies (Sept. 2016)

"Secondary patents" as an example of the type of patent rights that WTO Members can freely choose to accept or reject, making use of the "flexibilities" in Article 27.1 TRIPS Agreement.<sup>82</sup> The term "secondary patents" to refer broadly to patents that in effect extend the original patent based on varying methods of use, formulations, dosages and forms of constituent chemicals.<sup>83</sup> Others, such as the 2016 Correa Guidelines, refer to these as "improvement inventions," and similarly argue against their patentability along similar lines.<sup>84</sup> The HLP Report encourages governments to "adopt legislation to limit excessive patenting that stifles health technology R&D and access."<sup>85</sup> While asserting that such patents can "prolong exclusivity (commonly known as 'evergreening')" and thereby limit "patient access to health technologies."<sup>86</sup>

In connection with COVID-19 pandemic situation, the flexibility on the exemptions from patentability will help government to have easier access to medicine that is needed for healing of COVID-19, if the improvement of the previous invention only caused by varying methods of use, formulations, dosages and forms of constituent chemicals. However, this

flexibility can only be effective after the Patent of the medicine has already expired.

#### **g. Limits on Data Protection**

As a condition for permitting the sale or marketing of a pharmaceutical product, drug regulatory authorities usually require pharmaceutical companies to submit test or registration data demonstrating the safety, quality and efficacy of the product as well as information relating to the products' physical and chemical characteristics. Such information is generally collectively referred to as test data.<sup>87</sup> Once the required test data is submitted by the originator company, some drug regulatory authorities may rely on this data to approve subsequent applications for similar products or, to rely on proof of prior approval of a similar product in another country. Generic manufacturers need only to prove that their product is chemically identical to the brand name, the original product and, in some countries, that it is bio-equivalent. This approach was adopted in most countries prior to the TRIPS Agreement and enables swift introduction of generics into the market without extra registration data-related costs.<sup>88</sup> However, there are different opinions on the scope of the obligation that the TRIPS Agreement

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<sup>83</sup> *Ibid.*

<sup>84</sup> Carlos Correa, Guidelines for the Examination of Pharmaceutical Patents: Developing a public health perspective (ICTSD, WHO, UNCTAD, Working Paper 2006) [hereinafter "Correa Guidelines I"]; Carlos M. Correa, Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective (UNDP 2016).

<sup>85</sup> High-Level Panel on Access to Health Technologies, *op. cit.*

<sup>86</sup> Eric M. Solovy and Pavan S. Krishnamurthy, *TRIPS Agreement Flexibilities and Their Limitations: A Response to the UN Secretary-General's High-Level Panel Report on Access to Medicines*, (US: George Washington International L. REV. 1, Forthcoming 2017).

<sup>87</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>88</sup> Carlos Correa (2002), *op. cit.*

places on countries with respect to the protection of test data. Article 39.3 of the TRIPS Agreement requires Members to provide protection for undisclosed test or other data submitted for the purposes of obtaining marketing approval against "unfair commercial use". Proponents of higher standards of protection argue for an interpretation of Article 39.3 that grants exclusive rights over the test data. The argument is that the originator of the data deserves a return on the often-significant investment in conducting tests. This approach of granting data exclusivity has been adopted in the United States and the European Union. In the United States, the exclusivity period is five years (for new chemical entities),<sup>89</sup> while the EU Directive has been recently amended to increase the exclusivity period from six years to ten.<sup>90</sup> Thus, drug regulatory authorities are not permitted to rely on an originator's test data to approve other registration application during this period of exclusivity.

Test data need only be protected against "unfair commercial use" when three conditions are met; that is: 1) where national authorities require the data to be submitted; 2) if the data is undisclosed (and not already public data); and 3) if "considerable effort" was involved in generating the data. In addition, protection

is required only for new chemical entities, which means that applications for second indications, formulations and dosage forms may be excluded from protection.<sup>91</sup>

