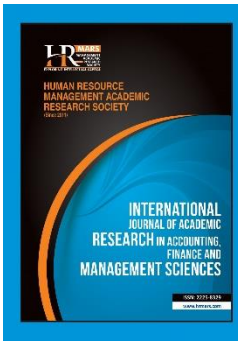


INTERNATIONAL JOURNAL OF ACADEMIC RESEARCH IN ACCOUNTING, FINANCE AND MANAGEMENT SCIENCES

HRMARS MANAGEMENT ACADEMIC RESEARCH SOCIETY
EXPLORING INTELLECTUAL CAPITAL

www.hrmars.com
ISSN: 2225-8329

Waiving Pharmaceutical Intellectual Property Rights: Harmonizing Patent and Competition Policy

Wan Liza Md Amin, Mawaddah Munirah Zulfakar

To Link this Article: http://dx.doi.org/10.6007/IJARAFMS/v13-i2/18177 DOI:10.6007/IJARAFMS /v13-i2/18177

Received: *10* May 2023, ***Revised:*** *12* June 2023, ***Accepted:*** *28* June 2023

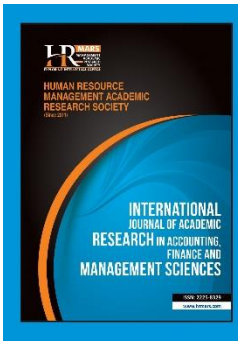
Published Online: *16* July 2023

In-Text Citation: (Amin & Zulfakar, 2023)

To Cite this Article: Amin, W. L. M., & Zulfakar, M. M. (2023). Waiving Pharmaceutical Intellectual Property Rights: Harmonizing Patent and Competition Policy. *International Journal of Academic Research in Accounting Finance and Management Sciences*, *13*(2), 1045–1060.

Vol. 13, No. 2, 2023, Pg. 1045 - 1060

http://hrmars.com/index.php/pages/detail/IJARAFMS | **JOURNAL HOMEPAGE**


INTERNATIONAL JOURNAL OF ACADEMIC RESEARCH IN ACCOUNTING, FINANCE AND MANAGEMENT SCIENCES
HRMARS MANAGEMENT ACADEMIC RESEARCH SOCIETY
EXPLORING INTELLECTUAL CAPITAL
www.hrmars.com
ISSN: 2225-8329

Waiving Pharmaceutical Intellectual Property Rights: Harmonizing Patent and Competition Policy

Wan Liza Md Amin, Mawaddah Munirah Zulfakar
Faculty of Law, Universiti Teknologi MARA, 40450 Shah Alam, Selangor, MALAYSIA.
UiTM Competition Law and Policy Research Interest Group
Email: mawazul93@gmail.com

Abstract
Unequal access to vaccines between high-income and lower-income countries has highlighted the role of Intellectual Property rights as leverage or bargaining tool by pharmaceutical companies in procurement and distribution. India and South Africa 2020 initiated a proposal for Intellectual Property (IP) temporary waivers for Covid-19 patent vaccines to suspend the proprietary rights of the patent owner. This article aims to answer whether total or temporary dismantling of IP rights is the best response to a health emergency while ensuring the industry remains competitive. This article employs qualitative method works of literature through thematic analysis of secondary data. Academic literature on the justification of IP waivers and competition policies, oligopolistic pharmaceutical market structure, provisions of Malaysia Patent Act 1983, TRIPS Agreement, and Competition Policies. Our analysis proposes stakheolders' mutual benefits framework through harmonisation of IP rights and competition policy toward a holistic approach to ensure mutual benefit for all stakeholders. The novelty findings outcome would accelerate the pharmaceutical market development in Level 1 of the market structure, fair competition, efficient vaccine production, and allocation for future pandemics.
Keywords: Pharmaceutical Industry, Competition Policy, Patent Waiver, Intellectual Property, Oligopolistic

Introduction

Covid-19 pandemic has unraveled issues surrounding the pharmaceutical industry such as intellectual property (IP) rights restrictions, disruptions in supply and demand, and unequal distribution of vaccines to lower income countries (LIC) (Jecker et al., 2021). For example, the uneven Covid-19 vaccine roll outs have heightened the blame towards IP rights and monopoly by pharmaceutical companies. The oligopolistic nature of the market i.e few pharmaceutical companies and high barriers to entry, lead to a concentrated industry that global population are depended on. The market control through IP rights on technology and know-how reduces the capacity of vaccine manufacturing and subsequently, reduces competition. IP was seen as something that has to be temporarily or completely removed not only in vaccine development but in other pharmaceutical products and therapeutics as well. In 2021, Malaysia has joined

other World Trade Organization (WTO) countries for temporary IP waiver to prevent IP from becoming a barrier to accessibility and affordability of essential health needs that is to combat the pandemic (Plüss et al., 2021). The proposal was initiated by South Africa and India in October 2020 is also aimed to enhance research and development (R&D), manufacturing, production, and the supply of essential medications during the Covid-19 pandemic (CodeBlue, 2021).

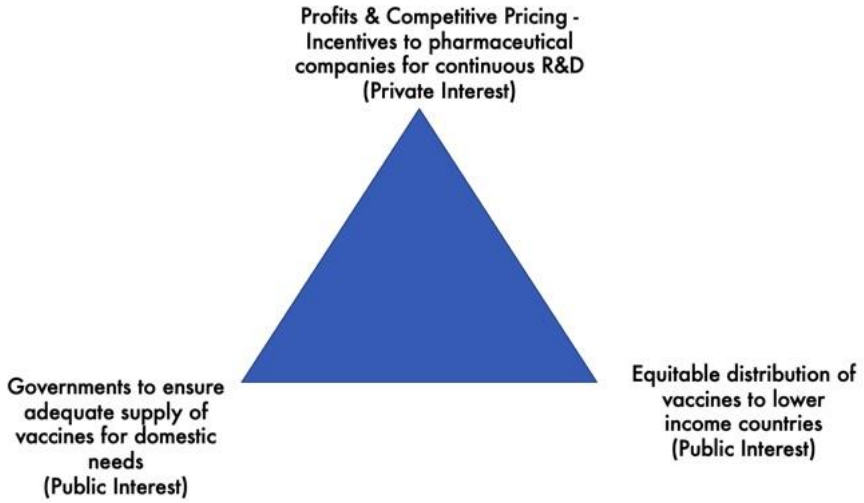


Diagram 1: This diagram reflects the conflicting public and private interest between stakeholders.

