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OUTLOOK OF ARBITRARY MEASURES OF FAIR AND EQUITABLE TREATMENT UNDER HEALTH URGENCY: THE WAIVER OF PHARMACEUTICAL PATENT

Clara Amanda Musu[*], Dona Regina Napitupulu[**], Marla Satika Qurratu'aini[***]

ABSTRACT

Patent has long been recognized as an important subject of investment particularly for Pharmaceutical Companies. In its development, patents have become one of the most prominent tools in international health investment for its economic benefit sourced from its exclusive right. Most of the Multilateral and Bilateral Investment Treaties recognized intellectual property rights as protected investments, which allows patent holders to benefit from the substantive and procedural safeguards granted by the applicable treaty for foreign investments. In the situation of health urgency, many patents rights are being waived by the government to make the innovation more affordable and accessible to citizens. In this situation, tension in the governance of pharmaceutical patents between patent holders and state authorities is an example of a broader recurring dynamic in international law: the tension between foreign investors' private interests and the host state's regulatory autonom. This research paper will discuss whether the patent waiver enacted by the government is considered as an arbitrary action under the Fair and Equitable Treatment standard as it causes harm to the foreign investor by analyzing several precedent jurisprudences through juridical normative methods.

Keywords: foreign direct investment; arbitrary; patent.

I. INTRODUCTION

One of the most crucial standards under the international investment agreements is the Fair and Equitable Treatment ("**FET**"). It is considered as an absolute norm in the sense that norm that has its own meaning, and is often not satisfied by only treating the investor the same way the host state treats its own citizens or other foreigners. Under the said standard, foreign investors are protected from governmental or administrative action that could harm the investment. Because of its application could be broadened to fit new definitions, the criterion of fair and equitable treatment is said to be elastic. Due to the sheer elasticity of the fair and equitable treatment standard, it is said to be the most often cited treaty standard in Investor-State arbitration, appearing in practically every claim brought by foreign investors against host countries.[1]

There are wide chances and circumstances where the host state action could infringe the FET standard, even if those actions were conducted for a legitimate purpose. Many tribunals opine that the FET standard poses a risk between protecting the foreign investment and on the other hand, this standard could hinder the government to perform a good governance. By this means, the FET standard is vague

[*] Faculty of Law Universitas Padjadjaran, Jl. Dipati Ukur 35 Bandung, email: clara19003@mail.unpad.ac.id.
[**] Faculty of Law Universitas Padjadjaran, Jl. Dipati Ukur 35 Bandung, email: dona19003@mail.unpad.ac.id.
[***]Faculty of Law Universitas Padjadjaran, Jl. Dipati Ukur 35 Bandung, email: marla19001@mail.unpad.ac.id.
[1] Lawal Oluwaseun Sidiq, "Variability of Fair and Equitable Treatment Standard According to the Level of Development Governance Capacity and Resources of Host Countries", *Journal of International Commercial Law and Technology*, Vol. 9, No. 4, 2014, p. 229.

as it is constituted as a standard that is independent from national legal order but its normative content is hardly substantiated by State Practice. It's important to keep in mind that a lot of time and effort has gone into determining whether the concept of a "Fair and Equitable Standard" only reflects the international minimum standard as contained in general principles of law and treaties, i.e. customary international law, or whether it extends beyond that minimum standard to also include sources of investment protection obligations found in treaties, or whether the standard is an autonomous self-contained. There is also a perspective that the "fair and equitable treatment requirement" is not confined to the international customary law's minimum standard norm, but rather considers the complete spectrum of international law sources, including general principles, recent treaties, and other conventional obligations.[2]

Since the first FET standard incorporated by Havana Charter on 1948, FET clause serves as the standard of protection that is used in most of the Multilateral Investment Treaties or Bilateral Investment Treaties. In the multilateral level, *the Draft United Nations Code of Conduct on Transnational Corporations*, stipulates:[3]

> *"Transnational corporations should receive [fair and] equitable [and non-discriminatory] treatment [under] [in accordance with] the laws, regulations and administrative practices of the countries in which they operate [as well as intergovernmental obligations to which the Governments of these countries have freely subscribed] [consistent with their international obligations] [consistent with international law]."*

