

**APRIL:****Covid-19: A Case for Compulsory Licensing**

# COVID-19:

## A CASE FOR COMPULSORY LICENSING

*“As scientists around the world race to produce the first vaccine for the coronavirus which brings about the disease known as Covid-19, we explore the role and mechanism of compulsory licensing in combating the virus.”*

### **Introduction**

On March 20, the World Health Organisation (WHO) launched the aptly-named Solidarity Trial to investigate if any of the existing drugs or their combinations would be effective against Covid-19. The megatrial is part of the global efforts to create the first vaccine for the coronavirus which at the time of writing has infected more than 1.1 million people in at least 175 countries and claimed 64,427 lives<sup>1</sup>.

In the face of this crisis, the scale of which has eclipsed the SARS in 2002-2003 and MERS in 2012<sup>2</sup>, compulsory licensing may be the leg-up that provides access to life-saving drugs, as the global scourge of the pandemic continues.

### **Compulsory Licensing**

Compulsory licensing compels the patent owner to permit others to manufacture a patented invention or its equivalent which is then sold at a much lower price to the market. This is seen as an exception to the general principle that a patent owner has complete monopolistic rights over its invention to the exclusion of everyone else – a monopoly that is legally enforceable.

Compulsory licensing allows authorities to step in when a market fails, or in the case of this pandemic, to ensure access to vital cures which may be patented by granting rights to make their generic equivalent. Naturally, patent holders consider this an affront to their exclusive rights to the patents which they had spent time and costs to develop.

Compulsory licensing has been used in a few instances, most of them by developing countries. In a WHO technical brief in 2017, up to 10 developing countries have issued compulsory licences between 2003 and 2014, including Brazil, Ecuador, India, Indonesia, Malaysia, Thailand and Zimbabwe<sup>3</sup>.

<sup>1</sup> The New York Times (n.d.), Coronavirus Map: Tracking the Global Outbreak. Retrieved from The New York Times: <https://www.nytimes.com/interactive/2020/world/coronavirus-maps.html>.

<sup>2</sup> Jiachuan Wu & Denise Chow (5 March 2020), Are coronavirus diseases equally deadly? Comparing the latest coronavirus to MERS and SARS. Retrieved from NBC News: <https://www.nbcnews.com/health/health-news/coronavirus-diseases-comparing-covid-19-sars-mers-numbers-n1150321>.

<sup>3</sup> World Health Organisation (WHO) (2017), Country experiences in using TRIPS safeguards: Part 1. Retrieved from WHO's Institutional Repository for Information Sharing: <https://apps.who.int/iris/handle/10665/272977>.

**APRIL:****Covid-19: A Case for Compulsory Licensing****India**

In March 2012, India approved its first ever compulsory licence for a generic drug maker, Natco, to make and sell a drug known as “Sorafenib tosylate” sold as Nexavar which is a crucial drug for patients with kidney and liver cancer<sup>4</sup>.

The compulsory licence allowed Natco to produce a generic version of Nexavar at about USD115 per patient per month. This represented a 97% reduction on the USD3,725 that its patent owner, Bayer AG, would charge<sup>5</sup>. It was also disclosed that only 200 patients had access to Nexavar in 2011, against the demand of 8,842 patients<sup>6</sup>.

Bayer did not go down without a fight. It took its case up to the Supreme Court of India who chose to uphold the Bombay High Court’s findings and dismissed Bayer’s Special Leave Petition<sup>7</sup>. Among others, the High Court observed that Bayer had failed to make its Nexavar “available to the public at reasonably affordable price”<sup>8</sup>.

**United States**

In the United States, the threat of compulsory licensing was sufficient to reduce drug prices.

In September 2001, a terror attack worthy of a season in the TV series “24” hit media companies and congressional offices. Anonymous letters laced with deadly anthrax spores began making its calculated appearance at various high level facilities all over the country. It killed five people and infected 17 more<sup>9</sup>.