In facing the unprecedented pandemic, the universal IP policies and health emergency response were inconsistent (Lindsey, 2021). Each of the stakeholders has an individual interest that may conflict with one another. For example, on the part of the government, in Malaysia's 2022 Budget, RM 4 million was allocated to manage Covid-19 including procurement of vaccines and antiviral drugs through the National Immunisation Programme as well as upgrades on healthcare facilities (Ministry of Finance Malaysia, 2021). Secondly, the pharmaceutical industry advanced innovation in infectious disease research and enjoys an increase in profits for certain medications and devices used for Covid-19 treatments (GlobalData Healthcare, 2020). The profits are used to fund follow-on research projects which is a form of private interest. For example, the MRNA technology in vaccines is effective against new variants and can be the developed to treat other diseases such as cancer and HIV/Aids. This development will be stunted if IP is waived (Lyn, 2021). Thirdly, in meeting global needs, unequal access to vaccines becomes an issue. It was projected that in 2021, sufficient vaccines will be supplied to vaccinate 70% of the global population. However, HIC has reserved according to the country's demands, and certain vaccine-producing countries have restricted export for domestic supply. LIC is even deprived of first-shot vaccines while HICs have enough supply to offer booster shots to their citizens (Ngakhusi, 2021). The conflicting public and private interest, as well as other contributing factors such as manufacturing production and capacity, production, distribution logistics, considering national policies and global condition, becomes the determining variables in the accessibility of vaccines. These uncertainties reduce the level of global preparedness for a pandemic (Andrenelli et al., 2021).

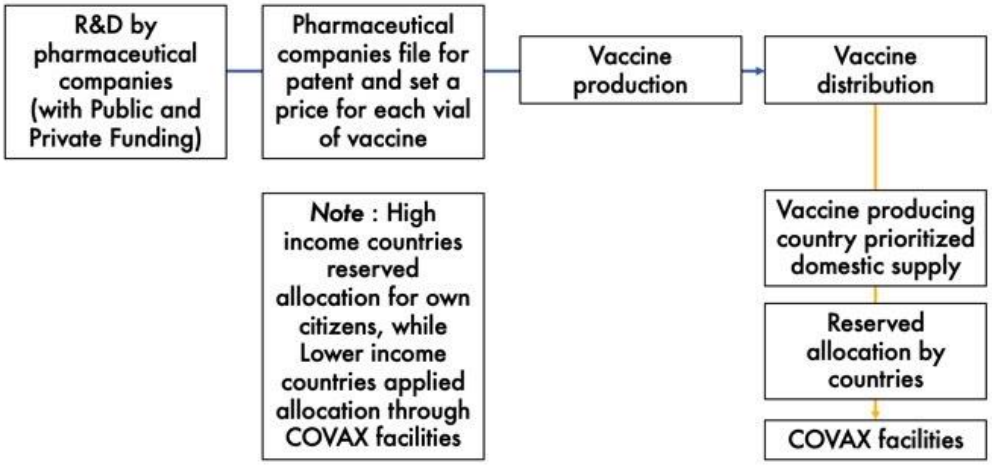


Diagram 2 : This digram explains in general the flow of development, production, and distribution of vaccines.

IP rights allow pharmaceutical companies to develop vaccines and prevent competitors to reproduce the invention. This provides leverage for the companies to set a price for each vial of vaccines. The proposal urged the temporary waiver of the provisions in the TRIPS Agreement for several years or until the majority of the global population is vaccinated. The suspension will allow the production of vaccines to be authorized without consent by pharmaceutical companies, loosen monopoly power of IP holding companies and accelerate production of generics and other medications (FMT Reporters, 2021). The proposal was met with two opposing views which support or go against the patent waivers. An example of statements that supports patent waivers is from the Legal Experts from Doctors without Borders in Geneva, who stated that waiver is necessary due to the inconsistent IP regulations for raw materials and vaccine technologies. This allows streamlined regulations for global application. Furthermore, IP blocks competition and maintains monopoly in order to keep prices high. Similarly, Gaétan de Rassenfosse from the Federal Institute of Technology in Lausanne (EPFL) highlights that the exclusionary nature of IP that can limit production following licenses can become a barrier to access (Plüss et al., 2021). Both the World Health Organisation (WHO) and The Joint United Nations Programme on HIV/AIDS (UNAIDS) also supported the proposal. The waiver will reduce transaction costs, and eliminate barriers to R&D and supply that can prevent the transfer of technology, diagnosis, and treatments of Covid-19 (Chade, 2021). BRICS countries (Brazil, Russia, India, China, and South Africa) highlighted the need for sharing of vaccine doses, the transfer of technology, and the development of local production capacities and supply chains for pharmaceutical products (The Economic Times, 2021). IP facilitates an oligopolistic market in vaccines, as the companies are the rightsholders with significant control over the vaccines, resulting in an inequitable supply of vaccines (Thambisetty et al., 2022).