Another example from the Multilateral Level that contains the FET standard is the *Draft OECD Multilateral Agreement on Investment (1998).* The draft gave corporations the right to sue governments if national health, labor, or environmental legislation jeopardized their interests, and it aimed to create a new body of universal investment laws that would grant corporations unconditional rights to engage in financial transactions anywhere in the world, regardless of national laws or citizens' rights. The General Treatment clause under this agreement stipulated:[4]

> *"Each Contracting Party shall accord to investments in its territory of investors of another Contracting Party fair and equitable treatment and full and constant protection and security. In no case shall a Contracting Party accord treatment less favorable than that required by international law."*

In the Bilateral framework, the FET standard is also included in almost every Bilateral Investment Treaty to guarantee the investor's right. For instance in the Indonesia-Singapore Bilateral Investment Treaties, that was renewed in 2018, stipulated as follows:[5]

> *"Each party shall accord to investments fair and equitable treatment and full protection and security"*

The example above show how FET has become one of the most important standards in the foreign investment and has been used in almost all of the multilateral and bilateral investment treaties, in order to protect investors' rights in foreign countries. Over the last decade, the rapid expansion of the FET standard in international investment law and investment disputes has been remarkable. The standard

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[2] OECD, "Fair and Equitable Treatment Standard in International Investment Law", *OECD Working Papers on International Investment*, Washington: OECD Publishing, 2004, p. 20.

[3] Article 48, The United Nations Code of Conduct on Transnational Corporations, Current Studies, Series A (New York, 1986) UN Doc. ST/CTC/SER. A/4, Annex 1.

[4] Article IV, The Multilateral Agreement on Investment Draft Consolidated Text, Negotiating Group on the Multilateral Agreement on Investment (MAI), 1998.

[5] Article 3 Agreement Between the Government of the Republic of Indonesia and the Government of the Republic of Singapore on the Promotion and Protection of Investment ("Indonesia-Singapore BIT"), entered into force March 9, 2021.

has almost become an unavoidable component of international investment treaties at both the multilateral and bilateral levels, as well as investment arbitration, because including it in the treaties implies that investors have a fairness safety net in regards toward other investment protection standards.

At this stage in the development of the FET requirement, it is reasonable to identify specific sorts of improper and discreditable State behavior that would violate the norm. One of the concepts of FET is Arbitrariness. Arbitrariness in decision-making is related to the motivations and goals that drive the given behavior and refers to a conduct that constitutes a disregard of due process of law. Arbitrary behavior is defined as "based on prejudice or desire rather than reason or evidence." An arbitrary measure is the government's action that causes harm to an investor without serving any valid purpose or providing a rational explanation, but instead relies on prejudice or bias.

Foreign Direct Investment has increased dramatically in recent decades, and many of the world's largest corporations have moved their manufacturing operations to other parts of the globe. One of the fastest growing sectors in Foreign Direct Investment is the pharmaceutical industry.[6] It is common for most of the big pharmaceutical companies in the world i.e., Johnson & Johnson, Pfizer, Eli Lilly, Novartis, Roche, and even other mid-sized pharmaceutical companies to expand their market by investing and making subsidiaries in other foreign countries. Pharmaceutical companies create subsidiaries in several foreign countries for a variety of purposes, including: expanding into new profitable sectors, increasing income, and diversifying their holdings to effectively manage risk.[7]

A pharmaceutical product's sale does not constitute an investment. Investments require a particular duration, risk, and commitment to economic development, which are not present in simple sales of goods. The most crucial asset in Pharmaceutical Companies is innovation or practical implementation of ideas from the scientist. In order for them to create a new innovation, the Pharmaceutical Company has to invest a lot of time and money in research and development. Translating the new knowledge from Research and Development will produce pharmaceutical innovations, which is the main source of profits for Pharmaceutical Companies. Patents and other types of intellectual property protection are generally known to be crucial in fostering pharmaceutical innovation. This is due to the long, expensive, and risky process of creating and bringing a new drug to market, while the costs of imitation are cheap. Patents shield a new innovation from competition against chemically identical entrants for a period of time after it has been approved and commercialized.[8] Therefore, governments are obliged to give protection for pharmaceutical companies' investments in the form of patents for their invention. Pharmaceutical companies frequently argue that pharmaceutical patent protection allows them to invest billions of dollars in the development of new treatments while also ensuring that they will be able to profit from sales.[9]

Due to the lengthy, costly, and risky nature of the research and development process compared to the lower levels of investment, patents have generally been known as crucial incentives to foster innovation, particularly the development of new prescription medicine or vaccines. Most of the scholars and researchers have consistently found patents to be relatively more important to research and development in pharmaceuticals industries than in other industries, when compared to other forms of

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[6] Valentina Vadi, "Access to Essential Medicines & International Investment Law", *The Journal of World Investment & Trade,* Vol. 8, No. 4, 2007, p. 505.