Enter Ciprofloxacin (Cipro), the antibiotic drug that is prescribed for patients suffering from anthrax and other bacteria. Cipro had been a mega earner for its owner, again Bayer AG, who reportedly raked in USD 1.04 billion from the drug in 1999<sup>10</sup>.

The sudden increase in demand for Cipro amid the anthrax scare hiked the price of one pill in the US from USD 4-5 to USD 7<sup>11</sup>. For a recommended intake of two pills a day for 60 days, the total price tag of USD 840 puts Cipro beyond the reach of average Americans. By comparison, the cost of the same drug in India produced by a generic manufacturer was USD10 per month<sup>12</sup>.

The then United States Secretary of Health and Human Services, Tommy Thompson, declared its intention to grant compulsory licence for Cipro unless Bayer agreed to lower its prices. Seemingly forced to a corner, Bayer eventually agreed and reduced its price to about USD 1 per pill<sup>13</sup>.

4 Intellectual Property Watch (12 March 2012), India Grants First Compulsory Licence, For Bayer Cancer Drug. Retrieved from the Intellectual Property Watch: <https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-licence-for-bayer-cancer-drug/>.

5 Bayer Corporation v Union of India & Ors, Writ Petition No. 1323 of 2013 (Bombay High Court 15 July 2014). Paragraph 14(a). Retrieved from Indian Kanoon: <https://indiankanoon.org/doc/28519340/>.

6 Ibid, paragraph 13(c).

7 Khaitan & Co (15 December 2014), Compulsory license granted for Nexavar to continue, holds Supreme Court. Retrieved from Lexology: <https://www.lexology.com/library/detail.aspx?g=382da65e-855a-4e1d-a263-bad4b7032b8a>

8 Bayer v Union of India, paragraph 14(e).

9 National Public Radio (15 February 2011), Timeline: How The Anthrax Terror Unfolded. Retrieved from NPR: <https://www.npr.org/2011/02/15/93170200/timeline-how-the-anthrax-terror-unfolded>.

10 Kavaljit Singh (5 November 2011), War Profiteering: Bayer, Anthrax and International Trade, Asia-Europe Dialogue Project. Retrieved from Corpwatch: <https://corpwatch.org/article/war-profiteering-bayer-anthrax-and-international-trade>.

11 Ibid.

12 Steward, H., Denny, C., and Clark, A. (23 October 2011), Bayer bows to pressure on anthrax antidote. Retrieved from The Guardian: <https://www.theguardian.com/business/2001/oct/23/anthrax.businessofresearch>.

13 The Guardian (24 October 2011), Bayer cuts price of anthrax drug. Retrieved from The Guardian: <https://www.theguardian.com/money/2001/oct/24/personalfinancenews.business1>.

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Back home, in October 2003, Malaysia became the first country to grant a compulsory licence for three HIV/AIDS drugs patented by GlaxoSmithKline and Bristol-Myers Squibb, namely, Didanosine, Zidovudine and a fixed-dose combination of Lamivudine and Zidovudine<sup>14</sup>.

This came after the patent owners refused to offer more discounts beyond the 30-40% already offered. In response, Malaysia resorted to issuing the compulsory licence which enabled it to reduce the costs of the drugs by 81% and increase its treatment capacity from 1,500 to 4,000<sup>15</sup>.

Fast forward to September 2017, the Malaysian government granted its second compulsory licence to bring in generics of the hepatitis C drug, Sofosbuvir (Sovaldi), for which the patent is held by Gilead Sciences.

Prior to the grant, the cost of the full hepatitis C treatment using Sovaldi for a patient was RM 300,000 and only about 500 patients, out of a pool of 500,000, had access to the drug<sup>16</sup>. The compulsory licence enabled the price of the 12-week treatment to be reduced to between RM 1,000 and RM1,200 – a 99.6% reduction<sup>17</sup>.

