The Impact of Bilateral Investment Treaties on Health-related Intellectual Property Rights in the TRIPS Agreement

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Abstract

The COVID-19 pandemic created unprecedented challenges for the international community. One of the most pressing issues of 2021 is the need to balance between private rights and public interests when addressing equitable access to COVID-19 vaccines. The thesis determines whether bilateral investment treaties and treaties with investment provisions appropriately balance the rights and interests of intellectual property right holders, investors, and the public in Saudi Arabia and Australia on the issue of COVID-19 vaccine development, manufacturing, and distribution in light of the TRIPS Agreement. The thesis uses the methodologies of qualitative content and legal interpretation analysis.

The thesis first investigates the nature and distinctive features of investment treaties signed by Australia and Saudi Arabia during the COVID-19 crisis. It then explores the application of these treaties and the TRIPS Agreement to the regulation of health-related IP rights and investigate areas of congruence and divergence between the treaties and the TRIPS Agreement regarding the regulation of health-related IP rights. Further, the clarification of priorities in the case of overlap and the existing dispute resolution mechanisms in light of the COVID-19 crisis are explored. Finally, key implications of the pandemic for regulating health-related IP rights related to the development and distribution of COVID-19 vaccines are identified, and the compliance of vaccine deals negotiated by Saudi Arabia and Australia with the TRIPS Agreement and investment treaties are evaluated.

The study results show that both countries have experienced certain problems in conducting vaccination campaigns; nonetheless, their vaccine agreements provide a sufficient number of doses for their populations. Regarding bilateral treaties signed by Australia and Saudi, most are in line with the TRIPS rules and do not prevent use of the flexibilities offered by the TRIPS Agreement to overcome the pandemic's spread. The Australia–U.S. free trade agreement is a significant exception. This agreement prevents the Australian government from utilizing parallel importation to obtain additional doses of certain vaccines and complicates the use of compulsory licenses due to restrictions put on the transfer of know-how. This is a significant reduction of the benefits which would otherwise be available under the TRIPS agreement.

The research concludes that the existing flexibilities of the TRIPS Agreement enable flexible arrangements to facilitate vaccination campaigns in Australia and Saudi Arabia if they are available under bilateral investment treaties. In particular, the proposed TRIPS Waiver has the potential to make significant contributions to vaccine availability as long as it is not negated by bilateral treaties.

Keywords: The TRIPS Agreement, bilateral investment treaties, treaties with investment provisions, health-related intellectual property rights, COVID-19 vaccines.

Declaration

"I, Abdulrahman Fahim M Alsulami, declare that the PhD thesis entitled 'The Effect of Bilateral Investment Treaties on Health-related Intellectual Property Rights in the TRIPS Agreement' is no more than 80,000 words in length including quotes and exclusive of tables, figures, appendices, bibliography, references and footnotes. This thesis contains no material that has been submitted previously, in whole or in part, for the award of any other academic degree or diploma.
Except where otherwise indicated, this thesis is my own work".

"I have conducted my research in alignment with the Australian Code for the Responsible Conduct of Research and Victoria University's Higher Degree by Research Policy and Procedures.

Signature	Date
Abdulrahman Alsulami	16 December 2021

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Table of Contents

List of Abbreviations

BITs	*bilateral investment treaties*
COVAX	*The COVID-19 Vaccines Global Access Facility*
FTAA	*Free Trade Area of the Americas Agreement*
FTAs	*Australia's free trade agreements*
ISDS	*investor-state dispute settlement*
IPRs	*Intellectual Property Rights*
MFN	*Most-favoured-nation*
ME	*Middle East*
TRIPS	*Agreement on Trade-Related Aspects of Intellectual Property Rights*
MENA	*Middle East and North Africa*
TPPA	*Trans-Pacific Partnership Agreement*
WTO	*World Trade Organization*
UNCITRAL	*The United Nations Commission on International Trade Law*
EU	*European Union*
WIPO	*World Intellectual Property Organization*
WB	*World Bank*
WTO	*World Trade Organization*

CHAPTER ONE: INTRODUCTION

1.1. Research Background and Problem Statement

The maintenance of an optimal balance between the interests and rights of stakeholders constitutes one of the main goals of the international intellectual property ('IP') law. The TRIPS Agreement, which is known as a document outlining the minimum standards of IP protection, seeks to accomplish such goals as 'reducing distortions and impediments to international trade, promoting effective and adequate protection of IPRs, and ensuring that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade'.[1] The standards introduced by the TRIPS Agreement are supposed to be incorporated into the national legislation of signatory countries.[2]

Further, these standards should be also considered when signing bilateral investment treaties ('BITs') and other treaties with investment provisions. In practice, however, there are significant divergences between provisions of the TRIPS Agreement, investment treaties and local regulations, which add uncertainty to the regulation of IP law.[3] This problem becomes especially evident during health crises when the existing IP law frameworks might limit the access of residents of developing and least-developed countries to necessary drugs and vaccines.[4] In such situations, a balance between stakeholders' rights and interests becomes a pressing issue.

The regulation of health-related IP rights used to be an object of intense debates even before the COVID-19 pandemic. Inconsistencies and even contradictions between the TRIPS Agreement and investment treaties contributed to the growing confusion concerning the best way to balance stakeholders' interests in order to protect medical companies' investments and, at the same time, reduce inequalities in relation to access to medications and vaccines.[5] Stakeholders are looking for the best way to ensure supply of vaccines and medicines to all the people while preserving rewards to their creators. This problem became especially topical due to the outbreak of the COVID-19 pandemic, as it created unprecedented challenges for the international community in relation to vaccine equity and the relevance of IPR frameworks within the context of health emergencies.

The COVID-19 crisis contributed to the topicality of this problem, emphasising that the existing legal frameworks prevent populations of developing and underdeveloped countries from accessing COVID-19 vaccines. As a result, the pace of immunisation campaigns in various corners of

[1] Declaration on the TRIPS Agreement and Public Health 2001.WT/MIN (01)/DEC/2
[2] Andrew Newcombe and Lluis Paradell, *Law and Practice of Investment Treaties: Standards of Treatment* (Kluwer Law International, 2009).
[3] Bertram Boie, 'The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?' (Working Paper No 2010/19, World Trade Institute, November 2010) <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.
[4] Peter Yu, 'The Objectives and Principles of the TRIPS Agreement' (2009) 46 *Houston Law Review* 979–1046.
[5] Susy Frankel, 'Challenging Trips-Plus Agreements: The Potential Utility of Non-Violation Disputes' (2009) 12 *Journal of International Economic Law* 1023–65.

the globe is fundamentally different.[6] Inequitable access to vaccines undermines the international community's ability to overcome the current pandemic and prevent the occurrence of similar crises in the future.

A critical examination of IP barriers to vaccine distribution is becoming a topical research area. Certain efforts to explore this problem have already been made. Concurrently, it seems justified to state that insights gained from general discussions of vaccine manufacturing and distribution might be too broad for making any practical recommendations concerning the acceleration of vaccination campaigns. The balancing of stakeholders' interests in each country with the help of investment treaties strongly affects IPR frameworks that are relevant for the regulation of vaccine-related IP rights; accordingly, the study could benefit from discussing this problem in case of some specific countries. The literature already offers certain examples of studies based on the cases of specific states, such as Ireland[7] and Canada.[8] However, the cases of most countries remain under-researched. In particular, the problem in question has not been investigated yet in Saudi Arabia and Australia, although, as shown above, the cases of both these countries are interesting from the perspective of the problem.

In general, it seems justified to conclude that the existing literature displays a series of research gaps that predetermine the topicality of the current thesis. First, it offers a limited number of insights into the significance of TRIPS flexibilities and the constituents of international IPR frameworks within the context of the COVID-19 pandemic. Several stakeholders have put forward their opinions on this matter; however, most of these could not be found in peer-reviewed sources. Numerous articles dedicated to the issue of the TRIPS Waiver, including those written by Andre[9],

[6] Israel, the United States, the United Kingdom, Germany, Italy, Iceland, the United Arab Emirates and Chile have already vaccinated 62.45%, 51.77%, 62.91%, 60.15%, 60.80%, 76.80%, 76.03%, and 71.11%, while such states as Peru, Guatemala, Zimbabwe, Nigeria and Tanzania have vaccinated only 25.07%, 6.87%, 10.85%, 0.68%, and 0.50% of their citizens respectively (Our World in Data, 'Coronavirus (COVID-19) Vaccinations', *Our World in Data* (online, 31 August 2021) <https://ourworldindata.org/covid-vaccinations>.)

[7] Aisling McMahon, 'Patents, Access to Health and COVID-19 – The Role of Compulsory and Government-Use Licensing in Ireland' (2020) 71 *Northern Ireland Legal Quarterly* 331–58.

[8] Jeremy De Beer and E. Richard Gold, 'International Trade, Intellectual Property, and Innovation Policy: Lessons from a Pandemic' In Colleen M Flood, Vaness MacDonnell, Jane Philpott, Sophie Theriault and Sridhar Venkatapuram (eds), *Vulnerable: The Law, Policy and Ethics of COVID-19* (University of Ottawa Press, 2020) 579–89.

[9] James Andre, 'France Expands Vaccine Rollout as Macron Voices Support for Patent Waiver', *France 24* (online, 6 May 2021) <https://www.france24.com/en/france/20210506-france-expands-vaccine-program-as-macron-voices-support-for-patent-waiver>.

Visontay[10], Hannah et al[11], Bosse, Kang and Thambisetty[12], reveal subjective opinions of the articles' authors and some stakeholders. Some of these arguments appeal to emotions rather than rational considerations and, thus, could be hardly considered credible. Further, many of them discuss the perspectives of only some parties, primarily the public, and disregard the perspective of patent holders. This literature is critically examined in the thesis in respective chapters instead of putting the results of the review in a single chapter.

Second, the discussion of TRIPS-plus provisions of BITs and treaties with investment provisions in most studies is not aligned with the principles of utilitarianism. The majority of sources discuss TRIPS-plus clauses in a theoretical context and do not analyse the significance of particular provisions for solving specific health care crises. In contrast, the current study seeks to discuss the relevance of various TRIPS-plus provisions in Australian and Saudi BITs from the perspective of their possible implications for the regulation of vaccine-related IP rights during the COVID-19 pandemic.

Third, most studies on the regulation of vaccine-related IP rights mention only some flexibilities of the TRIPS Agreement, failing to discuss all of them in detail. Such articles as those written by Frankel[13] focus on some specific aspects of TRIPS-plus provisions in investment treaties. At the same time, those researches that seek to draw the *big picture* of TRIPS-plus clauses, such as the one published by Boie,[14] are overly general and lack essential details. Most studies prioritise compulsory licences over other TRIPS flexibilities. Fourth, none of the existing studies systematically analyses and compares the significance of TRIPS-plus provisions in the investment treaties signed by Saudi Arabia and Australia within the context of the COVID-19 pandemic.