[7] Patrick Scott and Georges Corbineau, "Our Exclusive Database of Multinational Pharmaceutical Companies and Their Subsidiaries", <https://www.pharmaceutical-technology.com/features/our-exclusive-database-of-multinational-pharmaceutical-companies-and-their-subsidiaries/> accessed on December 10, 2021.

[8] Henry G. Grabowski, et. al., "The Roles of Patents and Research and Development Incentives in Biopharmaceutical Innovation", *Intellectual Property & Innovation,* Vol. 34, No. 2, 2015, p. 302.

[9] Chandra Mohan, et. al., "Patents–An Important Tool for Pharmaceutical Industry", *Research and Reviews: Journal of Pharmaceutics and Nanotechnology,* Vol 2, No. 2, 2014, p. 13.

intellectual property protection i.e., trade secrets, trademarks, and copyrights or even strategic complementary assets i.e., sales, service, and manufacturing advantages.[10]

In general, most Bilateral Investment Treaties also mention intellectual property rights in defining protected investments. Yet these treaties do not contain a clear and precise regulation of intellectual property rights. In reality, by treating intellectual property rights as protected investments, Bilateral Investment Treaties allow Intellectual property holders to benefit from the substantive and procedural safeguards granted by the applicable treaty for foreign investments.[11] In recent treaties, Investment treaties not only guarantee substantive protection for investors' rights, but they also give intellectual property owners direct access to investor-state arbitration, which can be an effective dispute resolution process for resolving alleged intellectual property infringement claims. This can be seen in most of the Multilateral and Bilateral Investment Treaties that recognized Intellectual Property Rights as a covered investment. For instance The 2005 German Model BIT defines investment as:

> *"every kind of asset, in particular […] intellectual property rights, in particular copyrights,* ***patents****, utility-model patents, industrial designs, trade-marks, trade-names, trade and business secrets, technical processes, know-how, and good will, while returns encompass royalties."*[12]

The United State 2012 Model BIT defines investment as:

> *"every asset that an investor owns or controls, directly or indirectly, has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. Forms that an investment may take include [...]* ***intellectual property rights****.*[13]

Herewith, the patent has long been recognized as an important subject of investment particularly for Pharmaceutical Companies. One has to remember that Bilateral Investment Treaties and Multilateral Investment Treaties do not set substantial standards on intellectual property, but rather protect the rights of investors who use intellectual property as an investment.

However, the tension in the governance of pharmaceutical patents between patent holders and state authorities is an example of a broader recurring dynamic in international law: the tension between foreign investors' private interests and the host state's regulatory autonom.[14] This is because a lot of patent rights are being waived by the host state as a response for health urgency. A patent waiver refers to the government's waiver of rights in an invention emerging from pharmaceutical companies' research in order for private organizations to enhance commercialization, and speed up the technology's outcome from the lab to the market. In recent years, patent-waiver has been a controversy considering many health and economic problems occuring in the world.

On the one hand, governments are obliged to protect their populations from threats to health by enacting public health policies that scope every aspect, including patent rights owned by foreign investors. The ability of the government to exercise its right allows them to enforce quarantine, health, and inspections laws to interrupt or prevent the spread of disease.[15] On the other hand, patent waiver will substantially infringe the patent exclusive rights and make the investor no longer enjoy the

[10] Iaian Cockburn and Genia Long, "The Importance of Patents to innovation: Update Cross-Industry Comparisons with Biopharmaceuticals", *Experts Opinion on Therapeutic Patents,* Vol. 25, No. 7, 2015, p. 3.
[11] Valentina Vadi, "Towards a New Dialectics: Pharmaceutical Patents, Public Health and Foreign Direct Investment", *NYU Journal of Intellectual Property & Entertainment Law,* Vol. 5, No. 1, 2015, p. 115.
[12] Germany Model BIT 2005.
[13] United States Model BIT 2012.
[14] Valentina Vadi, *Op. Cit.,* p. 119.
[15] Jorge E. Galva, *et.al.,* "Public Health Strategy and the Police Powers of the State", *Public Health Reports,* Vol. 120, No. 1, 2005, p. 25.

economic benefits of the patent. Herewith it is need to analyzed whether the wide scope of FET is possible to include Patent Waiver practices. In correlation with this background, the authors formulates problems of this issue as follows:

1. What kind of State's measure is considered as arbitrary under the Fair and Equitable Treatment Standard?
2. Does the State's Patent waiver under health urgency violate the arbitrary standard?