This move won Malaysia acclaim from medical organisations such as Médecins Sans Frontières (also known as Doctors Without Borders)<sup>18</sup> and the Malaysian AIDS Council (MAC)<sup>19</sup>. At the Global Summit of Intellectual Property and Access to Medicines in Morocco in 2018, Malaysia received the Leadership Award in Intellectual Property and Access to Medicines<sup>20</sup>.

**Legal Framework**

So how does compulsory licensing work?

One may gather from the above examples that compulsory licences are only issued in exceptional circumstances, and that is true. Granting compulsory licences is rarely without opposition from patent holders and companies in the industry who do not wish to see this become the norm. As with Bayer's legal challenge in India, Malaysia continues to face intense criticisms and lobbying against its affirmative action on Sofosbuvir<sup>21</sup>.

14 Chee Yoke Ling (2006), Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option, Third World Network. Retrieved from Third World Network: <https://www.twn.my/title2/IPR/pdf/ipr09.pdf>.

15 WHO (2014), Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context. Retrieved from WHO: [https://apps.who.int/PDS\\_DOCS/B5144.pdf](https://apps.who.int/PDS_DOCS/B5144.pdf).

16 Lekhya Kintada (10 April 2019), Compulsory Licensing for Hepatitis C Medication in Malaysia. Retrieved from Public Citizen: <https://www.citizen.org/news/compulsory-licensing-for-hepatitis-c-medication-in-malaysia/>.

17 Chee Yoke Ling (9 March 2019), Using compulsory licence for affordable medicines. Retrieved from Astro Awani: <http://english.astroawani.com/malaysia-news/using-compulsory-licence-affordable-medicines-200558>.

18 Médecins Sans Frontières (MSF) (11 February 2019), Malaysia's compulsory license for sofosbuvir is a positive step for public health and innovation. Retrieved from MSF: <https://msfaccess.org/malysias-compulsory-license-sofosbuvir-positive-step-public-health-and-innovation>. 19 Malaysian AIDS Council (MAC) (11 September 2017), Malaysian AIDS Council welcomes Government move to issue compulsory license on lifesaving hepatitis C medicines. Retrieved from MAC: <https://www.mac.org.my/v3/malaysian-aids-council-welcomes-government-move-to-issue-compulsory-license-on-lifesaving-hepatitis-c-medicines/>.

20 Loh Foon Fong (19 January 2018), Malaysia awarded for gutsy move. Retrieved from The Star: <https://www.thestar.com.my/news/nation/2018/01/19/malaysia-awarded-for-gutsy-move-govt-invokes-compulsory-licensing-for-affordable-hepatitis-c-medicin>.

21 The Pharmaceutical Research and Manufacturers of America (8 February 2019), PhRMA Decries Damaging Foreign Practices in Special 301 Filing. Retrieved from PhRMA: <https://www.phrma.org/press-release/phrma-decries-damaging-foreign-practices-in-special-301-filing>.

**APRIL:****Covid-19: A Case for Compulsory Licensing****TRIPS Agreement**

Compulsory licensing is formally recognised in the TRIPS Agreement<sup>22</sup> which came into effect on 1 January 1995 and signed by members of the World Trade Organisation (WTO), including Malaysia. The TRIPS Agreement remains the most comprehensive multilateral agreement on intellectual property. It sets out provisions for copyright, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits and undisclosed information (trade secrets).

In 2001, the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) was adopted by WTO members to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the TRIPS Agreement. The Doha Declaration addresses growing concerns over patent rules hindering access to affordable medicines in developing countries in their efforts to control the spread of diseases of public health importance, such as HIV, tuberculosis and malaria.

The Doha Declaration enshrines the principles publicly advocated by WHO over the years, namely, the re-affirmation of the right of WTO members to make full use of the safeguard provisions of the TRIPS Agreement to protect public health and enhance access to medicines for developing countries. It reaffirms, among others, the right to compulsory licensing<sup>23</sup>.