An analysis of scholarly sources illustrates that the regulation of health-related IP rights has received a significant amount of attention in the literature. Some studies critically examine the significance of vaccine-related IP rights and provide valuable insights into the TRIPS-plus provisions of some investment treaties. Simultaneously, this problem remains under-researched within the context of the COVID-19 pandemic. The current pandemic, at the same time, displays a set of unique

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[10] Elias Visontay, 'India Wants Access to Cheap Copies of Covid Vaccines. So Why Is Australia Holding Out?' *The Guardian* (online, 29 April 2021) <https://www.theguardian.com/australia-news/2021/apr/30/india-wants-access-to-cheap-copies-of-covid-vaccines-so-why-is-australia-holding-out>.

[11] Erin Hannah, James Scott, Silke Trommer and Sophie Harman, 'TRIPS Waiver: US Support Is a Major Step but No Guarantee of COVID-19 Vaccine Equity', *The Conversation* (online, 12 May 2021) <https://theconversation.com/trips-waiver-us-support-is-a-major-step-but-no-guarantee-of-covid-19-vaccine-equity-160638>.

[12] Jocelyn Bosse, Hyo Yoon Kang and Sive Thambisetty, 'Trips waiver: There's More to the Story than Vaccine Patents', *The Conversation* (online, May 7 2021) <https://theconversation.com/trips-waiver-theres-more-to-the-story-than-vaccine-patents-160502>.

[13] Susy Frankel, 'Challenging Trips-Plus Agreements: The Potential Utility of Non-Violation Disputes' (2009) 12 *Journal of International Economic Law* 1023–65.

[14] Bertram Boie, 'The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?' (Working Paper No 2010/19, World Trade Institute, November 2010) <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.

features that make it fundamentally different from all the previous health care crises. The unprecedented scale of the pandemic resulted in a situation when many countries faced the threat of the shortage of COVID-19 vaccines. They still struggle with obtaining necessary vaccine supplies and, thus, have been considering a variety of alternative approaches towards securing high-quality COVID-19 vaccines, which translates into the unprecedented topicality of the research problem. The current research, therefore, seeks to analyse the regulation of vaccine-related IP rights in light of the interaction between the TRIPS Agreement and investment treaties in a new context.

Another critical feature of the current study that addresses an evident research gap is its practical focus. Unlike most other works exploring TRIPS-plus provisions of investment treaties, the scope of this research is not limited to a simple legal analysis. The study puts this legal analysis into the practical context, utilising the utilitarian approach to explore the existing avenues for facilitating the vaccination campaigns in Saudi Arabia and Australia in light of the countries' obligations under the TRIPS Agreement and investment treaties. Such an approach helps describe the magnitude of the problem of TRIPS-plus provisions in the present scenario. One aspect of this research that contributes to its novelty is connected with the author's attempt to study a theoretical problem within a practical context.

The thesis analyses secondary sources that are dedicated to the TRIPS Agreement, TRIPS flexibilities, TRIPS-plus provisions of investment treaties and the importance of the existing IPR frameworks in the context of the COVID-19 pandemic. Relevant sources are discussed throughout the thesis describing and critiquing the current arrangements and exploring improvements and alternative approaches. A review of the relevant literature has enabled the identification of the research problem, placed it into context, suggested methodologies to address it and identified the research gaps.

This thesis seeks to explore the balancing of stakeholder interests in BITs affecting the manufacture and distribution of COVID-19 vaccines in light of the TRIPS Agreement. Saudi Arabia and Australia have been selected as examples of countries whose vaccine supply arrangements seem especially noteworthy in the above-mentioned context. The second chapter of the thesis following this introduction presents the discussion of BITs, treaties with investment provisions and the TRIPS Agreement at the global level. The legal framework regulating health-related IPRs consists of a variety of layers: national laws, international arrangements, such as the TRIPS Agreement, and a variety of other documents, such as BITs, treaties with investment provisions, and contracts between governments and pharmaceutical companies. The instruments incorporated in the system of health-related IP rights include patents, trademarks, copyrights and trade secrets.[15] These instruments are discussed in detail in Chapter 2.

[15] Nikolaus Thumm, *Intellectual Property Rights: National Systems and Harmonization in Europe* (Springer, 2013).

Patents are widely discussed in relation to the equitable access to vaccines and drugs. In the most general view, they could be defined as 'the legal right of an inventor to exclude others from making or using a particular invention'.[16] Patents are available for all inventions, including not only products but also processes if they meet the criteria of novelty, inventive steps and industrial application capability.[17] A patent is a powerful mechanism that could prevent other parties from 'making, using, offering for sale, selling, or importing for these purposes that product'[18] without the consent of an owner. The scope of patents is limited by four exceptions defined by the European Patent Convention[19] and the clause pertaining to the expansion of a patent term. Further, patent protection could be bypassed using a compulsory licence. The literature on the patent system is reviewed in Chapter 2 in relation to the IPR framework on the vaccine market.

The instrument of trade secrets constitutes another significant mechanism of protecting health-related IP rights. Trade secrets pertaining to manufacturing processes have become a key mechanism of protecting vaccine-related IP rights.[20]Along with the patent protection system, these instruments are discussed in detail in Section 2.4 of Chapter 2. Even if a generic manufacturer receives and successfully uses a compulsory licence to bypass patent protection, they might still struggle with producing drugs or vaccine because of the lack of necessary know-how.[21] The marketing approval and clinical data are protected by the TRIPS Agreement as well as by numerous investment treaties. Obtaining access to such data might be problematic due to the absence of corresponding mechanisms that could force pharmaceutical companies to reveal trade secrets. Moreover, some investment treaties, such as the free trade agreement between Australia and the United States, explicitly prevent parties from disclosing marketing approval data or issuing auxiliary orders to facilitate the transfer of know-how to generic manufacturers.[22] In this situation, it seems justified to argue that trade secrets have become a critical layer of the IPR framework in the health care industry.

The TRIPS Agreement was signed in 1995 with the purpose of expanding trade by introducing a set of consistent rules regulating IP rights. It created an initial layer of protection extending to all inventions, providing parties with an opportunity to rely on this layer in any country that is a World Trade Organization (WTO) member. Extensive critical literature on the TRIPS Agreement is discussed in Section 2.1. In particular, special emphasis is laid on Section 5 of the TRIPS Agreement, including Article 27 and Article 31.

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[16] Bronwyn Hall, 'Patents and Patent Policy' (2007) 23 *Oxford Review of Economic Policy* 568–87.
[17] TRIPS Agreement, Article 27.
[18] Ibid.
[19] The European Patent Convention.
[20] Jody Westby, *International Guide to Privacy* (Chicago, 2004: American Bar Association).
[21] David Levine, 'Covid-19 Should Spark a Reexamination of Trade Secrets' Stranglehold on Information', *Stat News* (online 10 July 2020) <https://www.statnews.com/2020/07/10/covid-19-reexamine-trade-secrets-information-stranglehold/>.
[22] *Free Trade Agreement*, Australia–United States of America, 2004.

Chapter 2 also includes the discussion of investment treaties and possible areas of divergence between the TRIPS Agreement and TRIPS-plus clauses of investment treaties. Most investment treaties reaffirm the TRIPS Agreement's provisions. For instance, the IPR chapter of the free trade agreement between Australia and the Republic of Korea states that 'the Parties recognize the importance of the Declaration on the TRIPS Agreement and Public Health' and that 'in interpreting and implementing the rights and obligations under Article 13.8, the Parties are entitled to rely upon the Doha Declaration'.[23] Therefore, in most situations, investment treaties are consistent with the TRIPS Agreement.

Simultaneously, in some situations, areas of divergence between investment treaties and the TRIPS Agreement create so-called TRIPS-plus provisions that introduce additional layers of protection for investors. Yannaca-Small[24] and Grierson-Weiler and Laird[25] argue that the standard of the fair and equitable treatment might provide investors with a chance to take legal action in the case they believe that their treatment was inconsistent with their legitimate expectations. Further, the term 'minimum standards of treatment' arguably allows incorporating the TRIPS Agreement into the system of IP protection under investment law owing to the document's role as a set of clauses pertaining to the *flow* of international IPR protection.[26] Various paths for investor-state dispute settlements and the *umbrella clause* might also introduce possible areas of divergence between investment treaties and international IP law, even though these inconsistencies are unlikely to be significant. Some investment treaties, at the same time, offer radical clauses that limit or even completely eliminate the flexibilities offered by the TRIPS Agreement. For example, Chapter 4 provides a critical discussion of the free trade agreement between Australia and the United States with the focus on significant TRIPS-plus dimensions introduced by the document.

Chapter 3 discusses investment treaties and the TRIPS Agreement within the context of the Kingdom of Saudi Arabia, exploring such important issues as the system of IP rights' protection in the country, investment treaties' provisions on standards of treatment, compulsory licensing and dispute settlement as well as the areas of congruence and discrepancies between Saudi investment treaties and the TRIPS Agreement. The same topics are covered in the fourth chapter of the thesis with regard to Australia.

The fifth chapter examines the most important arrangements related to vaccine supplies. COVID-19 vaccines enjoy various IPR protection layers preventing generic manufacturers from producing vaccines without the explicit consent of IP rights' holders. Whereas inventors of the early

[23] *Free Trade Agreement*, Australia–Republic of Korea, 2014.
[24] Katia Yannaca-Small, 'Fair and Equitable Treatment Standards: Recent Developments' in August Reinisch (ed), *Standards of Investment Protection*, (Oxford University Press, 2008), 111.
[25] Todd Grierson-Weiler and Ian A. Laird, 'Standards of Treatment' in Peter Muchlinski, Federico Ortino and Christoph Schreuer (eds), *The Oxford Handbook of International Investment Law*, (Oxford University Press, 2008), 262.
[26] Andrew Newcombe and Lluis Paradell, *Law and Practice of Investment Treaties: Standards of Treatment* (Kluwer Law International: 2009).

vaccines in the middle of the 20th century did not patent their products in an attempt to make them available for everyone,[27] clarifications provided in *Diamond v. Chakrabarty* led to the emergence of 11,818 vaccine-related patents during the period between 1920 and 2000.[28] Nowadays, vaccine-related IP rights are protected by patent law, which inhibits the access of many developing countries to vaccines.[29] Notably, the focus of several vaccine-related patents has recently shifted to the manufacturing processes, as the protection of industrial processes turned out to be more effective than the protection of antigens and most other ingredients of a vaccine. Plotkin, Robinson, Cunningham, Iqbal and Larsen claim that 'many vaccine patents protect the manufacturing process rather than the antigen that is produced by the process, which is not always the analogous case for small molecule pharmaceutical products'.[30] An analysis of the literature also reveals that the protection of vaccine-related IP issues has been shifting to the framework of trade secrets since, in the opinion of various practitioners, the value in the industry could be better protected as trade secrets.[31] A combination of protection layers creates an elaborate system of barriers that are impenetrable for generic manufacturers even if they use a compulsory licence issued by a host government.