On the contrary, those who are against the proposal, highlight that IP waivers will allow competitors to acquire technologies and information that have been initiated by other entities. Furthermore, waivers are not necessary as countries are allowed to take advantage of the flexibilities provided by TRIPS Agreements such as ‘compulsory licensing’ to bypass IP due to health emergencies (Nature Editorial, 2021). Pharmaceutical companies contended that IP waivers will not accelerate vaccine manufacturing. This is due to the risk of supply disruptions as raw materials are sourced worldwide, together with insufficient technologies and know-how (Okonjo-Iweala, 2021). The International Federation for Pharmaceutical

Manufacturers and Association (IFPMA) stated that the industry has consistently pushed back on any loosening of IP protections. This is because strong IP protection has enabled companies to be developed rapid, safe, and effective vaccines (Plüss et al., 2021).
In this article, the identified constraints are on the application of intellectual property rights on pharmaceutical products and the oligopolistic nature of the vaccine market that affects competition and accessibility of not only vaccine but other medications as well.

Literature Review

Patent rights grant a temporary monopoly in exchange for disclosure for 20 years as stipulated by Section 35 of the Patents Act 1983 which is peri materia to Article 33 of TRIPS Agreements. Patent rights also allow the patent owner to gain benefits from its R&D efforts by commercialising the invention and excluding unlicensed reproduction of the process or product patent. This is according to the rights of the patent owner in Section 36(1) and (2) of the Patents Act. Patent protection that is too strong can hinder distribution and innovation thus leading to reduced output. On the other hand, if its too weak, it can reduce incentive for the companies to conduct follow-on research (Marcowitz-Bitton & Kaplan, 2021)
Around 100 out of the 164 WTO member states supported the waiver. Countries such as Switzerland, have opposed a full IP waiver open to compromise (Thomson Reuters Foundation, 2021). The companies argued that strong IP protection helped to develop vaccines at a faster rate and to prepare for a possible future pandemic. However, from the lens of other stakeholders obtained from works of literature, a patent is seen as a form of barrier to innovation. For example, patent restricts access to information, and technologies and constrict access to essential healthcare (Thomson Reuters Foundation, 2021). The TRIPS Agreement allows for waiver of obligations in the Agreement in exceptional circumstances, according to stipulated terms and condition and on an agreed timeframe (Althabhawi & Kashef Al-Ghetaa, 2023). It is subjective whether Covid-19 pandemic and its subsequent effcts qualifies as exceptional circumstances for suspension of IP rights. This article will include discussions on pharmaceutical market structure, competition policies, patent waiver justifications and compulsory licensing as an alternative to patent waiver.

Pharmaceutical Market Structure

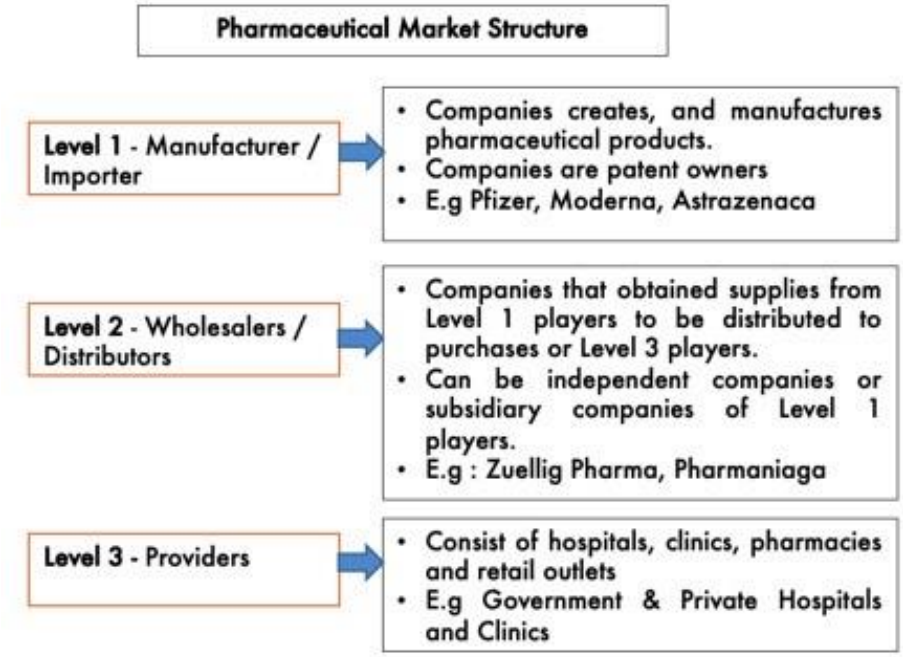


Diagram 3 : The diagram explains the three levels of pharmaceutical market structure (Sood et al., 2021).

Vaccine are produced by companies in Level 1 of the market tier. Companies conducted as well as research institutes conduct R&D and file for a patent for the invention. In Malaysia, Institute for Medical Research (IMR) of the National Institutes of Health (NIH), MOH is in progress to develop Covid-19 vaccines to initiate and boost vaccine research (Nathan, 2022).

Table 1
Leading companies by number of COVID-19 drugs and vaccines as of June 2022 (Statistica.com, 2022)

No.	Company	Number of medications and vaccines
1	Sorrento Therapeutics	18
2	Moderna	12
3	GlaxoSmithKline	10
4	Pfizer	10
5	ImmunoPrecise Antibodies	10
6	Novartis	9
7	Tonix Pharmaceuticals	9
8	Eli Lilly	8
9	Johnson & Johnson	8
10	Grifols	8

From the table above, vaccine manufacturing and production are concentrated in high and middle-income countries. Furthermore, major pharmaceutical companies with huge capital, together with public and private funding can maximise research capabilities to produce more vaccines (Swagel, 2021). Furthermore, HICs with sufficient monetary budgets made an early

reservation to the companies even before the vaccines are approved for production. IP rights have been used as a form of bargaining power by the companies to monopolise the invention and set a price that only HICs can afford to purchase. This potential shortfall increases the risk that people in LICs will need to wait even longer for their first doses (Nature Editorial, 2021). In April 2021, Malaysia received 268, 800 doses of Asrazeneca Vaccines via the COVAX Facility and followed by 599, 200 doses in May 2021. Malaysia through MOH and MOSTI has collaborated with WHO and UNICEF to procure vaccines for Malaysians (Choong & Novakovic, 2021).