The reference to compulsory licensing is in Article 31<sup>24</sup> of the TRIPS Agreement. It is supplemented by Article 31bis pursuant to the Protocol Amending the TRIPS Agreement<sup>25</sup> which became effective on 23 January 2017 upon receiving acceptance from the requisite two thirds of the member states.

Collectively, the Articles set out the conditions for granting a compulsory licence. They also set out the legal basis for WTO members to grant special compulsory licences exclusively for the production and export of affordable generic medicines to other members who cannot locally produce medicine in sufficient quantities.

Article 31bis is particularly helpful to developing and least developed countries who lack the manufacturing prowess to manufacture their own drugs. It was first put to use in October 2007 when Canada and Rwanda submitted notifications to WTO for Rwanda to import 260,000 packs of TriAvir, a HIV drug, over two years<sup>26</sup>.

**Malaysian Patents Act 1983**

The provisions in Article 31 were codified into Sections 48 to 54 and 84 of the Malaysian Patents Act 1983<sup>27</sup> (Patents Act). Sections 48 to 54 deal with requests from applicants for compulsory licences to be granted, while Section 84 concerns government-authorized use of patents.

22 World Trade Organisation (WTO) (n.d.), TRIPS Agreement (as amended on 23 January 2017). Retrieved from WTO: [https://www.wto.org/english/docs\\_e/legal\\_e/31bis\\_trips\\_01\\_e.htm](https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm).

23 WHO (n.d.), The Doha Declaration on the TRIPS Agreement and Public Health. Retrieved from WHO: [https://www.who.int/medicines/areas/policy/doha\\_declaration/en/](https://www.who.int/medicines/areas/policy/doha_declaration/en/).

24 WTO (n.d.), Part II – Standards concerning the availability, scope and use of Intellectual Property Rights. Retrieved from WTO: [https://www.wto.org/english/docs\\_e/legal\\_e/27-trips\\_04c\\_e.htm](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm).

25 WTO. (n.d.), How to accept the Protocol Amending the TRIPS Agreement. Retrieved from WTO: [https://www.wto.org/english/tratop\\_e/trips\\_e/accept\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/accept_e.htm).

26 WTO (4 October 2007), Canada is first to notify compulsory licence to export generic drug. Retrieved from WTO: [https://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm).

27 The Patents Act 1983 has yet to be amended to codify Article 31bis into national law. The Act is available at: [http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act\\_291.pdf](http://www.agc.gov.my/agcportal/uploads/files/Publications/LOM/EN/Act_291.pdf).

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### Application for Compulsory Licence in Malaysia

Section 49 allows any person to apply for compulsory licence in the following cases:

- (a) where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason; or
- (b) where there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet public demand without any legitimate reason.

Section 49 further requires the applicant to show that:

- (a) his application is made after the expiration of three years from the grant of the patent, or four years from its filing date, whichever is the later (duration requirement); and
- (b) he has made effort to obtain authorisation from the patent owner on reasonable commercial terms, but such efforts have not been successful within a reasonable period of time (contact requirement).

There is no guidance on what crosses the threshold for a compulsory licence to be granted. But the choice of words in Section 49, namely, “legitimate” and “reasonable” suggests that the Registrar of Patents may evaluate applications based on practical considerations, among others. This inference is reinforced by Article 31(a) of the TRIPS Agreement which states that “authorisation of such use shall be considered on its individual merits”.

Section 52 sets out the conditions which the Registrar may fix before issuing a compulsory licence. They include the following:

- (a) the scope of the licence specifying in particular the period for which licence is granted;
- (b) the time limit within which the applicant shall begin to work the patented invention in Malaysia; and
- (c) the amount and conditions of the royalty that the applicant is to pay the patent owner.