Accordingly, Chapter 5 emphasises that such substantial barriers enable medical companies, such as Pfizer and Johnson & Johnson, to negotiate vaccine supply issues with the governments of different countries, thus directly affecting the access of various nations to high-quality vaccines against COVID-19. Considering the dangers of COVID-19, constrained resources of many developing and underdeveloped countries, and a high level of interdependence between various countries in today's globalised world, several specialists have voiced their concerns about the continuous exposure of poor countries to risks associated with COVID-19, which, in turn, might further devastate these states' social, political and economic conditions.[32] Journalists, politicians, scientists, and regular citizens have publicly called for the abandonment of IP rights frameworks in respect of the development and distribution of COVID-19 vaccines so that pharmaceutical companies would sell

[27] Siang Yong Tan and Nate Ponstein, 'Jonas Salk (1914-1995): A Vaccine against Polio' (2019) 60 *Singapore Medical Journal* 9–10.
[28] France Innovation Scientifique and Transfert, 'Patent Landscape Report on Vaccines for Selected Infectious Diseases', *WIPO* (Web Document, 2012) <https://www.wipo.int/edocs/pubdocs/en/patents/946/wipo_pub_946_3.pdf>.
[29] Peter Maybarduk and Sarah Rimmington, 'Compulsory Licenses: A Tool to Improve Global Access to the HPV Vaccine?' (2009) 35 *American Journal of Law & Medicine* 323–50.
[30] Stanlley Plotkin, James Robinson, Gerard Cunningham, Robyn Iqbal and Shannon Larsen, 'The Complexity and Cost of Vaccine Manufacturing – An Overview' (2017) 35 *Vaccine* 4064–71.
[31] Nuala Moran, 'The Rise of Trade Secrets in Biotechnology', *Science Business* (online, 25 June 2008) <https://sciencebusiness.net/news/70454/The-rise-of-trade-secrets-in-biotechnology>.
[32] Seth Berkley, 'Equitable Access to COVID-19 Vaccines Must Remain a Priority if We Are to End This Crisis: In My View', *OECD* (Web Page, 2020) <https://www.oecd-ilibrary.org/sites/60779fc2-en/index.html?itemId=/content/component/60779fc2-en>.

vaccines at a non-profit price and allow other firms to use their trade secrets, know-how and ingredient formulas to facilitate vaccination campaigns.[33]

Consequently, some firms responded to these calls: AbbbVie gave up the IP rights on Kaletra, Gilead Sciences reversed course on enforcing exclusivity on Remdesivir, and GlaxoSmithKline announced that it would seek to sell a vaccine at non-profit prices.[34] At the same time, the majority of companies refused to make any voluntary pledges or abandon any IP rights in relation to vaccines, seeking to maximise their profits by engaging in negotiations with governments of wealthy states. Rutschman clarifies that most developed states have been approaching the vaccine issue during the COVID-19 crisis in line with the so-called 'vaccine nationalism' approach, reserving both vaccines and technologies that are necessary for their manufacturing and distribution for themselves.[35] As a result, developing and least developed countries' access to vaccines remains low.

A balance in negotiations between governments and vaccine manufacturers currently seems to favour the latter. The sensitivity of the situation allows pharmaceutical firms, such as Pfizer, to sign favourable agreements, charging premiums for selling their vaccines to many developed countries. The situation with Israel, which agreed in November to purchase two million doses of Pfizer's vaccines for $56 each, illustrates how the superior negotiating capacity of pharmaceutical companies has been allowing them to maximise their profits during the pandemic.[36] Simultaneously, it should be noted that the situation recently changed, as the expansion of vaccine supplies provides governments with an opportunity to use regulatory instruments to ensure the highest possible quality of vaccines. Particularly, the USA recently cancelled its contract with Emergent BioSolutions for contaminating 15 million doses of Johnson & Johnson's vaccines.[37] A balance in negotiations between governments and vaccine manufacturers remains an intriguing research problem.

The international community has offered several alternative approaches towards addressing the problem discussed above, including patent pools, voluntary pledges and public funding. Patent pools could be defined as 'an agreement between two or more patent owners to license one or more of

[33] Molly Callahan, 'Should Pharmaceutical Companies Give up Their Patent Protections to Find a Vaccine for COVID-19?', *News & Northeastern* (online, 14 April 2020) <https://news.northeastern.edu/2020/04/14/should-pharmaceutical-companies-give-up-their-patent-protections-to-find-a-vaccine-for-covid-19/>.
[34] Ibid.
[35] Ana Santos Rutschman, 'The Intellectual Property of COVID-19', *Saint Louis University School of Law* (Web Document, 2020) <https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1537&context=faculty>.
[36] Katie Shonk, 'Government Negotiations: Pfizer's Rocky Road to US Covid-19 Vaccine Deals', *Harvard Education* (online, 25 January 2021) <pon.harvard.edu/daily/business-negotiations/government-negotiations-pfizers-rocky-road-to-u-s-covid-19-vaccine-deals/>.
[37] Zachary Stieber, 'US Cancels Contract with Major COVID-19 Vaccine Manufacturer', *The Epoch Times* (online, 2021) <https://www.theepochtimes.com/mkt_morningbrief/us-cancels-contract-with-major-covid-19-vaccine-manufacturer_4090080.html?utm_source=morningbriefnoe&utm_medium=email2&utm_campaign=mb-2021-1107&mktids=8f6850ca508e34d23651239c0ee807b6&est=%2BwlifJMwI4hZY6hPXeFnU%2Fh3CQhETFLgcxm80uryYHQ%2FiAC63gIIqa%2B3vdxEPmWsKC2V>.

their patents to one another or to third parties'.[38] Contreras et al. argue that patent pools are a promising solution because they allow overcoming fragmentation problems and so-called 'thickets'.[39] IPR pools used to be a relatively popular mechanism during the outbreak of SARS[40], the H5N1 influenza and the N1H1 influenza[41], when they used to serve as private arrangements between a limited number of IPT owners; however, they have hardly proved their effectiveness during the COVID-19 pandemic. The COVID-19 Technology Access Pool (C-TAP) is currently the most well-known patent pool that emerged in response to the outbreak of the coronavirus. It seeks to facilitate sharing of information related to clinical trials' results and gene sequencing research.[42] At the same time, like any other patent pool, C-TAP is voluntary; further, it also promotes the idea of intensifying collaboration between licensors and licensees rather than an equitable access to technologies.[43] Therefore, the ability of C-TAP as well as any other current patent pool to reduce IP barriers to the manufacturing and distribution of COVID-19 vaccines remains questionable.

Similar to patent pools, IPR pledges also do not seem to be an effective instrument of ensuring equitable access to COVID-19 vaccines. Various voluntary pledges on COVID-related ingredients and technologies were made during the period between March 2020 and May 2020 by AbbVie, SMITHs Group, Medtronic, Fortress and Labrador Diagnostics, University of California Berkeley Innovative Genomics Institute, Oxford University and Allen Institute for AI; additionally, some organisations have also declared coordinated pledges, including Open COVID Pledge, Harvard-MIT-Stanford, Open COVID-19 Declaration and Welcome Trust Publishers' Pledge.[44] Although the mechanism has proved its potential by facilitating the technology transfer in vaccine-related fields, its effectiveness in relation to COVID-19 vaccine distribution remains low because of a low number of organisations that have made voluntary pledges.

The assistance of international organisations and governments of developed states is currently the only instrument that has demonstrated its effectiveness in enabling developing and

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[38] World Intellectual Property Organization (WIPO), 'Patent Pools and Antitrust – A Comparative Analysis', *WIPO* (Web Document, March 2014) <https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf>.
[39] Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters and Frank Tietze, 'Pledging Intellectual Property for COVID-19' (2020) 38 *Nature Biotechnology* 1146–49.
[40] James Simon, Eric Claassen, Carmen Correa and Albert Osterhaus, 'Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling' (2005) *Bulletin of the World Health Organization* 707–10.
[41] Maurice Cassier, 'Flu Epidemics, Knowledge Sharing, and Intellectual Property', *HAL* (Web Document, 2010) <https://halshs.archives-ouvertes.fr/halshs-02165461/document>.
[42] World Health Organization, 'WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020', *WHO* (Web Page, 11 March 2020) <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.
[43] Ana Santos Rutschman, 'How "Vaccine Nationalism" Could Block Vulnerable Populations' Access to COVID-19 Vaccines', *The Conversation* (online, 17 June 2020) <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689>.
[44] Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters and Frank Tietze, 'Pledging Intellectual Property for COVID-19' 38 *Nature Biotechnology* 1146–49.

underdeveloped countries to access vaccines. The mechanism of pooled procurement, which was designed and implemented by these stakeholders, is among the few options seeking to exercise a balanced approach towards facilitating the vaccines' distribution without violating the existing framework of IPR protection and utilising the instrument of compulsory licensing.[45] This approach does not damage the rights of IP right holders, while also adhering to the *greatest good* principle by providing residents of developing and least-developed countries with vaccines. COVAX, which is co-led by the World Health Organization, CEPI and Gavi, aims to ensure that all the states receive a sufficient number of COVID-19 vaccine doses regardless of their wealth. The COVAX facility pools the purchasing power of all the stakeholders and uses it to 'equitably distribute vaccine doses to help protect the most at-risk groups in all participating countries'.[46] In accordance with the official website of WTO, COVAX currently guarantees a sufficient amount of doses to vaccinate at least 20% of populations, thus prompting vaccination campaigns among the most vulnerable population groups.[47] By the end of August 2021, COVAX managed to ship more than 251 million vaccines to 141 countries.[48] The utilisation of this mechanism may be regarded as one of the most promising options to ensure an equitable access to vaccines without violating the existing IP barriers.

Unfortunately, none of the instruments discussed above offers a complete resolution to the problem of inequitable access to COVID-19 vaccines. Such a situation is inconsistent with the utilitarian principles of justice because the inability of developing and least-developed countries to vaccinate their populations not only magnifies the risks to their residents' health and lives but also negatively affects the world's recovery from the crisis owing to the need to maintain strict travel restrictions and quarantine measures, which in turn damage the world's economy. The scope of patent pools and voluntary pledges remains limited. At the same time, COVAX has a number of shortcomings predetermining its inferior performance as compared to the traditional approach taken by governments of developed countries that have pre-ordered a sufficient number of vaccine doses directly from pharmaceutical companies. First, while the planned coverage of 20% of a country's population might seem high for such countries as Nigeria and Mali, which have not vaccinated even 1% of their citizens yet, all the countries will need to use some other instruments to secure vaccines' doses because vaccinating only 20% of citizens will not be enough for overcoming the pandemic. Second, the pace of vaccine supplies' delivery under the COVAX program is relatively slow. Some countries received their first doses of vaccines only in the first quarter of 2021, even though many developed countries were already executing their vaccination campaigns at that time. Such a slow

[45] Anthony So, 'Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross-Sectional Analysis' (2020) 371 *BMJ* 1–8.
[46] Gavi, 'COVAX', *Gavi* (Web Page, 2020) <https://www.gavi.org/covax-facility>.
[47] World Health Organization, 'COVAX: Working for Global Equitable Access to COVID-19 Vaccines', *World Health Organization* (Web Page, 2020) <https://www.who.int/initiatives/act-accelerator/covax>.
[48] Gavi, 'COVAX Vaccine Roll-Out', *Gavi* (Web Page, 12 May 2021) <https://www.gavi.org/covax-vaccine-roll-out>.

process of vaccine delivery is unacceptable since strict quarantine measures imposed by states to control the disease's spread hurt their economies and constrain the effectiveness of recovery measures.