The small number of manufacturers following WHO standards creates a concentrated industry that is oligopolistic with high entry barriers and reduced competitiveness and output brought into the market, thus prices are high and high profits for the companies (Balasubramaniam & Sita, 2014). To balance demand and supply, tenuous arrangements and communication between stakeholders are necessary to ensure equitable supply to the purchasers (Brouwers et al., 2021) . Emer Cooke, WHO Director of the regulation and prequalification department stated that "According to the WHO, nearly one-third (32%) of vaccines have fewer than four suppliers, while nearly two-thirds (63%) have two or fewer prequalified products. COVID-19 has shown just how vulnerable medical product supply chains are when relying on a small number of manufacturers for raw materials and final products" (Lobo, 2021).

Oligopolistic Endogenous Conditions

An oligopolistic market is characterised by high entry and exit barriers, few dominant companies, collusion, product differentiation, and interdependence (Hovenkamp et al., 2019). The high entry and exit barriers are not only due to the complex nature of the industry, and high horizontal market concentration from collusion and mergers and acquisition but also from the huge capital required not only for R&D but also to recoup sunk costs. Sunk costs can consist of investments spent for R&D, facilities, and production (Shulman et al., 2021). Information and regulations can also become a barrier to competition from generics. These factors creates inefficiencies for pharmaceutical development and in long term, if without intervention, the market will become unsustainable (Mittra et al., 2011). Experts have suggested that stakeholders such as governments and international organisations implement structured policies for long-term accessibility that resolves the oligopolistic constraints (Lobo, 2021). The primary goal in innovation is to enhance efficiency, to accelerate pharmaceutical R&D process time, and reduce costs (Kim et al., 2022).

Competition Policies

Competition authorities pharmaceutical market to ensure that the prices of essential medications are not marked up excessively by pharmaceutical companies, that falls within the provisions of Competition Act 2010. The principle of fair market internalised in the competition law and policies, together with interventions by authorites such as the European Union, highlights regulations that promotes competitive process, and the use of proper tools to prevent anti-competitive conduct that violates Articles 101 and/or 102 of the TFEU. The policies are in place to ensure that pharmaceutical companies do not collude or abuse of their dominant position, jepardising the access to medicines (Pitruzzella & Arnaudo, 2017). In the pharmaceutical market, competition rules are aimed to enhance access to affordable pharmaceutical products and at the same time, innovation in R&D. European competition

authorites encourage Covid-19 related cooperation between competitors and intervene in possible anti-competitive conduct. For example, Netherlands Competition Authority have inquired on refusal to share technology. Roche Dignostics subsequently agreed tp share technology with competitor for Covid-19 testing production expansion (Hosseini, 2021).
The pharmaceutical industry invokes the implementation essential facilities doctrine (EFD), companies cannot refuse to grant access to the essential facility i.e the product patent, to the competitors. This doctrine can be invoked at times of health emergency if the patent owner is the only entity that owns invention that can be used to combat the said emergency. For example, the use of compulsory licensing (Goyal et al., 2013).

Patent Waivers Justification

Supply shortages occurred when IPs were used to block competition, thereby disrupting vaccine supplies. For example, due to IP rights, only 4 companies can produce plastic bioreactor bags for vaccines. With the fact that TRIPS granted 20-year patent rights and it is often evergreened by companies, LICs are deprived of having access to cheaper alternatives and fulfilling the countries' health needs (Sundaram & Chowdhury, 2021). Once the waiver is granted at the national level, it would suspend the enforceability of IP rights and diversify the supply of Covid-19 medical products and vaccines. For example, the manufacturing of IP-protected products by third parties will not be an infringement, even produced without authorisation by the patent holder (Gurgula, 2021). Waiver removes proprietary barriers attached to the product and process in the transfer of vaccine-related technology. Complex when there are multi-layers of rights owned by multiple entities that dictate any transfer on permissive and collaborative gesture (Barnes-Weise et al., 2022). This will reduce the accessibility gap between HICs and LICs by enabling other companies to produce a sufficient quantity of vaccines. Pharmaceutical companies should not be counting their profits but help end the misery (Ismail, 2021). The suspension of patents, the development of production, the dissemination of tools and know-how, quality production everywhere, and the public financing of a public good (Mbaye & Sardjono, 2022). Public money has been used to develop these medical solutions which should be made available in the public domain (Piedagnel, 2021). Government can further collaborate in R&D without interference by the private interest of the industry, thus allowing the production of COVID-19 vaccines and medications to be done at a larger capacity and cheaper cost (Médecins Sans Frontières, 2021). Lifting these patents would remove legal barriers that would prevent other companies from producing these vaccines, and allow more doses to be manufactured at lower prices for its supporters (Mbaye & Sardjono, 2022). IP rights waiver is an instrument to improve supply and reduce the cost of essential pharmaceutical products during pandemics, governments and policymakers need to initiate robust policies to that effect (Adigwe & Oturu, 2022).