II. RESEARCH METHODS

The writing of this research paper uses a normative juridical legal research method that examines legal issues referring to the applicable norm system and is intended to seek scientific truth from a normative side. This paper was written using a statutory approach as well as a theoretical-descriptive conceptual approach. The data analysis for this research paper was carried out by qualitative analysis, namely classifying, grouping, and finding patterns in the data and set forth in descriptive narratives. In terms of data sources, the approach of data used in this research paper, such as; primary law materials which includes basic norm, national law, and international conventions or treaty, and jurisprudence; secondary law materials such as doctrine, books, publication by international organization, and journal articles from imminent researchers.

III. DISCUSSION AND RESULT

A. State's Arbitrary Conduct Under the Fair and Equitable Treatment Standard

One of the most habitual and customary ingredients of international investment treaties is the obligation of a host state to comply with fair and equitable treatment that is explicitly emphasized in a clause. This latter form of treatment – arbitrariness – has rarely been the focus of scholarly works and, thus, its scope and meaning are difficult to ascertain.[16] Thresholds for arbitrariness are determinedly and reliably high.

A disallowance of arbitrary measures or conduct–arbitrariness is commonly included in the non-impairment standard and appears in more than 60% of investment protection treaties.[17] The term of arbitrariness itself brings out a scope of implications and connotations. What is inconsistent from an ordinary perspective of the word might contrast particularly based on what is erratic from a legitimate perspective. Nevertheless, several arbitral tribunal have emphasized that prohibition or arbitrariness is part and parcel of the Fair and Equitable Treatment Standard, in its ordinary meaning, the term 'arbitrary' refers to "derived from mere opinion", "capricious", "unrestrained", and "despotic".[18]

These phases are frequently incorporated into investment treaties, and they are often paired with terms such as Fair and Equitable Treatment, National Treatment, or even Most Favored Nation clause. The precise dividing line between the FET and the other clause is a bit difficult to establish because individual aspects of these stages have their own unique meanings that are still somewhat vague. The accepted viewpoint is that the right to Fair and Equitable Treatment extends well beyond the rights to Most Favored Nation and National Treatment standard, even if in the latter situation, the foreigner's

[16] Jacob Stone "Arbitrariness, the Fair and Equitable Treatment Standard, and the International Law of Investment" *Leiden Journal of International Law*, Vol. 25, No. 1, p. 77-107.
[17] UNCTAD," Investment Policy Hub, International Investment Agreements Navigator" <https://investmentpolicy.unctad.org/international-investment-agreements/iia-mapping> accessed on January 13, 2022.
[18] *Oxford English Dictionary*, 1989, Second Edition, Clarendon Press, Oxford, vol. XVIII, p. 464.

rights are considerably expanded and reinforced by the responsibility not to subject the foreigner to "unreasonable measures."[19]

A number of scholars have arrived at the conclusion that the term "unreasonableness" is equivalent with the term "arbitrariness." There is a distinction, however, between arbitrariness and 'unreasonableness,'.. It's worth noting that other writers and tribunals have treated the concept of 'reasonableness' in the same way as the FET test does. However, a number of tribunals also have looked into the concept of reasonableness as a stand-alone responsibility.[20] Several International Investment Treaties contain stand-alone clauses that explicitly prohibit 'arbitrary' measures. The typical Arbitrariness indications tend to apply to investments and not investors, they refer to measures rather than treatment, and they are breached by measures that impair investment. To some International Investment Treaties, there is no substantive distinction between a specific prohibition of investment impairment by arbitrary measures and the obligation to avoid arbitrariness under the fair and equitable treatment standard. An arbitrary measure that violates a stand-alone clause would equally violate a fair and equitable treatment clause. If there is no rationale or justification for a legitimate government policy (for example, if the measure discriminates against investors based on a specific content), the measure might be termed 'unreasonable.'[21]