There is an obvious public health interest in limiting data protection, so that the timely entry of generic competition is not unnecessarily hindered or prevented. Generic manufacturers may not enter the market until they are able to rely on the use of the originators' test data, as it is too time-consuming and expensive for the generic industry to repeat the safety and efficacy testing. There are also significant ethical questions regarding conducting human clinical trials in particular, when data already exists on quality and efficacy. Exclusive rights over test data can provide patent-like protection even where pharmaceuticals are not covered by patents or, do not meet the standards of patentability in a country or, prevent the registration of a product produced under a compulsory license. In either case, access to the generic medicine is affected.<sup>92</sup> For developing countries it will be important to clarify the extent to which test data is protected within the domestic law. As with other provisions of the TRIPS Agreement, flexibility is provided in terms of countries' ability to determine the appropriate means of protecting test data.<sup>93</sup> It is clear that the

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<sup>89</sup> *Ibid.*

<sup>90</sup> EU Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use (Official Journal of the European Communities No. L 311/67) as amended by Directive 2004/27/EC in 2004 (Official Journal of the European Union No. L 136/34).

<sup>91</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*

<sup>92</sup> *Ibid.*

<sup>93</sup> Carlos Correa (2002), *op. cit.*

<sup>94</sup> Commission on Intellectual Property Rights (IPR Commission), *Integrating Intellectual Property Rights and De-*

TRIPS Agreement does not require data exclusivity; the obligation is to protect against unfair commercial use. Developing countries should allow drug regulatory authorities to approve equivalent generic substitutes on the basis of reliance on the originator data.<sup>94</sup>

Indonesia does not implement the data protection approach like in the United States and the European Union. This condition will give positive impact to the access of medicine, mainly for the easiness of the production of generic medicines in Indonesia. This limits on data protection can help the Government in facing the COVID-19, since there is no second layer for pharmaceutical product protection as it is based on data protection or data exclusivity.

#### **h. Implementation of the WTO Decision on the Implementation of Paragraph 6 of the Doha Declaration 2001**

The WTO addressed the problem of countries with insufficient or no manufacturing capacity and their inability to make effective use of compulsory licensing in the so-called Paragraph 6 negotiations. Paragraph 6 of the Doha Declaration 2001 instructed WTO Members to find "an expeditious solution" to address this problem, which they eventually did in August 2003.<sup>95</sup> In the exporting country, patent status of the medicine is

also relevant if the medicine is patent-protected; the generic manufacturer would need a compulsory license to produce and export. It is recommended that whenever possible, countries should consider using measures less cumbersome than the system in the WTO Decision. The Decision does not preclude other options available under the TRIPS Agreement and the Doha Declaration, as is clearly stated in Paragraph 9 of the Decision. Thus, where no relevant patent is in force in the exporting country, production and export of the generic version of a medicine patented elsewhere can take place without the need of a compulsory license.<sup>96</sup> Paragraph 6 "recognizes that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." Compulsory licensing, formally referred to as "other use without authorization of the right holder" in Article 31 of the TRIPS Agreement, occurs when "the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government." Paragraph 6 of the Declaration instructs the TRIPS Council to find "an expeditious solution to this problem" of WTO Members

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*velopment Policy*, (London: IPR Commission, 2002).

<sup>95</sup> Sisule F. Musungu and Cecilia Oh, *op. cit.*. Although they missed the deadline of December 2002 as set out in the Doha Declaration, WTO Members finally adopted a solution to the Paragraph 6 problem, after intensive negotiations, on August 30, 2003 in Geneva.

<sup>96</sup> *Ibid.*

<sup>97</sup> Eric M. Solovy and Pavan S. Krishnamurthy, *op. cit.*

that are unable to make effective use of compulsory licensing due to insufficient manufacturing capacity, a direction which ultimately led to the amendment of the TRIPS Agreement.<sup>97</sup>

In Indonesia, Paragraph 6 Doha Declaration 2001 has been implemented by three decrees namely (1) Presidential Decree of the Republic of Indonesia Number 83 of 2004 on the Implementation of Patents by the Government on Anti-Retroviral Medicines; (2) Presidential Decree of the Republic of Indonesia Number 6 of 2007, and Regarding Amendments to the Presidential Decree Number 83 of 2004 on the Implementation of Patents by the Government on Anti-Medicines Retroviral; and (3) Presidential Regulation of the Republic of Indonesia Number 76 of 2012 on the Use of Patents by the Government on Antiviral and Antiretroviral Drugs.<sup>98</sup>