Compulsory Licensing as Alternative to Patent Waiver

Patent waiver carries the risk that the inventions will be used freely by competitors, without any reward to the patent owner (Althabhawi & Al-Ghetaa, 2023). The expensive invention can be exploited through unauthorized reproduction. The crisis has highlighted the inconsistency between the patent system and the right to health. The capacity to generate patent-eligible inventions is limited in low-income and middle-income countries, where most patents are foreign-owned. The immediate concern of these countries is to acquire a fair share of recent technological advances, which continue to be controlled almost exclusively by high-income countries (Althabhawi & Al-Ghetaa, 2023). European Union suggested compulsory licensing

under Article 31 (b) TRIPS as an option during a national emergency. However, it was contended that compulsory licensing can only be granted if there is an existing patent and does not apply to patent applications on a country-to-country basis. The fact that the mRNA technology for vaccines has multiple patent rights holders and patent licensees also caused a significant hurdle to apply for a compulsory license as having to seek clearance on each of the patent status. Furthermore, the authorised use is restricted to only domestic supply and cannot be exported (Gurgula, 2021). Compulsory licensing requires extensive negotiation with applicants and patent holders. Furthermore, the government has the obligation to pay compensation to patent holders, which will exert a heavy burden on low-income and middle-income countries in pandemic situations. Lastly, production must be reserved exclusively for the applicant's domestic market. Thus, compulsory licensing flexibility is a time-consuming and complex process. TRIPS flexibilities are not as effective as a patent waiver (Althabhawi & Al-Ghetaa, 2023). A type of compulsory license, the 'government use' is a right for a country to use the patent during health emergencies without negotiating with the holder beforehand (Mbaye & Sardjono, 2022). Malaysia's rights of government' is laid down in Section 84 (1) (a) of the Patents Act 1983, which can be applied during a national emergency. The short-term mechanisms, that may be utilised by governments for the protection of public health at the national and global level, such as compulsory licensing and government use, will facilitate better access to patent-protected COVID-19 medicines during this pandemic (Gurgula, 2021). It was suggested that the application of compulsory licensing requires substantive revisions and clarifications for it to be effective. There is a need to simplify the application and implementation processes as a way to proritise its use in the future (Rubin & Saidel, 2021).

Method

Qualitative Method

The article employs qualitative methods for data collection in the form of doctrinal research. The doctrinal research will focus on written works of literature from secondary sources (Kharel, 2018). An analysis is made of government statutes mainly the Patents Act 1983 and Competition Act 2010, intellectual property and competition policies, data, and reports by the countries' Intellectual Property Organisation, Competition Commission, and pharmaceutical market players. Global data on the pharmaceutical market and competition law from different countries are retrieved from organisation such as Organisation for Economic Co-operation and Development (OECD), United Nations Conference on Trade and Development (UNCTAD), World Health Organisation (WHO), and globally available data from reputable websites. Data collected are analysed through thematic analysis. It is a method for identifying, analyzing, organizing, describing, and reporting themes found within a data set (Braun & Clarke, 2006). This paper identified specific themes of examining vaccines market structure for vaccines, oligopolistic characteristics, patent waiver justifications, and the nature and application of compulsory licensing. The discussions and findings contribute to addressing the gap analysis should temporary or total patent waiver should be globally enforced to develop a competitive vaccine market framework. The framework provides further research on global societal well-being.

Results and Discussion

Temporary or total dismantling of Intellectual Property i.e patent in pharmaceutical, the best response to public health emergencies to be inline with competition principle of essential facilities.

Intellectual property is the basis of innovation. New solutions to problems are constantly discovered from continuous research with the system warrants a legal right as a return of investment. Furthermore, due to the nature of the pharmaceutical product, a safe product cannot be produced without the correct technology and know-how (Jomo, 2021). The IP rules essentially give companies a monopoly over the production of medicine, tests, and technologies and in effect stop countries from allowing other manufacturers from producing and exporting vaccines to another country without legal risks (Plüss et al., 2021) The proprietary rights attached to the invention also ensures that there is accountability to invention by the patent owner. A patent waiver might solve the problem of access to information, but it still requires proper collaboration and transfer of technology to assist other companies in producing vaccines (Rutschman & Barnes-Weise, 2021). If waiver is granted and there is dissemination of the invention's know how to competitors, there is a risk that competitors will not reproduce the invention as safe and high quality as the original patent owner. Here again, accountability will be the main issue if there are health risks to future products.

Furthermore, vaccine patent is not the main cause of the unequal distribution of vaccines to the global population. The oligopolistic structure of the pharmaceutical market, with a high barrier to entry, reduces the number of competitors in the market. With stringent requirements by local and foreign entities such as WHO, vaccine production is limited to only a handful of companies. Furthermore, trade barriers, bottlenecks in supply chains, and difficulty to source raw materials as well as an unwillingness of countries to share doses contributed to insufficient supply (Plüss et al., 2021). Not all countries have the capacity and infrastructure to produce and distribute vaccines, thus even if there is a suspension of IP that allows competitors to have access to the knowledge, it might not fulfill the objective to enhance vaccine production (Rubin & Saidel, 2021).

Together with competition policy, the exercise of IP rights can be done to create a competitive market and to prevent any abuse of trade secrets (Uddin, 2022). An optimal allocation of resources can assist in an efficient innovative process to protect society's welfare (Althabhawi & Al-Ghetaa, 2023). There is a need to ensure long-term allocative efficiency in terms of the distribution of pharmaceuticals. The decision on whether to waive an IP right must consider balancing between public and private interest, long-term pharmaceutical R&D, and prioritising the aim to vaccinate the global population (Lyn, 2021).

This article highligths that temporary or total suspension of IP rights is not the best response, but it can be applied in a modified manner as a long-term solution through a structured framework This is to ensure a balanced mutual benefits to all stakeholders without risking a total removal of the patent rights.