References to “scope” and “time limit” of the licence effectively allow the Registrar to ensure that the compulsory licence would only be used for the reasons upon which it is granted. In addition, subsection (c) requires royalty to be paid to the patent owner. In this regard, Article 31(h) states that the amount should commensurate with the “economic value of the authorisation”, as opposed to the amount that the patent owner would ask for if it were to grant a licence voluntarily.

To further safeguard the patent owner’s interests, Section 53 restricts the scope of a compulsory licence by stating that it:

- (a) shall not be assigned unless it is assigned along with the goodwill, business or that part of the goodwill or business in which the patented invention is used; and
- (b) shall be confined to the supply of the patented invention predominantly in Malaysia.

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Under Section 84(1), the Minister in charge<sup>28</sup> may allow a government agency or a third party to use the patented invention without the patent owner's consent in the following cases:

- (a) where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or
- (b) where a judicial or relevant authority has determined that the manner of exploitation by the patent owner or his licensee is anti-competitive.

The Doha Declaration, which led to the addition of Article 31bis, allows each member state to determine what constitutes a national emergency or other circumstances of extreme urgency. It further adds that public health crises such as "HIV/AIDS, tuberculosis, malaria and other epidemics" fall within such scope<sup>29</sup>.

Section 84(1) makes no mention of the duration or contact requirement which we see in Section 49. This essentially means the Malaysian government need not enter into negotiations nor apprise the patent owner prior to exercising its powers under Section 84(1). This appears to be a step further than what is spelt out in Article 31(b) of the TRIPS Agreement, which only allows member states to waive the contact requirement "in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use".

Notwithstanding the relative freedom given to the Minister under Section 84(1), the other subsections under Section 84 do provide some safeguards for the patent owner who is subject to a compulsory licence in the context of a national emergency. Notably:

- (a) the patent owner must be notified as soon as possible of the decision to issue the licence;
- (b) the use of the patented invention shall be limited to the purpose for which the licence is granted;
- (c) the patent owner must be paid an adequate remuneration. The assessment similarly hinges on the economic value of the licence and the patent owner may make his views heard;
- (d) the use must be for public non-commercial use;
- (e) the licence shall not stop the patent owner from using his patent;
- (f) the use must only be predominantly for the supply in Malaysia;
- (g) the licence may be varied or terminated if there is change in the circumstances leading to the grant of licence; and
- (h) the patent owner may appeal to the Court against the Minister's decisions made under Section 84.

<sup>28</sup> Presently, the Minister of Domestic Trade and Consumer Affairs Minister.

<sup>29</sup> WTO (14 November 2001), Declaration on the TRIPS Agreement and Public Health, paragraph 5(c). Retrieved from WHO: <https://www.who.int/medicines/areas/policy/tripshealth.pdf?ua=1>.

**APRIL:****Covid-19: A Case for Compulsory Licensing****Compulsory Licences for Combating Covid-19**

Malaysia has yet to invoke the Patents Act in relation to Covid-19. This may change once a drug or a combination of drugs is found to have therapeutic effect on patients infected with the virus or a vaccination is ultimately uncovered. Clinical trials that have begun worldwide now veritably involves Malaysia, who was chosen by WHO to run studies on four of the most promising therapies presently known<sup>30</sup>. Meanwhile, other countries have begun wielding their corresponding legislations to do so:

- (a) On 17 March, the Chilean Chamber of Deputies adopted a resolution declaring a compulsory licence for vaccines, drugs, diagnostics, devices, supplies and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of people infected by the virus in Chile<sup>31</sup>;
- (b) On 19 March, Israeli's attorney general issued a compulsory licence for lopinavir/ritonavir (Kaletra), an HIV drug owned by AbbVie that is being tested as a potential cure for Covid-19<sup>32</sup>. Not a stranger to compulsory licences, Israel has reportedly granted seven licences in the past to facilitate local production<sup>33</sup>; and
- (c) On 20 March, Ecuador approved a resolution to request its Minister of Health to issue compulsory licences over patents related to coronavirus<sup>34</sup>.