The next two chapters in the thesis shift the focus to the obtainment of vaccine supplies in Saudi Arabia and Australia. Their emphasis is placed on recent developments in obtaining vaccine supplies in the countries, the relevance of investment treaties from the perspective of securing vaccine doses, the countries' participation in the COVAX program and the nations' negotiations with vaccine developers. The sixth chapter concludes that the Saudi vaccination campaign is being implemented at an adequate pace, although the country lags behind some other countries in the region. It points out that vaccine hesitancy and supply chain disruptions remain the key barriers inhibiting swift vaccination of the population; it also provides a critical discussion of the country's participation in the COVAX facility and the relevance of alternative approaches towards obtaining substantial amounts of vaccine supplies. The seventh chapter offers a similar discussion in the case of Australia. At the same time, the section illustrates that unlike Saudi Arabia, Australia faces significant obstacles to the utilisation of TRIPS flexibilities to obtain additional vaccine supplies owing to TRIPS-plus provisions in some investment treaties. A special emphasis is placed on the free trade agreement between Australia and the United States.

A discussion of alternative approaches towards obtaining vaccine supplies that go beyond direct negotiations between governments and pharmaceutical companies can be found in the eighth chapter. In particular, this section addresses instruments such as public funding, patent pools, IPR pledges, compulsory licensing and other proposals. Concurrently, the ninth chapter speculates on the relevance of these mechanisms for Australia and Saudi Arabia. Finally, a summary of the study's findings, recommendations for practitioners, recommendations for further research and reflections on the study's limitations are presented in the last chapter of the thesis.

Saudi Arabia is a conservative country with a strong religious background and a unique culture that is becoming increasingly attractive for investors. Its ambitious Vision 2030 projects, favourable legislative changes and continuous progress in the Ease of Doing Business report indicate the government's commitment towards adapting the image of a state that protects investors' interests.[49] Simultaneously, certain restrictions on FDI and a weak regulatory framework with respect to protecting IP rights as demonstrated by the case of beoutQ negatively affect the state's ability to balance the interests of different stakeholders in regulating health-related IP rights.[50] A series of investment treaties signed by the Kingdom of Saudi Arabia seek to provide investors with an additional layer of protection with the help of various clauses, such as the one guaranteeing the most-favoured-nation treatment. Unlike Saudi Arabia, Australia is a developed state with a mature

[49] Mohammed El Said, *Intellectual Property Law in Saudi Arabia* (Kluwer Law International B.V., 2018).
[50] Sam Carp, 'BeIN Seeks US$1bn from Saudi Arabia over BeoutQ "privacy plague"', *SportsPro* (online, 2 October 2018) <https://www.sportspromedia.com/news/bein-sports-saudi-arabia-beoutq-piracy>.

legislative system. The latter has an effective system of IP rights protection that is consistent with the best practices of developed nations.[51]

The dynamic IPR protection framework of Australia is sometimes criticised by specialists. For instance, US and Australian pharmaceutical companies have recently expressed their dissatisfaction with the fact that under the AUSFTA, it is necessary to notify patent holders if a third party requests marketing approval of products that are associated with these patents.[52] The system of IPR protection in the country, which comprises the state's commitments under international agreements and investment treaties as well as local regulations and is praised for its robustness and effectiveness, is discussed in detail in Chapter 4. The experiences of these two countries may provide guidance on the use of BITs in regulating access to health-related IP. This is explored further in Chapter 9. This thesis poses its research questions in Section 1.2 and seeks to answer them through the methodology described in Section 1.3.

1.2. The Aim and Research Objectives

The main goal of this thesis is to investigate whether and to what extent BITs and treaties with investment provisions appropriately balance the rights and interests of IP right holders, investors and the public in Saudi Arabia and Australia on the issue of COVID-19 vaccine development, manufacturing and distribution in light of the TRIPS Agreement. The proposed topic is becoming increasingly important due to the international community's inability to overcome the COVID-19 crisis without effective vaccination campaigns and the emergence of an evident pattern related to the unequal distribution of COVID-19 vaccines among different nations.[53]

Both Saudi Arabia and Australia are among those countries that have already achieved certain progress in their vaccination campaigns. The states managed to secure substantial supplies by purchasing vaccines directly from different manufacturers.[54] Notably, despite the fact that these states were engaged in negotiations with various companies, both of them eventually focused on collaboration with Pfizer and AstraZeneca.[55] Unfortunately, the pace of vaccination campaigns in the two countries was relatively slow as compared to such countries as Israel, the United States, or the

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[51] Nicholas Tyacke et al, 'Pharmaceutical IP and Competition Law in Australia: Overview', *Thomson Reuters Practical Law* (Web Page, 1 July 2019) <https://uk.practicallaw.thomsonreuters.com/9-565-4226?__lrTS=20200527190720991>.

[52] IBP, *Australia: Oil, Gas, Resources, and Exploration Handbook, Volume 3 South Australia – Strategic Information and Regulations* (Lulu, 2013) 42.

[53] Council for Trade-Related Aspects of Intellectual Property Rights, 'Waiver from Certain Provisions of the TRIPS Agreement', *WTO* (Web Document, 16 December 2020) <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?&Language=ENGLISH&SourcePage=FE_B_009&Context=Script&DataSource=Cat&query=@Symbol=IP/C/W/*&DisplayContext=popup&languageUIChanged=true>.

[54] Josh Holder, 'Tracking Coronavirus Vaccinations around the World', *New York Times* (online, 10 April 2021) <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html>.

[55] Andreas Gebert, 'What COVID Vaccines are Used in Different Countries, Including the UK, US, China and Israel', *ABC* (online, 10 April 2021) <https://www.abc.net.au/news/2021-04-10/covid-vaccine-astrazeneca-pfizer-used-in-different-countries/100058960>.

United Arab Emirates. Delays of AstraZeneca delivery slowed down the vaccination campaigns both in Saudi Arabia and in Australia.[56] In Australia, unacceptable vaccination rates exposed the government to censure from various stakeholders who criticised politicians in terms of seeking agreements with other manufacturers, such as Moderna, Inc. and Johnson & Johnson.[57] A relatively low speed of the vaccination campaigns highlights the importance of discussing alternative approaches towards vaccine delivery in relation to these two states.

Whilst both Australia and are considered as *wealthy* states, certain alternative approaches related to obtaining vaccines were discussed regarding these countries. Specifically, even before the pandemic, Saudi Arabia was trying to encourage generic manufacturers to act as contract manufacturing organisations and partner with international pharmaceutical companies.[58] Further, Saudi Arabia continues looking for alternative approaches towards obtaining vaccines because in addition to paying $5 for AstraZeneca vaccines as opposed to $3.50 that is paid by the European Commission,[59] the country often suffers from delays in the supply of these vaccines.[60] Australia also faced delays in its vaccination campaigns. Nevertheless, the Australian government continues to oppose most of the alternative approaches reviewed above. In particular, Australia has voiced its disagreement with the WTO's proposition regarding vaccine patents for poor countries because of concerns related to insufficient investment protection and IPR violations.[61] A detailed investigation of the governments' position on these alternative approaches seems noteworthy and topical.

The popular discussion of the existing legal frameworks' failure to provide residents of developing and least-developed countries with access to drugs and vaccines is hardly relevant to the cases of Saudi Arabia and Australia, as both are among the wealthiest countries in the world. Nevertheless, an analysis of the TRIPS Agreement's flexibilities within the context of the COVID-19 crisis could be useful as a part of wider criticism of the TRIPS regime as a mechanism that puts most countries at a disadvantage. From this perspective, it seems important to analyse whether the findings

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[56] BBC, 'Covid: Australia Falls 85% Short of Vaccine Delivery Goal', *BBC* (online, 31 March 2021) <https://www.bbc.com/news/world-australia-56585365>.
[57] Elias Visontay, 'From Reassurance to Shambles: How Australia's Coronavirus Vaccine Rollout Unravelled', *The Guardian* (online, 9 April 2021) <https://www.theguardian.com/society/2021/apr/10/from-reassurance-to-shambles-how-australias-coronavirus-vaccine-rollout-unravelled>.
[58] Emad Shabbir, 'Generic Companies Acting as CMOs for Global Pharma in Middle East', *The Pharma Letter* (online, 5 August 2019) <https://www.thepharmaletter.com/article/generic-companies-acting-as-cmos-for-global-pharma-in-middle-east>.
[59] Jason Beaubien, 'Price Check: Nations Pay Wildly Difference Prices for Vaccines', *NPR* (online, 19 February 2021) <https://www.npr.org/sections/goatsandsoda/2021/02/19/969529969/price-check-nations-pay-wildly-different-prices-for-vaccines?utm_campaign=storyshare&utm_source=twitter.com&utm_medium=social&t=1614345696192>.
[60] Oliver Holmes, 'Brazil, Saudi Arabia and Morocco "told of delay in Covid jabs from India"', *The Guardian* (online, 21 March 2021) <https://www.theguardian.com/world/2021/mar/21/brazil-saudi-and-morocco-told-of-delay-in-covid-jabs-from-india>.
[61] Elias Visontay, 'Australia Hesitant to Back Plan to Let Poor Countries Make Cheap Copies of Covid Vaccines', *The Guardian* (online, 10 March 2021) <https://www.theguardian.com/australia-news/2021/mar/10/australia-urged-to-back-plan-to-let-poor-countries-make-cheap-copies-of-covid-vaccines>.

of such studies are valid in the case of Australia and Saudi Arabia and their attempts to supply ongoing vaccination campaigns.

The application of alternative approaches towards securing vaccine doses for Saudi Arabia and Australia is becoming increasingly topical along with the growing support of patent waiver calls. As it is known, the proposal of Joe Biden to initiate patent waivers in order to accelerate vaccination campaigns was supported by politicians in several other countries, including French President Emmanuel Macron.[62] Australia currently continues opposing a patent waiver, even though it recently joined New Zealand, Canada and three other states in a compromise proposal to urge the World Trade Organization to assist developing and underdeveloped countries with negotiating vaccine deals with pharmaceutical corporations.[63] The Saudi government's position on this issue has not been voiced yet. The available evidence provides a compelling reason to believe that a detailed investigation of the interaction between the TRIPS Agreement and investment treaties in case of Saudi Arabia and Australia could facilitate an enriched understanding of the ways in which vaccine supply deals could be executed within and outside the existing legal frameworks. The chosen research problem is topical from the practical perspective since it discusses the ways in which countries could obtain sufficient amounts of vaccine doses for their populations based on scenarios that take diverse approaches towards dealing with the existing IPR barriers towards swift vaccine distribution.

The overarching research question of the thesis is as follows: do BITs and treaties with investment provisions appropriately balance the rights and interests of IP right holders, investors and the public in Saudi Arabia and Australia on the issue of COVID-19 vaccine development, manufacturing and distribution in light of the TRIPS Agreement? The study seeks to answer the following sub-questions:

1. What are the distinctive features of investment treaties regulating health-related IP rights in Australia and Saudi Arabia in light of the COVID-19 crisis?
2. How do the TRIPS Agreement and investment treaties regulate health-related IP rights in the fields of licensing, parallel importing and privacy of health-related IP rights in Saudi Arabia and Australia in light of the COVID-19 crisis?
3. What are the key areas of congruence and divergence between the TRIPS Agreement and investment treaties in Saudi Arabia and Australia concerning the regulation of health-related IP rights, the clarification of priorities in case of overlapping, and the existing dispute resolution mechanisms?