Harmonization of IP and competition law and policy

IP law and competition policy are complementary, thus should be applied harmoniously in a specific industry. Competition policy also act as a check and balance to the exercise of IP rights by pharmaceutical companies to prevent abuse of dominant position i.e in Sections 4 and 10 of the Competition Act. For example, invoking essential facilities doctrine, through

compulsory licensing, to compel companies to loosen IP protection to their invention (Marquardt & Leddy, 2003). This is to allow access of technology and know hows, in certain circumstances such as health emergency and unavailability of the products in the country. The competition concern will lie in the term of the licensing agreements. The agreement must be procompetitive and fosters innovation in research (OECD). Furthermore, the transfer of technology is greatly dependent on balanced interfaces of both IP rights and competition law because the harmonization of suitable IPRs and competition regime is essential to facilitate wide-scale innovation, transfer, and diffusion of technologies. The temporary waiver will consider the suspension of 20 year monopoly rights that are enjoyed by patent owner in the Patents Act and TRIPS Agreement. If the invention have multiple patent owner, there should be a systematic way of bypassing any patent impediments, as a measure to facilitate production of vaccines and other medication by competitor. This TRIPS flexibility regulates conduct to ensure access in pharmaceuticals and the market will remained competitive.

Proposed Framework

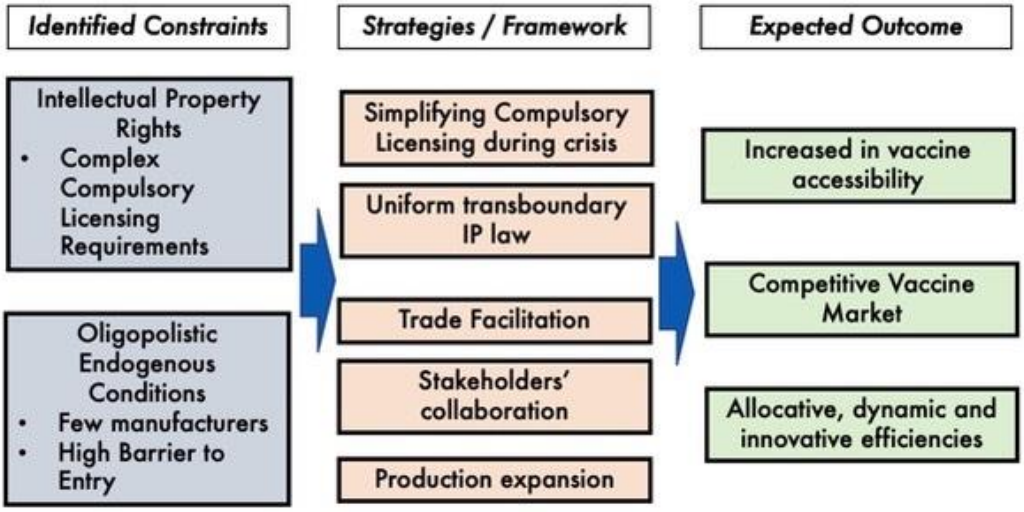


Diagram 4 : This diagram explains the Competitive Pharmaceutical Market Framework : Harmonising IP and Competition.

The respond to a public health emergencies or when there are grave needs to have access to certain medications, it requires negotiation and intervention between governments and the market players. Restructuring of a system can be implemented gradually or in a modified manner, through regional and global strategies. This article proposed a framework to overcome the identified constraints in the vaccine market.

i) Restructuring of Intellectual property rights

a) Simplifying compulsory licensing during crisis

Although Compulsory Licensing is allowed by the national patent law as well as TRIPS Agreement, but the process to obtain authorisation was said to be time consuming and largely troublesome. With the aim to be able to reduce the gap of vaccine and medications between HICs and LICs, the application and negotiation process between countries and patent owner should be simplified and with better implementation. Collaborations between relevant authorities and agencies will reduce inefficiencies and thus, improved the use of Compulsory Licensing when it is needed. Rather than total suspension on IP rights, negotiations between

the parties will ensure that the invention will still be protected whilst allowing the sharing of technology and know how. The temporary suspension of IP can be applied, without a set of agreement that can inhibit competition. This will ensure there is no impediment in the development of pharmaceuticals in Level 1 of the market structure and accessibility of the pharmaceutical products in level 2.

b) Uniform transboundary IP law and policies

The patent system only has the effect within the country that the invention is registered, will lead to discrepancies in patent enforcement. Due to the nature of a pharmaceutical invention, a product may have multiple layers of patent owner in a single product. At the same time, the creation of a finished product also may involved multiple raw materials with different patent owner. The two situation will cause problems in order to obtain compulsory licensing and other IP licences. Thus, IP authorities in Malaysia and other countries have to negotiation to form a uniform transboundary IP law or policies to streamline and facilitate the patent system. The policy takes into consideration the patent system of each of the country to blend into an acceptable IP policies.

ii) Oligopolistic endogenous conditions

The oligopolistic nature of the pharmaceutical market also contributed to the uneven roll outsTo reduce barriers to entry and increase participation of market players, this article proposed as per below

a) Trade facilitation

Countries are encouraged to eliminate trade restrictions in the supply of raw materials and in the export of finished products to the other countries. This is to prevent supply disruptions in the production of vaccines. Negotiations between the supplier and receiver countries is necessary by taking into account national and global policies. This is to create level playing field for the competitors and accelerate the distribution of vaccines to the global population.

b) Stakeholders' collaboration

WHO has identified the list of stakeholders either it is at the national (MOH, NPRA Immunisation Programme, pharmaceutical manufacturers, NGos, healthcare workers, citizens as beneficiaries), regional or global level (WHO, Unicef, COVAX) (WHO). The conflicting public and private interest of the stakeholders should be resolve through proper collaboration to reach a common understanding. This can reduce any inefficiency in the process of manufacturing raw materials, production and distribution of pharmaceuticals.

c) Production expansion

To prepare for the possibility of future health pandemics, countries and pharmaceutical companies should enhance the capability and the capacity for huge production, by prioritising domestic supply.