Though many International Investment Treaties contain clauses of both types, the inclusion of prohibitive 'arbitrary' measures clauses is thus seen as redundant. Hence, arbitrary conduct therefore can be seen as a sufficient but not as a necessary requirement for the violation of fair and equitable treatment. Despite all the arguable viewpoints of whether arbitrariness can stand alone in the FET standard in International Investment Treaties, In light of the above observations, there can be no doubt that arbitrariness is a legitimate basis for claim under international standards of investment protection. Investors may bring claims of arbitrariness under International Investment Treaty provisions that explicitly prohibit arbitrary state conduct.

The landmark case for the definition and threshold of arbitrariness is the *ELSI Case* (1989). The Judges defined arbitrariness as a wilful disregard of due process of law, an act which shocks, or at least surprises, a sense of judicial propriety.[22] The awards can be used to indicate that the measures are arbitrary if they cause harm to the investor without serving any apparent legitimate purpose; or if they are not based on legal standards but on discretion, prejudice, or personal preference; or if they are taken for reasons other than those stated by the decision makers, especially if a public purpose is merely a front on the different motive.

Another tribunal in *Genin v. Estonia* (2001) defines arbitrary action similarly which is a procedural irregularity that may have been present would have to amount to bad faith, a wilful disregard of due process of law or an extreme insufficiency action.[23]

In the case of *Sempra Energy v. Argentine* (2007) The Tribunal rejected the claim that the measures at that case had been arbitrary because "a finding of arbitrariness requires that some important measure of impropriety be manifest", while the measures in that case "responded to what the Government believed and understood to be the best response to the unfolding crisis" and had been "not entirely surprising" in the context, in which they had taken place. The claim of discrimination was

[19] Rumana Islam, "Interplay between Fair and Equitable Treatment (FET) Standard and other Investment Protection Standards", *Bangladesh Journal of Law,* Vol. 14, No. 1, 2014, p. 133
[20] Patrick Dunberry, "The Prohibition against Arbitrary Conduct and the Fair and Equitable Treatment Standard under NAFTA Article 1105" *The Journal of World Investment & Trade,* Vol. 15, No. 1, 2014, p. 124.
[21] Jacob Stone, *Op. Cit.,* p. 100.
[22] Elettronica Sicula S.p.A. (ELSI) (United States of America v. Italy), Judgments, 20 July 1989.
[23] Genin Eastern Credit Ltd. Inc. and AS Baltoil v. Republic of Estonia, Award, 25 June 2001, para. 316.

rejected because the Tribunal did not find "any capricious, irrational or absurd differentiation in the treatment accorded to the Claimant as compared to other entities or sectors.[24]

In *SD Myers v. Canada* (2008), The tribunal held that the arbitrary measure is a definitional element under the fair and equitable treatment standard. The tribunal held " ...the breach of a rule of international law by a host Party may not be decisive in determining that a foreign investor has been denied "fair and equitable treatment", but the fact that a host Party has breached a rule of international law that is specifically designed to protect investors will tend to weigh heavily in favor of finding a breach of Article 1105".[25]

In *B3 Croatian Couriers* v. *Croatia* (2019), the Tribunal concluded that there is no rational explanation for the Government to re-monopolize a part of the postal services market, on the account that the intended effect of the action. The Tribunal further considers that the Respondent's conduct can only be understood as a bad faith attempt to protect the interest of other operators at the expense of its competitors.[26]

In *Occidental Exploration and Production Company v. The Republic of Ecuador* (2004), defines that Arbitrariness occurs when the host state enacts an uncertain measure that lacks clarity and causes investor's confusion over the regulatory framework even if not intended.[27]

In *Lemire v. Ukraine* (2011), the tribunal held that State is conduct an arbitrary measure when those measure were "manifestly violating the requirements of consistency, transparency, even-handedness, and non-discrimination" and "shock, or at least surprises, a sense of juridical propriety." The Tribunal also decided that by conducting an arbitrary measure, the State violated Fair and Equitable Treatment standards.[28]

In *Siemens v. Argentina* (2007), the Tribunal found that certain measures taken by Argentina do not seem to be based on reason. It noted that Argentina had never explained why they needed to start the immigration control sub-system (DNM sub-system) was not given after the system itself had started to operate, and why Argentina denied the possibility of SITS to correct the error. Eventually, it stated that "*[w]hile the Tribunal could accept that there may have been reasons to justify the temporary suspension of the DNM and RPN sub-systems, the Tribunal finds its permanent suspension arbitrary*".[29] Summing up, Professor Schreuer has defined arbitrary as:[30]

a. a measure that inflicts damage on the investor without serving any apparent legitimate purpose;
b. a measure that igs not based on legal standards but on discretion, prejudice or personal preference;
c. a measure taken for reasons that are different from those put forward by the decision maker;
d. a measure taken in wilful disregard of due process and proper procedure.