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[62] James Andre, 'France Expands Vaccine Rollout as Macron Voices Support for Patent Waiver', *France 24* (online, 6 May 2021) <https://www.france24.com/en/france/20210506-france-expands-vaccine-program-as-macron-voices-support-for-patent-waiver>.

[63] Elias Visontay, 'India Wants Access to Cheap Copies of Covid Vaccines. So Why Is Australia Holding Out?' *The Guardian* (online, 29 April 2021) <https://www.theguardian.com/australia-news/2021/apr/30/india-wants-access-to-cheap-copies-of-covid-vaccines-so-why-is-australia-holding-out>.

4. What are the most important implications of the COVID-19 crisis for the regulation of health-related IP rights related to the development, manufacturing and distribution of COVID-19 vaccines, especially through investment treaties and the TRIPS Agreement?

1.3. Methodology

The ability of certain investment treaties to act as a peculiar TRIPS-plus dimension is well-known. Some BITs and treaties with investment provisions offer additional clarifications extending beyond those described in the TRIPS Agreement or even interfering with them, such as exclusions related to compulsory licensing.[64] Castro voices a popular concern that the tendency of investment treaties to become 'all-encompassing' documents going far beyond the TRIPS Agreement's provisions disrupts the balance of stakeholders' interests by making this balance incline towards one side.[65] The outbreak of the COVID-19 crisis has escalated this problem even more.[66] Whereas certain pharmaceutical companies and even politicians supported the popular call to abandon or at least reduce the legal barriers to vaccine manufacturing and distribution, the majority of stakeholders rejected this proposal, contributing to a common scenario with an inequitable access to vaccines.[67] The mechanism of COVAX is currently the most well-known initiative aimed at addressing this problem and providing nations of developing countries with a sufficient number of doses that could protect the most vulnerable population groups.[68] However, as stated above, the program's scope is limited, whereas its implementation occurs in a slow manner. Therefore, states that have not yet secured sufficient vaccine supplies are forced to look for other approaches to obtain required amounts of vaccine doses.

The regulation of health-related IP rights within the context of the COVID-19 pandemic is a bright example of a medical problem that is being treated in a political manner. The available evidence provides a compelling reason to believe that the significance of vaccines has been changing along with the pandemic's expansion. In the beginning, stakeholders relied on the use of state power in the form of lockdowns and other restrictions to obtain a quick solution of the problem, minimising the number of new infections.[69] Such an instrument is a well-known mechanism that was widely used during the SARS epidemic; further, it succeeded in preventing pandemics of many dangerous

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[64] Bertram Boie, 'The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?' (Working Paper No 2010/19, World Trade Institute, November 2010) <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>

[65] Rosa Castro, 'Intellectual Property Rights in Bilateral Treaties and Access to Medicines: The Access of Latin America' (2006) 9(1) *The Journal of World Intellectual Property* 548.

[66] Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters and Frank Tietze, 'Pledging Intellectual Property for COVID-19' 38 *Nature Biotechnology* 1146–49.

[67] Ana Santos Rutschman, 'The Intellectual Property of COVID-19', *Saint Louis University School of Law* (Web Document, 2020) <https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1537&context=faculty>.

[68] World Health Organization, 'COVAX: Working for Global Equitable Access to COVID-19 Vaccines', *World Health Organization* (Web Page, 2020) <https://www.who.int/initiatives/act-accelerator/covax>.

[69] Scott Greer, Elizabeth King, Elize Massard da Fonseca and Andre Peralta-Santos, 'The Comparative Politics of COVID-19: The Need to Understand Government Responses' (2020) 15 *Global Public Health* 1413–16.

diseases, such as Ebola. However, the growing realisation of the highly contagious nature of the disease and the devastating economic and social implications of the lockdown forced states to change the predominant public health response to a combination of state power and vaccination. This strategy implies using the state power to coordinate and facilitate immunisation programs and relying on pharmaceutical companies to supply the vaccines.[70] As a result, pharmaceutical firms became powerful stakeholders having the potential to affect the response of different states to the pandemic, while their vaccines turned into a valuable resource within the medical, economic, social and geopolitical context.

The evidence at hand presents a persuasive reason to believe that the focus of Saudi Arabia and Australia will magnify the significance of this study's findings because of several reasons. First, both these countries have large economics and are integrated into the world's political, economic and financial system, which translates into a certain alignment of their legislative systems with international law. Second, their legislative systems have certain peculiarities that predetermine their difference from most other states.[71] Third, both of them have signed preliminary agreements with various pharmaceutical companies to facilitate the distribution of vaccines, while exploring the option of using alternative approaches towards securing sufficient amounts of vaccine doses. Therefore, the cases of these countries could provide a substantial amount of evidence for discussing IPR frameworks regulating vaccine development and distribution issues. Fourth, these states are fundamentally different from each other in terms of their IPR frameworks; therefore, their critical comparison from the perspective of the problem under investigation appears a promising research area. The author expects that the research problem chosen in this thesis could be significant, allowing the study to generate findings that could be regarded as valuable both from the theoretical and practical perspectives, concomitantly addressing an evident research gap and producing practical recommendations for stakeholders.

It should be also emphasised that both these countries are major importers of pharmaceutical IPs, drugs and vaccines. Today, both use excess supplies of vaccines as a part of their 'vaccine diplomacy' strategies.[72] Their legal systems differ fundamentally from each other. Saudi Arabia is undergoing the process of transforming a system that is currently based on Islamic law, whereas Australia already has a mature legal system that is largely based on Western concepts. Specifically, Saudi Arabia is in the process of incorporating international law, such as BITs, FTAs and the TRIPS Agreement, into its legal systems, which are alien to the traditional Islamic law.[73] In contrast,

[70] Frances Edwards and Steven Ott, 'Governments' responses to the COVID-19 pandemic' (2021) 44 *International Journal of Public Administration* 879–84.
[71] Mohammed El Said, *Intellectual Property Law in Saudi Arabia* (Kluwer Law International B.V., 2018).
[72] Eckart Woertz and Roie Yellinek, 'Vaccine Diplomacy in the MENA Region', *MEI* (Web Page, 14 April 2021) <https://www.mei.edu/publications/vaccine-diplomacy-mena-region>.
[73] Chad Cullen, 'Can TRIPS Live in Harmony with Islamic Law – An Investigation of the Relationship between Intellectual Property and Islamic Law' (2011) 14 *Science and Technology Law Review* 45–68.

Australia is already compliant with international arrangements such as the TRIPS Agreement because these arrangements reflect Western legal concepts, including those that form the basis of the Australian legal system.[74] Such fundamental differences between the countries' legal systems constitute an important argument in favour of the research problem's significance because the focus on these two jurisdictions could enrich the understanding of the degree to which the TRIPS Agreement and investment treaties balance stakeholders' rights within the context of COVID-19 vaccines in different settings.

1.3.1. Research Philosophy of the Study

The choice of a research philosophy is a critical aspect of any study. Traditionally, scholars distinguish between research paradigms such as positivism, interpretivism, realism, and pragmatism.[75] After considering the benefits and disadvantages of all these paradigms, pragmatism was chosen as the main research philosophy. Positivism requires the maximum degree of objectivity while excluding any possible biases from the scope of a study.[76] This scenario would be hardly possible in the current thesis, as interpretations of different provisions of investment treaties play an important role in the research. Interpretivism is a popular approach focusing on the integration of human interest into a study. As a rule, studies aligned with the principles of this paradigm revolve around the emotions, feelings, perceptions and opinions of humans.[77] The current study seeks to investigate the regulation of vaccine-related IP rights; therefore, interpretivism was not a suitable choice for the research philosophy.

Realism is another popular research philosophy in the social sciences. The principles of critical realism imply analysing reality through sensations and images of the real world that are reported by humans.[78] Despite the benefits of this philosophy, pragmatism was eventually selected due to its ability to cover the perspectives of different stakeholders and combine data from various sources. The goal of this thesis is ambitious and requires not only scrutinising the text of investment treaties and the TRIPS Agreement but also analysing the literature on different aspects related to IPR frameworks and the vaccine market as well as the investment environments in Saudi Arabia and Australia. Pragmatism seemed to be the optimal research philosophy for guiding such a study, as it allows accumulating data from different sources and then analysing the available information to answer research questions.[79] The superior flexibility of pragmatism became the main argument in favour of adopting this research philosophy in the thesis.

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[74] Donald Gordon, 'Legal Systems in Australia: Overview', *Thomson Reuters Practical Law* (Web Page, 1 March 2021) <https://uk.practicallaw.thomsonreuters.com/0-638-7137?transitionType=Default&contextData=(sc.Default)&firstPage=true>.
[75] Mark Saunders, Philip Lewis and Adrian Thornhill, *Research Methods for Business Students* (Pearson, 2012).
[76] Hilary Collins, *Creative Research: The Theory and Practice of Research for the Creative Industries* (AVA Publications, 2010).
[77] Stephen Littlejohn and Karen Foss, *Encyclopedia of Communication Theory* (Sage Publications, 2009).
[78] Ibid.
[79] Mark Saunders, Philip Lewis and Adrian Thornhill, *Research Methods for Business Students* (Pearson, 2012).

The conceptual framework of this study is based on the theory of justice that is interpreted through the lenses of utilitarianism. Utilitarianism can provide a theory of justice only if it is understood as a normative theory that uses a specific action-guiding principle to make decisions on particular actions to, subsequently, produce the greatest total utility.[80] Bentham argues that 'justice, in the only sense in which it has a meaning, is an imaginary personage, feigned for the convenience of discourse, whose dictates are the dictates of utility, applied to certain particular cases'.[81] John Mill and Henry Sidgwick pay a more substantial amount of attention to the concept of justice, offering direct avenues for the utilitarian interpretation of this notion. The scholars argue that the term *justice* is often misinterpreted and point out that actions that are aligned with the *just* rules are those that are conducive to the greatest happiness.[82] They also utilise this principle to explain the desert of punishments and rewards. In particular, rules that should be followed in regard to punishments should be conductive to the ends for which a punishment was introduced, whereas rules regulating rewards should have the effect of directing individuals' choices in the most socially productive way.[83]

Utilitarianism has certain difficulties with interpreting the concept of justice. In particular, it fails to explain the ways in which different people perceived the same rewards or punishments, elucidate differences in individuals' abilities to turn tangible benefits into well-being and apply forward-looking reasoning to the cases when individuals' actions are guided by backward-looking reasons.[84] However, these challenges are not likely to inhibit the application of the utilitarian concept of justice in this dissertation. The current study seeks to apply general criteria of utilitarianism to evaluate the justice of the regulation of health-related IP rights within the context of the COVID-19 pandemic using the principle of *the greater good* as the overarching criterion.

Pragmatism also plays an important role in developing the study's conceptual framework. The application of pragmatism in the context of COVID-19 vaccines implies presenting governments as rational decision-makers that could decide on actions aligned with public health interests. In accordance with the principles of pragmatism, the flexibilities of TRIPS and corresponding provisions in national laws exist to strengthen the position of governments in negotiations with pharmaceutical companies. Therefore, the quality of legal arrangements could be primarily evaluated based on whether they encourage parties to negotiate with each other and reach an agreement.[85] This interpretation of legal arrangements is often used in this study to determine if specific provisions strengthen or weaken governments' positions in negotiations with pharmaceutical companies and whether they empower governments to protect the population's public health.