Some pharmaceutical companies have gone on to pre-empt such measure. Following Israel's announcement on 19 March, AbbVie publicly waived its right to enforce its worldwide patents relating to Kaletra<sup>35</sup>.

As the global efforts to combat Covid-19 intensify, more countries could well turn to compulsory licences or equivalent legislations to allow researchers to have everything at their disposal to find treatments for the coronavirus in the race against time. This resonates with the WHO Director-General's repeated calls that to heal the world we must do it together:

"My message was threefold: we must fight, unite and ignite. Fight to stop the virus with every resource at our disposal; Unite to confront the pandemic together. We are one humanity, with one, common enemy. No country can fight alone; we can only fight together. And ignite the industrial might and innovation of the G20 to produce and distribute the tools needed to save lives. We must also make a promise to future generations, saying never again."<sup>36</sup>

<sup>30</sup> Zakiah Koya (28 March 2020), WHO chooses M'sia to run trials on new drug to fight Covid-19. Retrieved from The Star: <https://www.thestar.com.my/news/nation/2020/03/28/who-chooses-m039sia-to-run-trials-on-new-drug-to-fight-covid-19>. <sup>31</sup> The English translation of the resolution is available at: <https://www.keionline.org/chilean-covid-resolution>.

<sup>32</sup> Reuters (19 March 2020), Israel approves generic HIV drug to treat COVID-19 despite doubts. Retrieved from Reuters: <https://www.reuters.com/article/us-health-coronavirus-israel-drug/israel-approves-generic-hiv-drug-to-treat-covid-19-despite-doubts-idUSKBN216237>.

<sup>33</sup> Tal Band. (n.d.), The impact of public health issues on exclusive patent rights – Israel. Retrieved from The International Association for the Protection of Intellectual Property (AIPPI): <https://aiippi.org/download/committees/202/GR202israel.pdf>.

<sup>34</sup> Luis Gil Abinader (20 March 2020), Legislative Committee in Ecuador approves resolution on compulsory licensing of patents relating to the coronavirus. Retrieved from Knowledge Ecology International: <https://www.keionline.org/32429>.

<sup>35</sup> Mancini, D, M., and Kuchler, H. (23 March 2020), AbbVie drops patent rights for Kaletra antiviral treatment. Retrieved from Financial Times: <https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b>.

<sup>36</sup> WHO (27 March 2020), WHO Director-General's opening remarks at the media briefing on COVID-19. Retrieved from WHO: <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---27-march-2020>.

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# COVID-19:

## A CASE FOR COMPULSORY LICENSING

**Conclusion**

Compulsory licensing has been seen as a yardstick of the state of a country's patent system<sup>37</sup>, where countries with a mature patent system are found to be more likely to leverage compulsory licensing as a means to ensure access and affordability of crucial medicines.

Whilst countries may have the necessary legislative muscle to grant access to the vaccine for Covid-19 once it becomes available, the true challenge lies in how quickly they could coordinate their response to ensure timely and proportionate distribution of the vaccine, particularly to developing and least developed countries. This is exacerbated by the varying levels of commitment in different countries in curbing the pandemic which has drawn parallels to the deadly Spanish Flu that ravaged the world in 1918.

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<sup>37</sup> Son. K. (27 June 2019), Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis, *Global Health* 15, 42. (2019). Retrieved from BioMed Central: <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-019-0485-7>.

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Should you have any queries or require more information, please do not hesitate to contact us.

**LEE LIN LI**

Partner, Head of IP & Technology Practice Group.

For further information and advice on this article and/or on any areas of IP & Technology, please contact: [linli.lee@taypartners.com.my](mailto:linli.lee@taypartners.com.my)

**LOW KOK JIN** - Associate

[kokjin.low@taypartners.com.my](mailto:kokjin.low@taypartners.com.my)