Conclusions

Patent waiver i.e. suspension or suspension of IP rights is not the panacea to address the challenges in present global market. To overcome the IP and oligopolistic market issues, there is no one solution that fits all. IP is not the main factor that caused unequal access of vaccines to the total population. Gradual intervention to all the related factors are necessary to

streamline the supply process and warrants a better allocation and distribution. This can lead to an enhanced allocative, dynamic and allcative efficiency. Furthermore, patent system can be restructured to scrutinize patent application with the consideration of public health to prevent future impediments with regards to generic and bio-similar products. It is also necessary to facilitate application or procedure that can be used for example during national emergency or severe inaccessibility of essential medications especially to LICs. . The framework introduced in Item 4 provides a balance consideration to all the factors such as effection IP rights and competition policies, and public health. Trade facilitation, stakeholder's collaboration and production expansion are proposed as strategies to remove barriers to entry. This will enhance competition in the vaccine market. This framework can be implemented to enhance vaccines availability in any health related circumstances that leds to supply shortage.

Acknowledgement

We would extend our love to family members , UiTM Competition Law and Policy Research Interest Group, Geran Khas UitM , Sabbatical publication PM Dr Wan liza Md Amin. UITM TNCPI Offices and the law faculty for all their support and encouragement . To cite this paper wan liza Md amin & Mawaddah munirah zulfakar . wanliza @uitm.edu.my

References

Adigwe, O. P., & Oturu, D. (2022). The Role of Patent Waivers and Compulsory Licensing in Facilitating Access to Covid-19 Vaccines: Findings from a Survey Among Healthcare Practitioners in Nigeria. *PLOS Global Public Health*, *2*(7), e0000683. https://doi.org/10.1371/journal.pgph.0000683

Althabhawi, N. M., & Kashef Al-Ghetaa, A. A. (2023). The Covid-19 Vaccine Patent: A Right Without Rationale. *Medical Humanities*, *49*(1), 128–133. https://doi.org/10.1136/medhum-2022-012386

Andrenelli, A., Lopez-Gonzalez, J., & Sorescu, S. (2021, February 11). *Using Trade to Fight Covid-19: Manufacturing and Distributing Vaccines*. OECD. https://www.oecd.org/coronavirus/policy-responses/using-trade-to-fight-covid-19-manufacturing-and-distributing-vaccines-dc0d37fc/

Balasubramaniam, K., & Sita, V. (2014). Access to Vaccines and the Vaccine Industry—An Analysis. *Journal of Vaccines & Vaccination*, *5*(2). https://doi.org/10.4172/2157-7560.1000218

Barnes-Weise, J., Rutschman, A. S., & Adler, R. (2022). Assessment of the Proposed Intellectual Property Waiver as a Mechanism to Address the Covid-19 Vaccine Scarcity Problem. *Journal of Epidemiol Community Health*, *76*(4), 317–318. https://doi.org/10.1136/jech-2021-218409

Braun, V., & Clarke, V. (2006). Using Thematic Analysis in Psychology. *Qualitative Research in Psychology*, *3*(2), 77–101. https://doi.org/10.1191/1478088706qp063oa

Chade, J. (2021). *Vaccine patent waiver push takes centre stage in Geneva*. SWI Swissinfo.Ch. https://www.swissinfo.ch/eng/politics/vaccine-patent-waiver-push-takes-centre-stage-in-geneva/46491268

Choong, R., & Novakovic, D. (2021). *COVAX ships 828,000 doses of COVID-19 vaccines to Malaysia*. UNICEF Malaysia. https://www.unicef.org/malaysia/press-releases/covax-ships-828000-doses-covid-19-vaccines-malaysia

CodeBlue. (2021). Malaysia Co-Sponsors Covid-19 Vaccine Patent Waiver Proposal At WTO. *CodeBlue*. https://codeblue.galencentre.org/2021/09/17/malaysia-co-sponsors-covid-19-vaccine-patent-waiver-proposal-at-wto/

FMT Reporters. (2021). *Support Waiver on Covid-19 Vaccine Patents, Putrajaya Told*. Free Malaysia Today (FMT). https://www.freemalaysiatoday.com/category/nation/2021/05/15/support-waiver-on-covid-19-vaccine-patents-putrajaya-told/

GlobalData Healthcare. (2020). The impact Covid-19 on pharmaceutical companies worldwide. *Pharmaceutical Technology*. https://www.pharmaceutical-technology.com/comment/covid-19-pharmaceutical-companies-impact/

Goyal, Y., Malik, J., & Sharma, G. (2013). Essential Facilities Doctrine. *CUTS Centre for Competition, Investment & Economic Regulation*.

Gurgula, O. (2021). Compulsory Licensing V the IP Waiver: What Is the Best Way to End the COVID-19 Pandemic? *South Center*, *Policy brief 104*. https://doi.org/10.2139/ssrn.3944192

Hosseini, M. (2021). A Covid Competition Dilemma: Legal and Ethical Challenges Regarding the Covid-19 Vaccine Policies during and after the Crisis. *Public Governance, Administration and Finances Law Review*, *6*(1), 51–63. https://doi.org/10.53116/pgaflr.2021.1.5

Hovenkamp, H., Wong-Ervin, K., & Vinje, T. (2019). *Licensing of IP rights and competition law—OECD*. OECD. https://www.oecd.org/daf/competition/licensing-of-ip-rights-and-competition-law.htm

Jecker, N. S., Wightman, A. G., & Diekema, D. S. (2021). Vaccine ethics: An ethical framework for global distribution of COVID-19 vaccines. *Journal of Medical Ethics*, *47*(5), 308–317. https://doi.org/10.1136/medethics-2020-107036

Jomo, K. S. (2021). *COMMENT | Us Support for Vaccine Waiver Welcome, but More Needed*. Malaysiakini. https://www.malaysiakini.com/news/574354