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[80] John Mill, *Utilitarianism* (Courier Corporation, 2012).
[81] Jeremy Bentham, *The Principles of Morals and Legislation* (Hafner Publishing, 1948) 125–126.
[82] Ibid.
[83] Henry Sidgwick, *The Methods of Ethics* (Macmillan, 1874).
[84] Stanford Encyclopedia of Philosophy, 'Justice', *Stanford Encyclopedia of Philosophy* (Web Page, 26 June 2017) <https://plato.stanford.edu/entries/justice/#UtilJust>.
[85] Michael Alverstein, *Pragmatism and Law: From Philosophy to Dispute Resolution* (Routledge, 2017).

The thesis is also based on certain IPR concepts. In particular, the construct of public interest is widely discussed in the research in relation to the TRIPS Agreement. Article 7 of this document recognises states' rights to enforce IP rights 'in a manner conducive to social and economic welfare and to a balance of rights and obligations', whereas Article 8 explicitly empowers countries to promote the public interest.[86] Compulsory licenses, parallel importation, the transfer of know-how and other relevant measures are discussed in this thesis in light of the concept of public interest as formulated in the TRIPS Agreement. At the same time, the research also points at private interests as an important aspect of the problem under investigation. Protection of IPRs in the TRIPS Agreement is justified by an intention to protect private interests, thus stimulating research and innovation.[87] A balance between public interests and private rights, which is described in the literature as one of the most important principles of IP law,[88] is thoroughly investigated in the thesis in the context of the COVID-19 pandemic.

1.3.2. Justification of the Research Design

The selection of a research design is an important process following the selection of the research philosophy. Explanatory, exploratory and descriptive designs are used in the majority of qualitative and quantitative studies.[89] An exploratory design seeks to produce a substantial amount of data on some under-researched problem in an attempt to generate early insights into its nature and offer promising recommendations for further research.[90] An explanatory design, in turn, is primarily utilised in quantitative studies to measure a causal relationship between variables.[91] None of these designs could be utilised in the current thesis. The regulation of vaccine-related IP rights in the context of the COVID-19 pandemic is a relatively new topic; nonetheless, many experts have already shared their opinions and observations on this important issue. As a result, an exploratory design does not seem suitable for the study. An explanatory design also could barely assist with the completion of research objectives set in this thesis because a relationship between variables is not within the study's scope.

A descriptive design, at the same time, seems to be a rational choice for the thesis. Unlike the explanatory and exploratory frameworks, it is characterised by an ability to delve into the various nuances of particular research phenomena, events or processes, approaching specific issues from

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[86] *TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994; *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, 1869 UNTS 299, 33 ILM 1197 (1994).
[87] Sol Picciotto, 'Private Rights vs. Public Interests in the TRIPS Agreement' (2003) 97 *Proceedings of the Annual Meeting of the American Society of International Law* 167–172.
[88] Rebecca Rushnet, 'Intellectual Property as a Public Interest Mechanism' in Rochelle Dreyfuss and Justine Pila (eds), *The Oxford Handbook of Intellectual Property Law* (Oxford University Press, 2018).
[89] Neil Salkind, *Encyclopedia of Research Design* (Sage Publications, 2010).
[90] Colin Elman, John Gerrin and James Mahoney, *The Production of Knowledge: Enhancing Progress in Social Science* (Cambridge University Press, 2020).
[91] Victor Jupp, *The SAGE Dictionary of Social Research Methods* (Pine Forge Press, 2006).

various perspectives.[92] Considering that a critical investigation of the regulation of vaccine-related IP rights in the TRIPS Agreement and investment treaties requires a discussion of specific clauses of documents and other important aspects of the problem under investigation, the choice of a descriptive design is natural.

1.3.3. Discussion of Research Approaches

Both an inductive and a deductive approach will be utilised in the thesis to complete the main research goal and answer its research questions. A deductive approach will be used to examine general frameworks and regularities related to IP rights and then apply them in specific settings. An investigation of the most popular areas of congruence and divergence between the TRIPS Agreement and BITs, followed by a discussion on the ways in which these issues manifest themselves in the case of specific BITs and treaties with investment provisions signed by Saudi Arabia or Australia, is a bright example of the use of the deductive research approach in the thesis. In turn, an inductive approach will be applied to analyse provisions of specific BITs in a way that allows making general conclusions regarding the regulation of vaccine-related IP rights in Saudi Arabia and Australia.

1.3.4. The Choice of a Time Horizon

The nature of the study predetermines the use of a cross-sectional time horizon in the thesis. The academic literature indicates that most studies employ either a cross-sectional or a longitudinal horizon.[93] The former involves capturing the data with the help of a single intervention, focusing on a single point of time.[94] In contrast, the latter entails conducting several interventions to trace changes in data over time, continuously measuring the same variables or exploring the same phenomena.[95] The author does not seek to identify and describe changes in the regulation of vaccine-related IP rights over time. The study's main goal is to approach the research problem based on those trends relevant at the end of August 2021. Therefore, there is no need to employ a longitudinal horizon.

1.3.5. The Type of a Research Methodology

This research does not require the investigation of any quantitative patterns related to the regulation of vaccine-related IP rights. Its scope primarily includes various clauses of investment treaties and the TRIPS Agreement and the ways in which these clauses could interact with each other. Consequently, the study employs a qualitative research methodology. Qualitative research methods have the potential to not only find answers to research questions of interest but also explain how and why specific processes occur.[96] A qualitative methodology seeks to explore meanings rather than confirming or rejecting hypotheses; therefore, the scope of findings that could be produced using

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[92] Alex Edmonds and Thomas Kennedy, *An Applied Guide to Research Designs: Quantitative, Qualitative, and Mixed Methods* (SAGE Publications, 2016).
[93] Martin Blanche, Kevin Durrheim and Desmond Painter, *Research in Practice: Applied Methods for the Social Sciences* (Juta and Company Ltd, 2006).
[94] Paul Labrakas, *Encyclopedia of Survey Research Methods* (SAGE Publications, 2008).
[95] Scott Menard, *Handbook of Longitudinal Research: Design, Measurement, and Analysis* (Elsevier, 2007).
[96] Mark Saunders, Philip Lewis and Adrian Thornhill, *Research Methods for Business Students* (Pearson, 2012).

qualitative methods is relatively broad.[97] The current study approaches a relationship between the TRIPS Agreement and investment treaties in the context of vaccine-related IP rights from a broad perspective. The author intends to identify and discuss a variety of aspects of the problem under investigation, including even those that might have not been approached previously. In this situation, a qualitative research methodology was the only valid option for the researcher.

1.3.6. Research Methods

Overview of Research Methods

Primarily, the study investigates the relationship between clauses of the TRIPS Agreement and investment treaties in the context of the regulation of vaccine-related IP rights. At the same time, this problem is analysed in the context of Saudi Arabia and Australia. The case study method was employed to ensure that only treaties related to these two countries would be included in the scope of the study. The literature describes case studies as 'up-close, in-depth and detailed examination of a particular case or cases within a real-world context'.[98] This research method is optimal when a researcher seeks to examine a particular problem in specific settings. The instrument of document analysis was chosen as the key data collection technique. This method focuses on the review and evaluation of documents and assists researchers with retrieving necessary information from them.[99] As a variation of a qualitative content analysis, document analysis helps develop an understanding of specific phenomena and processes and generate empirical knowledge.

The author decided against carrying out an empirical study, such as one with interviews or focus groups. In theory, the author could have recruited experts with degrees in IPR law and asked them their opinions about the areas of congruence and divergence between the relevant clauses of the TRIPS Agreement and investment treaties. However, it would have been difficult to find experts with substantial knowledge of this problem in the context of both Saudi Arabia and Australia. Therefore, the author would have been forced to carry out several interviews with different experts and then combine their data within a consistent framework. Such a process seemed excessively complicated; furthermore, as stated above, it is highly unlikely that the author would be able to find interviewees with extensive knowledge of all the BITs and treaties with investment provisions under investigation. In contrast, the method of document analysis, which includes a review of relevant literature and publicly available information on vaccine development and distribution, seemed relatively simple and realistic.

The Scope of the Case Study

The case study focuses on documents such as the TRIPS Agreement, BITs signed by Australia and the Kingdom of Saudi Arabia and the countries' treaties with investment provisions that are currently in effect. The inclusion of both BITs and treaties with investment provisions into the

[97] Monique Hennnink, Inge Hutter and Ajay Bailey, *Qualitative Research Methods* (SAGE Publications, 2020).
[98] Kenneth Morland et al, 'A Case for the Case Study' (1992) 71 *Social Forces* 240–246.
[99] Elizabeth Bauchner, *Document Analysis* (Simon and Schuster, 2014).

study's scope is expected to enrich the understanding of the problem under investigation, especially considering that free trade agreements, such as the one between Australia and the United States, often offer substantial TRIPS-plus rules. In addition to these documents, the author also reviewed relevant literature on vaccine-related issues and different aspects of IPR law. Considering that the chosen problem is relatively novel, it has not been examined in detail in the academic literature; furthermore, the existing peer-reviewed sources hardly reflect recent developments related to vaccine-related IPRs, such as the situation around the TRIPS waiver. Therefore, some non-scholarly sources, such as articles published by scholars in blogs and online magazines, are also included in the scope of the case study.

Data Analysis

Data analysis is conducted in this thesis with the help of qualitative content analysis and legal interpretive analysis. The former is applied to analyse secondary sources, including peer-reviewed articles and other secondary sources discussing the problem under investigation. The latter, at the same time, is utilised to interpret the sources of law, including the TRIPS Agreement, treaties with investment provisions, national laws, court cases and other sources of law in Australia and Saudi Arabia as well as relevant international arrangements. As Posner explains, 'law is not a field with a distinct methodology, but an amalgam of applied logic, rhetoric, economics and familiarity with a specialized vocabulary and a particular body of texts, practices and institutions'.[100] Therefore, the author did not rely on a distinct methodology; rather, they applied common principles of the philosophical evaluation of legal rules' application to analyse relevant sources of law and areas of divergence and convergence between them by putting them into a broad context. Watal and Taubman propose a variety of interpretative approaches for reviewing issues on remuneration in a WTO panel, elucidating that they include not only strictly reading the text, but also 'considering the broader political context', 'taking account of broader public international law', and 'considering the implications of the customary international law of investment and investment treaties'.[101] Such a broad interpretative context seems necessary for the current study to determine whether the existing IPR frameworks balance the interest and needs of stakeholders in Australia and Saudi Arabia within the context of COVID-19 vaccines.