Therefore, any State's measures that contravene with the rule of law which are uncertain and prejudiced are deemed as arbitrary. Moreover, these measures are also recognized as EDF Test, a more elaborate test for what counts as an arbitrary measure was adopted in EDF *(Services)* which is as above.

[24] Sempra Energy International v. The Argentine Republic, ICSID Case No. ARB/02/16, Award, 20 September 2007.
[25] S.D. Myers vs. Canada, UNCITRAL, Award on Liability, 13 November 2008, para. 263.
[26] B3 Croatian Courier Coöperatief U.A. v. Republic of Croatia, ICSID Case No. ARB/15/5), Award, 5 April 2019, para 1002-1004.
[27] Occidental Exploration and Production Company v. The Republic of Ecuador, LCIA Case No. UN3467, Final Award, 1 July 2004, para. 163.
[28] Joseph Charles Lemire v. Ukraine (Decision on Jurisdiction and Liability) [2010] ICSID Case No. ARB/06/18, para. 262.
[29] Siemens A.G. v. The Argentine Republic, ICSID Case No. ARB/02/8, Award, 17 January 2007, para. 318-319.
[30] Christoph H. Schreuer, *Protection against Arbitrary or Discriminatory Measure,* Vienna: University of Vienna, 2007, p. 188

B. State's Patent Waiver Under Health Urgency Violate the Arbitrary Standard

A patent is an exclusive right granted by a government for an invention, which is a product or process that provides a new way of doing something or offers a new technical solution to a problem.[31] This right is generally termes intellectual property rights (**"IPRs"**) and is seen as an incentive for innovation. Thus a patent provides protection towards your invention when the owner disclose it publicly. Providing a right to exclude others from the practice of the invention offers them the opportunity to earn rents or profits when the innovation is higher than those they would earn if there were immediate free access to imitate the invention.

Recently there has been an opinion from several countries to implement a patent waiver. Patent waiver is a proposal to waive certain provisions of the Trade-Related Aspects of Intellectual Property Agreement ("**TRIPS Agreement"**). The TRIPS Agreement has set a minimum standard of protection for patent, copyright, trademarks, geographical indications, industrial designs, and trade secrets. TRIPS Agreement also provides certain exceptions to the intellectual property protection rules, such as in the event of a public health emergency. In this situation, members can waive the patent right of a patent holder, for example, to perform compulsory licensing that allows third parties to produce a patented product or process without the patent owner's consent. By compulsory licensing, the government can then create generic copies for the home market, as well as execute fast-track processes in the event of a health emergency.[32] Patent waiver is an excessive version of technology transfer that is the sharing of progressive products, processes, and other relevant knowledge for both commercialization or the greater good. This technology transfer commonly takes place through the licensing or sale of a patent rather than waiving a patent protection altogether.

In October 2020, South Africa and India proposed a waiver of certain obligations in the TRIPs Agreement that related to the prevention, containment, or treatment of Covid-19.[33] This waiver can be applied in a situation relating to health products and technologies, their materials or components, as well as their methods and means of manufacture that related to the treatment of Covid-10 that involves a range of products, technologies, and intellectual property.[34]

Patent waiver has become one of the discussions in public that is quite controversial globally. The discussion is whether the patent waiver has violated the arbitrary standard or rather the patent waiver is part of Governments' rational measures to respond to the health urgency. If we take a look back to the terms of arbitrary itself, arbitrary is a measure when the government's action causes harm to an investor based on prejudice or bias, without serving any valid purpose or a rational explanation.[35] In order to asses the arbitrary measures, the Patent waiver has to comply as follows:

1. **Causes Harm to the Investor**

   An invention may be patented if it is a novelty that is "non-obvious" and involves an "inventive step" relative to the prior art identified in the earlier search.[36] In order to create a novelty invention, the patent owner has to prepare qualified research and development, which indubitably requires intense time and costs a lot of money. The cost of acquiring a single patent family covered in the EU, US, and Japan can be around $100,000. These patents should be

[31] World Intellectual Property Organization, "Inventions and Patents", Module 3, p. 4.
[32] European Parliament, "World Trade Organization TRIPS Waiver to Tackle Coronavirus" <https://www.europarl.europa.eu/RegData/etudes/ATAG/2021/690649/EPRS_ATA(2021)690649_EN.pdf> accessed on January 12, 2022.
[33] IP/C/W/669 2 October 2020 (20-6725); IP/C/W/669/Rev. 1 25 May 2021 (21-4307).
[34] *Ibid*.
[35] Supra, Note. 30
[36] OECD, "Patent Systems and Procedures", OECD Patent Statistics Manual, 2009, page. 41

maintained annually to avoid the risk of expiration or loss of validity, which can cost about $75,000 over 20 years.[37] The money spent in the research and development is not only on the research portion but also on the development–or maintaining the invention that has already been created.

Waiving the patent terms will cause harm towards the patent holder since it will seize the right owned by the patent holder. By spending the time and cost on the research and development, the patent holder has the exclusive right to prevent other or any third parties from using the invention without the patent holder's permission. Coupled with the uncertainty that the waiver will remain in effect for an indefinite period. In this case to conclude, the patent waiver will harm the essence of the patent itself.

2. Serving Valid Purpose or Rational Explanation to Implement the Measures

The proposal does not contain limits on product coverage, scope, notification requirements, or any safeguards and proposes that there is no definite period for this waiver will remain in effect. It shows that the proposal is not to generate quick negotiations or solutions, instead, the proposal may be using the Covid-19 pandemic as an alibi to roll-back IPR, rather than a sincere effort based on good faith to expedite access to life-saving treatments globally.

Jayashree Watal, India's negotiator to the TRIPS Agreement which has been in the WTO secretariat for three decades, agrees stating that the proposal of the patent waiver is an indirect attempt to pressure the original manufacturer to cooperate and give a license production to companies.[38] This view makes the proposal of the patent waiver to be seen based on a bad faith, which is lured for the importance of public regarding the vaccine distribution, however it turns out to be a shortcut for countries that do not have the permission or can not manufacture the patent in order to suppress the patent owner to cooperate.

Moreover, it was said that this waiver would be a significant step to accelerate the expansion of the production and supply of Covid-19 medical products by allowing WTO members to facilitate both the production of generics and the exports to the needed countries. However, having the 'blueprints' does not guarantee the safeness and effectiveness of the production, as is the goal of this waiver. Simply put, even if a chef gives an instruction on how to bake a cake, the results of the cake will still be better than the one that is baked by a novice, even if they used the same recipe. It is because qualified knowledge and trade secrets are the main ingredients for the manufacture of quality, safe, and effective medicines or vaccines. It will be difficult for the government to compel the transfer of such information even under the waiver. Moreover, this condition would not be achieved through a patent waiver, and by putting aside the methods provided in the TRIPS Agreement *e.g.* voluntary or compulsory license. TRIPS Agreement itself has provided the flexibility during an extreme urgency situation for the government to implement the compulsory license, or usually known as government-use.[39]

Therefore, The most effective approach in this public health crisis situation is direct government support. The government can concentrate and scale up the prompt and effective use

[37] Josep Hadzima, "Examining the Relative R&D Spend to Patent Costs", <https://info.ipvisioninc.com/blog/examining-the-relative-rd-spend-to-patent-costs#:~:text=Ratio%20of%20Patents%20to%20R%26D&text=This%20can%20cost%20around%20%2475%2C000%20over%20the%20course%20of%20twenty%20years.&text=For%20these%20reasons%2C%20the%20ratio,%241%20million%20spend%20on%20R%26D.> accessed on December 14, 2021.

[38] Maximilian Steinbeis & Evin Dalkilic, "Three Crises and One Waiver" Verfassungsblog, 2021, <https://verfassungsblog.de/three-crises-and-one-waiver/>.

[39] Article 31 TRIPS Agreement.

of the existing flexibilities in the TRIPS Agreement. Also by improving the coordination by involving the private pharmaceutical sector to ensure all qualified generic manufacturers are willing and able to manufacture the vaccines are doing so and to increase the supply and bring more facilities up to standard.