## 2. Future of IP Legal System Relating to Public Health Post COVID-19 Pandemic

One may argue that the patent system should not be used to make access to drugs more difficult, especially during a

pandemic. Can we really justify IP laws that are used in a way that limits the availability of medicines and aims at increasing profits in times of health emergency? This moment of crisis is teaching us a clear lesson in matters of the philosophical justifications of IP, whereby egoistic theories are in capable of offering convincing arguments grounding IP Protection.<sup>99</sup> In effect, theories that consider personal gain both in terms of existential self-realization<sup>100</sup> or economic gain<sup>101</sup> as the only legitimate source of an ethical defense of IP and as an overarching reason in cases of conflicts between individual and societal well-being appear untenable. The COVID-19 pandemic shows the essential interconnectedness of human beings as a community of unity, where individual happiness becomes possible only in cases where a certain level of welfare is collectively shared.<sup>102</sup>

A global mechanism is needed to drive open and collaborative R&D and sustain production and supply for essential diagnostics, vaccines and therapeutics.<sup>103</sup> In order to address the COVID-19 challenges, global collaboration is needed to support developing and least developed

<sup>98</sup> <https://www.kebijakanidsindonesia.net/id/artikel/artikel-kontribusi/470-kebijakan-pelaksanaan-paten-obat-arv-oleh-pemerintah-indonesia> (accessed 24 May, 2020)

<sup>99</sup> A. Moore and K Himma, *Intellectual Property*, in EN Zalta (ed.), *The Stanford Encyclopedia of Philosophy*, (Stanford, CA: Metaphysics Research Lab, Stanford University, 2018). <<https://plato.stanford.edu/archives/win2018/entries/intellectual-property>>.

<sup>100</sup> GWF Hegel, *Elements of the Philosophy of Right*, A Wood (ed.) (Cambridge: Cambridge University Press, 1991).

<sup>101</sup> John Locke, *The Second Treatise of Government*, P Leslett (ed.) (Cambridge: Cambridge University Press, 1988).

<sup>102</sup> Enrico BONADIO and Andrea BALDINI, "COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health", *European Journal of Risk Regulation*, Vol. 00:00, (2020).

<sup>103</sup> COVID-19 Pandemic: Access to Prevention and Treatment is a matter of national and international security, Open Letter from Carlos Correa, to the Director Generals of the WHO, WTO and World Intellectual Property Organization (WIPO), (4 April 2020), <https://www.southcentre.int/wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf>.

countries to scale up testing capacity and to enable equitable and affordable access to approved treatments and vaccines.<sup>104</sup> The international health community, with WHO lead, should reassert the right of governments to use TRIPS flexibilities to protect public health. Governments can act swiftly to take policy and legislative measures to ensure that patents and other intellectual property rights do not erect barriers to access to medicines, diagnostics, vaccines and medical supplies and devices.<sup>105</sup> There is a need to review national and regional regulations to assess the extent to which they provide for the above-described TRIPS flexibilities. In particular, whether they permit the effective compulsory licensing or government use of products that are protected by patents. If not, the necessary reforms should be promptly introduced in order to streamline procedures and facilitate the implementation of such measures.<sup>106</sup>

Importantly, governments should include and operationalize in their laws and regulations provisions to allow the effective use of compulsory licenses and government non-commercial use to address patent barriers to access. To facilitate their implementation, the requirements under national laws and

procedures for the grant of these licenses should be simplified to the extent possible, in accordance with international legal obligations. Most countries include in their national patent laws provisions for compulsory licensing and government non-commercial use.<sup>107</sup> Although there are many examples of instances when compulsory licensing and government non-commercial use have been used, procedures for the speedy grant of such licenses may need to be implemented. These licenses do not preclude the patent holder from continuing to exploit the invention.<sup>108</sup> Voluntary licensing has many advantages. First, good relations with investors will remain established because it is not a coercive mechanism. Second, the brand image and reputation of the investor company will also be built. Third, pharmaceutical companies feel valued because they have spent research costs that are not cheap and take a long time to produce a drug. Fourth, we can work together to develop the national pharmaceutical industry going forward.<sup>109</sup>

#### **D. Closing**

Indonesia has implemented the TRIPS flexibilities in its IP legal system but there are still impediment on its implementation in facing the COVID-19 pandemic. There

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<sup>104</sup> Viviana Muñoz Tellez, *op. cit.*

<sup>105</sup> *Ibid.*

<sup>106</sup> *Ibid.*

<sup>107</sup> Carlos Correa, *Guide for the issuance of compulsory licenses and government use of patented pharmaceuticals*, (Geneva: South Centre, Forthcoming 2020). See WIPO compilation of provisions on compulsory licenses and government use by country [https://www.wipo.int/edocs/mdocs/scp/en/scp\\_30/scp\\_30\\_3-appendix1.pdf](https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-appendix1.pdf).