As explained in the Introduction, Saudi Arabia and Australia represent two fundamentally different legal systems. Therefore, one may suppose that their comparison might be complicated because of conflicting legal assumptions and fundamentally different cultures. Indeed, the literature indicates that Saudi legal culture is still largely dependent on Sharia law, which has significant implications for the independence of officials and judges, the competence of lawyers and judges and

[100] Terry Hutchinson and Nigel Duncan, 'Defining and Describing What We Do: Doctrinal Legal Research' (2012) 17 *Deakin Law Review* 83–119.
[101] Jayashree Watal and Antony Taubman, *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (WTO Press, 2015).

the understanding of legal persons and corporate law in a financialised global economy.[102] However, there is no evidence to believe that these issues could be relevant for the current study. This thesis does not seek to analyse the practice of protecting IP rights in Saudi Arabia and Australia. It focuses on the investigation of general principles and rules outlining the protection of vaccine-related IP rights in these two countries within the context of the COVID-19 pandemic. A detailed analysis of the national laws of the two countries and their law enforcement practices is not within the scope of this thesis. It solely focuses on determining whether the text of BITs and other treaties with investment provisions that were signed by the two countries adequately balances the rights and interests of different stakeholders in light of the TRIPS Agreement and within the context of the COVID-19 pandemic.

Despite evident differences between the legal cultures of Australia and Saudi Arabia, it should be noted that both of them prioritise *the greatest good of the greatest number* in line with utilitarian principles. Australian legal culture is based on natural law beliefs originating from the ideas of John Locke and the utilitarian ideas of Jeremy Bentham and John Austin, which resulted in the establishment of a legal system providing courts and judges with significant power in controlling the society.[103] The focus on achieving *the greatest good of the greatest number* empowers Australia to take practical measures for redistributing wealth via a welfare state safety net, which is evident in the case of Medicare and the National Pharmaceuticals Benefits scheme.[104] Another important implication of utilitarian philosophy is the prevailing interpretation of patents as contracts between the right holder and the public.[105] These arguments show that the utilitarian perspective dominates the Australian legal culture and practices, which has crucial implications for the state's approach towards vaccinating its population.

Utilitarian philosophy is also relevant for Islamic jurisprudence. Particularly, Alnemari argues that the concept of Maslahah clarifies that a decision should promote the goals of Sharia and, at the same time, should not result in great harm or lead to the loss of a bigger utility.[106] Moreover, Islamic law provides a unique moral context for interpreting health-related rights because of the intimate relation between Islam and medicine.[107] In light of these arguments, it seems justified to assume that both the Saudi and the Australian legal cultures introduce a shared context for prioritising the population's health in line with utilitarian philosophy. This shared goal does not indicate that these

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[102] Awad Alanzi, 'Exploring the Legal System in Saudi Arabia' (2020) 11 *International Journal of Innovation, Creativity and Change* 114–123.
[103] Alastar Davidson, *Invisible State: The Formation of the Australian State 1788–1901* (Cambridge University Press, 1991).
[104] David Henry, Suzanne Hill and Anthony Harris, 'Drug Prices and Value for Money: The Australian Pharmaceutical Benefits Scheme' (2005) 294 *Jama* 1630–1632.
[105] *Attorney General v Adelaide Steamship Co*, House of Lords (1913) AC 781 (Lord Parker).
[106] Hazim Alnemari, 'Utilitarianism in Classic Islamic Jurisprudence' (2017) 5 *Journal of Islamic Studies and Culture* 1–8.
[107] Hassan Chamsi-Pasha and Mohammed Ali Albar, 'Western and Islamic Bioethics: How Close Is the Gap?' 3 *Avicenna Journal of Medicine* 8–14.

legal cultures are similar, but it illustrates that differences between them could not invalidate any comparison of the regulation of health-related IP rights.

There is no premise to believe that the legal cultures of Australia and Saudi Arabia could prevent the researcher from comparing and interpreting the countries' BITs and other investment treaties. BITs and other investment provisions are usually written using universal legal language and terms that are applicable to the analysis of the TRIPS Agreement. Therefore, even though the legal practices of Australia and Saudi Arabia might differ due to their legal cultures, this factor could hardly affect the text of BITs and FTAs. Considering that the focus of this research is put on the text of investment treaties rather than their implementation, cultural issues do not require a thorough examination in this thesis.

1.3.7. Ethical Considerations

Ethical considerations are an essential part of any research. At the same time, their significance is especially evident in those studies that require collecting data from human respondents.[108] As stated above, this thesis does not include an empirical part seeking to collect primary data. The author will exclusively utilise secondary data collected from various sources. Accordingly, most ethical considerations that are discussed in academic research, such as the anonymity of respondents or participants' informed consent, are not relevant to this thesis. The author does not need special ethics permission to conduct the study because it is of no harm to human respondents and, accordingly, is not associated with any essential risks for others.

Simultaneously, it is important to emphasise that the author will follow all the conventional ethical codes, including honesty and integrity, objectivity, carefulness and respect for intellectual property. All the conclusions and assumptions made in the study will be based on data; furthermore, the data will be collected only from credible sources. Information published in a single online article will not be used for drawing conclusions on the problem under investigation, and the author will ensure that all the claims are supported by the available evidence. Accordingly, it is expected that the research will meet the criteria of honesty and integrity.[109] The author will also attempt to eliminate potential biases from the scope of the study. Even though certain non-scholarly sources will be included in the study, the researcher will thoroughly analyse them to prevent a scenario in which biased opinions of some experts could become the only basis for making far-reaching conclusions related to the research object. The author will also refrain from making any unjustified statements, ensuring that each argument and assumption is based on extensive evidence.

The principle of carefulness will be applied to avoid making careless mistakes. In particular, the author will carefully examine the texts of all the relevant treaties, double-checking each clause that could be discussed in the text of the thesis. Moreover, this thesis will be proofread at the end to

[108] Tina Miller et al, *Ethics in Qualitative Research* (SAGE Publications, 2012).
[109] Martyn Hammersley and Anna Traianou, *Ethics in Qualitative Research: Controversies and Contexts* (SAGE Publications, 2012).

minimise careless errors and oversights in the final version of the thesis. Finally, the respect for IP will be upheld in this study by crediting all the scientists and experts whose thoughts and findings are discussed in the study. In-text citations will be provided when the author refers to the findings of some other scholars or directly cites treaties' clauses.

1.3.8. Limitations

The thesis is likely to have four important limitations that should be considered when interpreting and analysing its findings. First, it focuses on the TRIPS Agreement and investment treaties; simultaneously, it does not delve into the specifics of the Australian and Saudi legislative systems with regard to vaccine-related IP rights. The research focuses on the investment treaties signed by Saudi Arabia and Australia and the TRIPS Agreement and not the countries' laws. The only aspect of national laws that would be relevant from the perspective of the problem under investigation is their compliance or non-compliance with the TRIPS Agreement. The brief analysis conducted in the thesis demonstrates that both the countries made their legislation systems compliant with the TRIPS Agreement; thus, an examination of the differences between the states' laws as well as the specifics of their enforcement will not be necessary for answering the overarching research question of this thesis. Simultaneously, even though this research does not examine specific IP laws in the countries and the procedures of their enforcement, the available evidence provides a compelling reason to believe that these factors are important issues affecting pharmaceutical companies' ability to protect their IP rights.

Second, the research captures recent trends regarding the COVID-19 pandemic. The situation with the spread of COVID-19 is dynamic; therefore, some conclusions of the study may no longer be relevant by the time the thesis is completed. Saudi Arabia and Australia will hardly cancel some relevant BITs or free trade agreements by that time, but it is possible that some major events will occur, radically changing the context of their discussion. Particularly, one may assume that developed states will agree to introduce the TRIPS waiver or, at least, reduce the scope of patent protection, thus rendering the discussion of certain patent-related IP rights irrelevant.

Third, the context of this study is explicitly linked to the COVID-19 pandemic. The COVID-19 outbreak has created unprecedented challenges for humanity, resulting in strict quarantine restrictions to prevent human losses. Significant threats caused by the virus gave rise to the discussion of unprecedented measures related to the international community's response to the crisis. The TRIPS waiver is a superior example of an instrument that has not been mentioned in the past in relation to the regulation of vaccine-related IP rights during other pandemics. In other words, the COVID-19 crisis created a unique context that significantly affects how the IPR law is approached. The findings of this study may, therefore, be applicable exclusively to the case of the COVID-19 pandemic, while their relevance for other vaccines, which do not address a large-scale crisis, could be questionable.

Finally, the last limitation that should be pointed out in this chapter is the lack of attention to the political and economic aspects of vaccination campaigns and vaccine-related negotiations. The

study's scope is limited; therefore, exploring all the important aspects of vaccine-related negotiations into the thesis did not seem possible. Simultaneously, some of these political and economic issues might critically affect how vaccines are purchased and distributed in various countries. These issues do not have a direct effect on vaccine-related IP rights; nonetheless, they could significantly influence the context in which these rights are regulated.

CHAPTER 2. REGULATION OF HEALTH-RELATED INTELLECTUAL PROPERTY RIGHTS UNDER THE TRIPS AGREEMENT AND INVESTMENT TREATIES

2.0. Introduction

This chapter explores the regulation of health-related intellectual property rights under the TRIPS Agreement and investment treaties. The first subsection presents an overview of the international treatment of health-related IP rights in light of the ongoing quest for obtaining COVID-19 vaccines, which includes a critical review of the existing areas of divergence and convergence between the TRIPS Agreement and investment treaties and a brief examination of recent trends underpinning the IP protection and distribution of COVID-19 vaccines.

The first section of Chapter 2 seeks to explore the role of the TRIPS Agreement in the regulation of health-related IP rights. It describes various provisions of the TRIPS Agreement from the perspective of the problem under investigation, including standards of treatment, flexibilities of the treaty, and criticism of the agreement. The second subsection investigates clauses of bilateral investment treaties and treaties with investment provisions that could affect health-related IPRs. The third subsection focuses on possible areas of convergence and divergence between investment treaties and the TRIPS Agreement with an emphasis on such issues as compulsory licensing, parallel importing, patent terms, data exclusivity, performance requirements, standards of treatment, and dispute settlement. Finally, the fourth subsection shifts the focus of the discussion to the role of the TRIPS Agreement and investment treaties in the regulation of vaccine manufacturing and distribution, elaborating on IPR protection on the vaccine market, access to vaccines, TRIPS-plus barriers to vaccine access, the TRIPS Waiver, and TRIPS-plus rules in regard to access to COVID-19 vaccines.

2.1. The Role of the TRIPS Agreement in the Regulation of Health-Related Intellectual Property Rights

2.1.1. Introduction of the TRIPS Agreement

The TRIPS Agreement plays a crucial role in the regulation of intellectual property rights. It was signed in 1995 in order to facilitate expansion of trade via the introduction of a consistent framework related to intellectual property rights. Before 1995, issues related to IPRs were addressed differently by various countries on the basis of their national legislative systems.[110] The TRIPS Agreement created an initial level of protection that extends to all the inventions, thus providing stakeholders with an opportunity to protect their investments in any country that was a member of the World Trade Organization. In particular, Article 27 stipulates that "patents are available for any inventions, whether products of processes, in all fields of technology provided that they are new,

[110] Jayashree Watal and Antony Taubman, *The Making of the Trips Agreement: Personal Insights from the Uruguay Round Negotiations* (Geneva, WTO Press: 2015).

involve an inventive step and are capable of industrial application"[111] and specifying that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".[112] A full set of measures protecting IPRs under the TRIPS Agreement include copyright, trademarks, geographical indications, patents, industrial designs, layout-designs, protection of undisclosed information, and control of anti-competitive practices.[113] The scope of the protection covers products, processes, and uses.