3. Not Based on Prejudice or Bias

The supporters of patent waiver stated that IPRs could become a barrier towards access to life-saving Covid-19 health technologies. [40] However, we know for sure that IPRs have played a main role in the development and availability in delivering vaccines throughout these years by encouraging investment, innovation, and the advancement of health science.[41] Thus in the absence of protection towards a patent, there is the prospect of easy imitation by the future market entrants, which may deter the would-be innovators from incurring fixed up-front costs on the research and development. Yet, with a guaranteed period of market exclusivity, inventors remain motivated to be able to continue their research and development of breakthrough medicines with a preeminent certainty that there will be a fair share of the effort that has been put into their innovation. A right towards a patent becomes something valuable enough to encourage a greater –but not easily granted– innovation; thus, this motivation is greater than the output restrictions on patented products and the discouragement of downstream innovations that depend on access to patented technology.

Moreover, it would be a mistake to try to cast the current crisis as a morality game in which the drug makers are faced with a choice between private profits and public health. Pharmaceutical companies will have no chance to defeat the virus without the capabilities of a formidable pharmaceutical industry, and the provision of appropriate incentives is also essential to ensure that the industry plays an integral and vital role. The rationale for the profits to be made by private companies in this current crisis is misguided since if we viewed it more objectively, those profits are only a drop in the bucket compared to the pandemic's staggering cost of life and economic damage.

Hence, Patent waiver implemented without a long examination and consideration will cause a domino effect in the future. If in the face of a pandemic the government chooses to immediately enforce a patent waiver, in the future if a new pandemic arises, there will be an absence of innovators trying to manufacture a treatment towards the disease thinking that their patents will be waived after all in the end.

IV. CONCLUSIONS

The arbitrary term is not commonly defined in IITs due to their open-ended nature, they do not lend themselves to an obvious definition. Tribunals referred to dictionary and publicists definitions in respect to those terms. In respect of the well-recognized definitions, tribunal referred arbitrariness as a measure that impose impairment towards investors, a measure without any legal justifications, a measure contrary to the due process of law, and a measure taken because of reasons that are not quite the same as those set forward by the decision maker. Some landmark cases use Professor Schreuer terms of arbitrary, which later the awards are known as a parameter named EDF test.

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[40] Global Development Policy Center, "Open Letter to TRIPS Council Members" Remove Barriers to Access for Critical Covid-19 Supplies", 2020, <https://www.bu.edu/gdp/2020/11/18/open-letter-to-trips-council-members/>. accessed on December 14, 2021.

[41] Anne Moore, "COVID vaccines: why waiving patents won't fix global shortage – scientist explains" The Conversation, 2021, <https://theconversation.com/covid-vaccines-why-waiving-patents-wont-fix-global-shortage-scientist-explains-158643> accessed on December 16, 2021.

IPRs has played a big role in the availability and development of multiple medicines, even vaccines. In this case, the waiver could harm the patent owner, the one who bears all the research and development, by seizing the exclusive rights towards the patent. Moreover, there is no clear purpose that is based on a factual reason given by the State that can lead to bad faith. If the State in overcoming the health urgency does not try to undertake another option and chooses to enact the patent waiver, it can violate the arbitrary standard.

In a pandemic situation, it is certainly frightening for all people worldwide, where countries are competing to find the most credible treatment to deal with. For these reasons, IPRs come as one of the impetus for innovators to create treatment, containment, and prevention against Covid-19. Thus it is not appropriately-wise to propose a patent waiver with the argument that it will become a barrier since patents are the way out of this health crisis. In this situation, it is appropriate to shift the view to a 'direct support regime'. The government may focus the efforts by incentivizing the manufacture of vaccines to prevent the spread of the virus and the other drugs to treat them. Governments can form a deal with pharmaceutical companies by insulating them from commercial risk. If the pharmaceutical company develops an effective vaccine and medicines, the government may buy it in predeterminedquantities to provide advance purchase commitments that guarantee a healthy and fair return.

Killing the goose that laid the golden egg may seem engaging in the short-term; however, it only ensures that no eggs are delivered in the next pandemic. Cooperation will not only lead us out of this pandemic but also put us in a better position to deal with the next one.

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