Kharel, A. (2018). Doctrinal Legal Research. *SSRN Electronic Journal*. https://doi.org/10.2139/ssrn.3130525

Lindsey, B. (2021). *Why intellectual property and pandemics don't mix*. Brookings. https://www.brookings.edu/articles/why-intellectual-property-and-pandemics-dont-mix/

Lobo, F. (2021). Restructuring the Global Vaccine Industry. *South Center*, *134*(1). https://doi.org/10.2139/ssrn.4083058

Lyn, A. L. K. (2021). *Patented Vaccines: Is Waiving The Way Forward?* Mondaq: Connecting Knowledge and People. https://www.mondaq.com/patent/1090224/patented-vaccines-is-waiving-the-way-forward

Marcowitz-Bitton, M., & Kaplan, Y. (2021). Recalibrating Patent Protection for COVID-19 Vaccines: A Path to Affordable Access and Equitable Distribution. *Bar Ilan University Faculty of Law Research Paper*, *21–26*. https://doi.org/10.2139/ssrn.3855033

Marquardt, P. D., & Leddy, M. (2003). The Essential Facilities Doctrine and Intellectual Property Rights: A Response to Pitofsky, Patterson, and Hooks. *Antitrust Law Journal*, *70*(3), 847–873.

Mbaye, F. D., & Sardjono, A. (2022). The Patent System During Global Pandemic and the Access to Medications and Vaccines. *Sriwijaya Law Review*, *6*(1), Article 1. https://doi.org/10.28946/slrev.Vol6.Iss1.1233.pp55-69

Mrdecins Sans Frontirres. (2021). *Countries obstructing COVID-19 patent waiver must allow negotiations*. Médecins Sans Frontières. https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations

Ministry of Finance Malaysia. (2021). *Budget Speech 2022: Keluarga Malaysia, Makmur Sejahtera*. Nasional Malaysia Berhad. https://budget.mof.gov.my/pdf/2022/ucapan/bs22.pdf

Nathan, L. (2022). *Malaysia Aspires to Be a Global Vaccine Manufacturing Hub*. Free Malaysia Today (FMT). https://www.freemalaysiatoday.com/category/nation/2022/04/27/malaysia-aspires-to-be-a-global-vaccine-manufacturing-hub/

Nature Editorial. (2021). A Patent Waiver on Covid Vaccines Is Right and Fair. *Nature*, *593*(7860), 478–478. https://doi.org/10.1038/d41586-021-01242-1

Ngakhusi, L. P. (2021). *Covid Vaccines: Widening Inequality and Millions Vulnerable*. UN News. https://news.un.org/en/story/2021/09/1100192

Okonjo-Iweala, N. (2021). *Trade in the Time of Pandemics*. SWI Swissinfo.Ch. https://www.swissinfo.ch/eng/business/trade-in-the-time-of-pandemics/46371248

Pitruzzella, G., & Arnaudo, L. (2017). On Vaccines, Pharmaceutical Markets, and a Role for Competition Law in Protecting (Also) Human Rights. *European Competition Law Review*, *38*(8), 347–352. https://doi.org/10.2139/ssrn.3033879

Pluss, J. D., Uehara, A., & Turuban, P. (2021, March 4). *Calls intensify for Big Pharma to break monopolies on Covid-19 vaccines*. SWI Swissinfo.Ch. https://www.swissinfo.ch/eng/business/calls-intensify-for-big-pharma-to-break-monopolies-on-covid-19-vaccines/46414146

Rubin, H., & Saidel, N. (2021). *Innovation beyond patent waivers: Achieving global vaccination goals through public-private partnerships*. Brookings. https://www.brookings.edu/articles/innovation-beyond-patent-waivers-achieving-global-vaccination-goals-through-public-private-partnerships/

Rutschman, A. S., & Barnes-Weise, J. (2021). *The COVID-19 Vaccine Patent Waiver: The Wrong Tool for the Right Goal*. Bill of Health. https://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/, http://blog.petrieflom.law.harvard.edu/2021/05/05/covid-vaccine-patent-waiver/

Shulman, J., Ahsan, R., & O'Malley, K. (2021). *Understanding Global Vaccine Economics and Research and Development*. The Sabin-Aspen Vaccine Science & Policy Group. https://www.sabinaspengroup.org/understanding-global-vaccine-economics-and-research-and-development/

Sundaram, J., & Chowdhury, A. (2021). *My Say: WTO is finished without a TRIPS waiver*. The Edge Malaysia. https://theedgemalaysia.com/article/my-say-wto-finished-without-trips-waiver

Swagel, P. L. (2021). *Research and Development in the Pharmaceutical Industry*. Congressional Budget Office. https://www.cbo.gov/publication/57126

Thambisetty, S., McMahon, A., McDonagh, L., Kang, H. Y., & Dutfield, G. (2022). Addressing Vaccine Inequity During the Covid-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond. *The Cambridge Law Journal*, *81*(2), 384–416. https://doi.org/10.1017/S0008197322000241

The Economic Times. (2021). BRICS backs India-South Africa's COVID-19 vaccine patent waiver proposal. *The Economic Times*.

https://economictimes.indiatimes.com/news/india/brics-backs-india-south-africas-covid-19-vaccine-patent-waiver-proposal/articleshow/83149877.cms

Thomson Reuters Foundation. (2021). *US vaccine patent waiver: A 'game changer' for the global south?* Eco-Business. https://www.eco-business.com/news/us-vaccine-patent-waiver-a-game-changer-for-the-global-south/

Uddin, M. (2022). Intellectual Property Rights and Competition Law for Transfer of Environmentally Sound Technologies. *Pace International Law Review*, *34*(2), 63. https://doi.org/10.58948/2331-3536.1419