<sup>108</sup> Viviana Muñoz Tellez, *op. cit.*

<sup>109</sup> <https://kumparan.com/erik-mangajaya-simatupang/akses-pada-obat-COVID-19-1tJqe1Xgqwt/full> (accessed 24 May, 2020)

are two conditions for implementation of TRIPS flexibilities, the first is a condition where the flexibility will be automatically implemented once Indonesia become WTO member, and the second is a condition when the TRIPS flexibility is possible to be implemented with a certain criteria and procedures. The first condition includes TRIPS flexibilities on (1) transition period, (2) exception to patent rights and (3) exemptions from patentability. The second condition includes TRIPS flexibilities on (1) compulsory license, (2) government use, (3) parallel import, (4) limitation of data protection and (5) implementation of paragraph 6 of Doha Declaration. The Government Use is the most effective flexibility to be used in encountering the COVID-19 pandemic. Since the government is a party which has the initiative and the executor to implement the flexibility, the procedure and time can be determined by government itself.

The issue of voluntary license which is a pro-active initiative from the right holder should be anticipated for IP legal system on public health as a lesson from this COVID-19 Pandemic for the future. Therefore, the provision on voluntary license should be provided in the future domestic patent law. The government should also start to promote and introduce the voluntary license approach to the right holders. This effort will achieve the objective of IP to balance the interest of the right holder and obligations to the public as provided in Article 7 of TRIPS Agreement.

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## Curriculum Vitae of the Author

**Dr. Andrieansjah, S.T., S.H., M.M.** graduated from **formal education**: Bachelor of Architectural Engineering (1994), Bachelor of Law (2010), Masters in Economic Management (2004) and Doctor of Law (2013); **non-formal education**: IASTP-II Intellectual Property Training at the UTS Australia (2002), Industrial Property Examination Training (Japan Patent Office-2003); Result Based Management of IP Office Training (APIC Tokyo 2010), International IP Negotiation Training-TWN/South Center (Kuala Lumpur-2017), and IP Mediation Training at the European Union Intellectual Property Office (Alicante-2019). **IP international negotiations and cooperation**: Indonesia-EFTA CEPA, Indonesia-Japan EPA, Indonesia-EU CEPA, Indonesia-Chile CEPA, Indonesia-Korean CEPA; ASEAN WGIP Cooperation, APEC, RCEP (ASEAN + 6 Countries); WIPO and WTO. **Books**: Industrial Design Examination Manual (UTS Sydney, Australia, 2002); Protecting Industrial Design Rights in Indonesia (2009); Industrial Design Rights in Intellectual Property Rights Regime: An Overview (2010); Training Modules for Industrial Design Examiner Candidates (2011); Teaching Module for Course on Industrial Design - Indonesia Open University (2012); Module for Basic Training on IPR: Protection and Development of Design and IC Topography (2012); Industrial Design Right based on the Novelty Assessment for Industrial Design (PT Alumni: 2013); Aspects of IP in International Treaties and Cooperation (2020); Protection and Novelty of Industrial Design in Indonesia and Several Countries (2020). **Articles**: Protecting Architectural Works with IPR (2007); Types of Application, Assessment of Novelty and the Utilization of Industrial Design Rights in Indonesia (Media HKI, 2007); Overview of Civil Case on Cancellation of Industrial Design Right, Precision Tooling vs Andreas STIHL (Media IPR; 2007); Partial Protection on Industrial Design (Media HKI 2009); Industrial Designs International Registration System (Media HKI 2010); Overlap Protection of Industrial Designs and Copyright (Media HKI 2010); Interpretation of the Word "Not Same" in Article 2, Paragraph (2) of the Law No. 31/2000 (Media HKI 2010); The Object of Protection in Industrial Design Right (2012); Comparative Study on Industrial Design Novelty Assessment System in the UK, USA, Japan, Australia and the European Union (IPR Journal AKHKI 2012); The Contribution of IPR Law in Achieving the Goal of Continuous Development (2017); IP and Economic Development (Media HKI 2018).