2.1.2. Standards of Treatment

The introduction of minimum standards of treatment for "persons of other Members" is one of the most important outcomes of the TRIPS Agreement. The document specifies that "each Member shall accord to the nationals of other Members treatment no less favorable than that it accords to its own nationals with regard to the protection (3) of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits".[114] At first sight, it might seem that the standards of national treatment are a controversial issue that essentially makes foreign nationals subject to the same laws to which locals are subject, without considering the substance of rules. At the same time, Boie clarifies that in practice, introduction of the national treatment standards "will require domestic regulation to be opened up to foreign players, and it requires ensuring that the rules at issue are de jure and de factor providing non-discriminatory treatment to foreign investors".[115] At the same time, the TRIPS Agreement limits the national treatment clause by provisions of the Pairs, Berne, and Rome Conventions as well as specific conditions set for broadcasters, producers of phonographs, and performers.

The national treatment often becomes the grounds for investor-state disputes. A general path for taking a legal action against a host state based on the clause of national treatment includes three steps described by Dolzer and Schreuer.[116] First, a tribunal is supposed to make a decision on whether "like circumstances" could be observed in the case of particular investments. Second, it should compare the treatment accorded to domestic and foreign investors and determine whether the former is more favorable than the latter. Third, a decision should be made in relation to the intent behind a

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[111] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter The TRIPS Agreement].
[112] Ibid.
[113] Ibid.
[114] The TRIPS Agreement
[115] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.
[116] Rudolf Dolzer and Christoph Schreuer, *Principles of International Investment Law* (Oxford, Oxford University Press: 2012).

state's justification for the difference between the treatments of foreign and domestic investors.[117] Inclusion of the national treatment clause in the TRIPS Agreement, therefore, is crucial from the perspective of possible disputes between states and investors.

The most-favored-nation treatment is another important standard provided in the TRIPS Agreement. The document states that "with regard to the protection of intellectual property, any advantage, favor, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members"[118], citing four exceptions from this clause.[119] The literature clarifies that the main goal of the MFN treatment's inclusion in the text of the TRIPS Agreement was to "level the playing field" for all the WTO Members by spreading equal rights across the globe.[120] This clause, therefore, has an important "opening up" potential, allowing participating countries to use the same standards of protection from treaties and agreements with the highest level of protection.

Both these standards of treatment are crucial from the perspective of the problem under investigation. In addition to defining substantive standards of protection of health-related IP rights, the TRIPS Agreement's provisions in regard to the national and most-favored-nation treatment also affect the regulation of IP rights' availability, enforcement, and scope. The national treatment, in particular, prevents states from discriminating persons from other WTO Member states based on their foreign status, whilst the MFN clause prevents discrimination among persons from various Member states.[121] Simultaneously, it is important to emphasize that certain limitations imposed on the national and most-favored-treatment standards by the TRIPS Agreement, such as those deriving from the Rome or Berne Convention, predetermine limitations of these treatment standards. Therefore, there is a likely scenario that MFN and national treatment clauses of the TRIPS Agreement and the same clauses from treaties with investment provisions might overlap. Such a scenario will be discussed in the section 2.3.

2.1.3. Flexibilities of the TRIPS Agreement

The TRIPS Agreement introduced four flexibilities that were supposed to help developing and underdeveloped countries to access medicines. First, all the countries had transitional periods before changing their legislation in line with the TRIPS Agreement. It is important to emphasize that the deadlines for developing and least developed countries were much longer than for developed ones. Second, these countries were also provided with five years to recognize patents in those industries that had not been protected before.[122] Third, Article 6 of the Agreement introduced the term "exhaustion of

[117] Ibid.
[118] The TRIPS Agreement.
[119] Ibid.
[120] Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford, OUP: 2008).
[121] Seymour Rubin, "Most-Favored-Nation Treatment and the Multilateral Trade Negotiations: A Quiet Revolution" 6 *Maryland Journal of International Law* 221-241.
[122] Jayashree Watal and Antony Taubman, *The Making of the Trips Agreement: Personal Insights from the Uruguay Round Negotiations* (Geneva, WTO Press: 2015).

rights", which applied not only to a number of years after which a stakeholder would lose IPRs but also to parallel importing.[123] Finally, the most well-known flexibility from the perspective of the problem under investigation was the option to use compulsory licenses.

Despite the document's attempt to create a universal system protecting intellectual property rights, it was heavily criticized by many stakeholders for its ability to prevent low-income countries from accessing drugs. From the perspective of utilitarianism, the document was widely viewed as a measure that supported the interests of large corporations rather than "the greatest good". Considering that the cost of developing a new drug used to constitute around $800 million[124] or $500-$2,000 million[125] at that time according to different estimates, a company from a developing country was highly unlikely to produce a new drug to treat a disease endangering the population. Simultaneously, barriers created by the TRIPS Agreement prevented it from bypassing the patent protection layer and use cheaper medicines, which had been a popular practice before 1995.[126] Therefore, the agreement created substantial challenges related to access to medicines.

The original text of Article 31 referring to the "other use without authorization of the right holder" clause provides countries with an opportunity to use the instrument of compulsory licenses, even though this term is not explicitly stated in the document's text. The Agreement allows states to use this mechanism "where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government".[127] At the same time, it introduces a number of limitations in regard to such unauthorized use, such as the presence of previous "efforts to obtain authorization from the right holder on reasonable commercial terms", the non-exclusive, liable, and non-assignable use limitation, restrictions of the license's scope to its purpose, the predominant focus on supplying domestic markets, the payment of an adequate remuneration to the right holder, and the decision's subjectivity to judicial review.[128] Some of these limitations were viewed by certain experts as inconsistent with the requirement of adequately balancing the rights and interests of different parties.

Intense discussions of the agreement's flexibilities led to the introduction of the 2001 Doha Declaration and a decision on Paragraph 6 in 2003. As a result, Member states were provided with an opportunity to waive Article 31(f) of the TRIPS Agreement. The original text of the Agreement stated that "any such use (without authorization of the right holder) shall be authorized predominantly for

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[123] Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford, OUP: 2008).
[124] Joseph DiMasi, Ronald Hansen and Henry Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs" (2003) 22 *Journal of Health Economics* 151-185.
[125] Christopher Adams and Van Brantner, "Estimating the Cost of New Drug Development: Is It Really 802 Million Dollars?" (2006) 25 *Health Affairs (Project Hope)* 420-428.
[126] Monique Mrazek, "Pharmaceutical Pricing in the Developing World: Issues of Access to Medicines" (2002) 2 *Expert Review of Pharmacoeconomics & Outcomes Research* 43-50.
[127] The TRIPS Agreement.
[128] Ibid.

the supply of the domestic market of the Member authorizing such use".[129] The 2001 Doha Declaration reaffirmed that "each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted"[130], recognizing that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement"[131]. The Declaration also confirmed the right to use the parallel importing mechanism, which positively affects drug prices and, accordingly, access to medicines.[132] Furthermore, the document extended the least-developing states' deadline for recognizing patents in technological industries that had not been protected before 1995 up to 2016. All these measures strengthened countries' position in negotiations with pharmaceutical companies.

A final decision of the WTO General Council in 2003 concerning this problem provided an explicit permission to import generic drugs to countries with poor domestic production capabilities. The Council's decision introduced the term "eligible importing Member"[133], defining it as "any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer".[134] In accordance with Bermudez and Oliveira, the Doha Declaration and the Council's decision on Paragraph 6 were enthusiastically perceived by the international community because they had reduced barriers to access to medicines for developing and underdeveloped countries.[135] Simultaneously, it should be noted that despite the flexibilities offered by the TRIPS Agreement, their practical use is constrained by a number of limitations.

The majority of countries rarely use compulsory licenses because of the fear that such practice might undermine their image of reliable trade partners and nations with liberal economies. Compulsory licenses issued by the government of Thailand in regard to generic versions of Efavirenz, Stocrin, Kalera, and Plavix are currently among the most well-known examples of the "radical" use of this instrument. In case of Efavirenz, for instance, the government triggered the public health crisis criterion to justify a compulsory license, which reduced the cost of the drug by around 50%, thus simplifying access to Aids treatment.[136] Simultaneously, even though the mechanism of compulsory licensing is legal, its implementation is problematic due to the pressure of pharmaceutical companies

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[129] Ibid.
[130] Doha Declaration on the TRIPS Agreement and Public Health 2001.
[131] Ibid.
[132] Sarah McKeith, "Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion" (2014) 6 *African Journal of Legal Studies* 287-314.
[133] General Council, "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health" (online at 1 September 2003) *WTO* <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm>.
[134] Ibid.
[135] Jorge Bermudez and Maria Auziliadora Oliveira, *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health* (Rio de Janeiro, WHO/PAHO: 2004).
[136] Amy Kazmin and Andrew Jack, "Thailand Breaks Aids Patent to Cut Costs" (online at 30 Nov. 2006) *Financial Times* <https://www.ft.com/content/851b6c34-8016-11db-a3be-0000779e2340>.

and developed states. Therefore, most states that employ this mechanism choose a cautious path in order to reduce possible tension rather than the "radical" avenue selected by Thailand. For instance, when issuing a compulsory license on Tamifu, Taiwan limited its manufacturing to domestic purposes, selected a short timeline up to 2007, established license fees to Roche, announced a plan to use those drugs which had been supplied by Roche before utilizing generic versions, and promised to revoke a license upon reaching an agreement with Roche.[137] Therefore, even though the Doha Declaration and the Council's Decision regarding Paragraph 6 reaffirmed and even broadened states' right to use compulsory licenses, practical implementation of this mechanism is challenging and is usually approached with caution.

It is also important to emphasize that despite the right of all the WTO members to use the mechanism of compulsory licensing, effectiveness of this instrument relies on several preconditions. If these conditions are not met, a license may be useless for a state entering into a health crisis. First, sufficient capacity is mandatory for a successful license. Qualified capacity accelerates the pace of generic drugs' mass production.[138] This problem may be bypassed with the help of import; however, in that case, a country could import generic drugs only if an exporting country has a compulsory license and if the importing member of the World Trade Organization notifies the WTO about an intention to import specific drugs because of its insufficient manufacturing capacity.[139] Second, a limited market size constraints countries' options in terms of compulsory licenses. Lee explains that pharmaceutical companies from countries with small market sizes are unwilling to take compulsory licenses because a potential profit would not cover their costs.[140] In theory, such a problem may be overcome my importing generic drugs, but this scenario is highly uncertain because importing nations would need to waive the Article 31(f) of the TRIPS Agreement and issue an importation compulsory license. Therefore, companies in small countries are often reluctant to take compulsory licenses.

Finally, the third precondition of the effectiveness of compulsory licenses is connected with know-how. As will be showed in the next chapters of the thesis, compulsory licenses could be utilized to bypass the patent law, but they do not require right holders to share their know-how. As a result, companies tasked with the manufacturing of generic drugs might be unable to produce them efficiently due to the lack of knowledge of commercialization, yield rates' optimization, and industrial secrets.[141] Practical implementation of compulsory licenses is often impossible without the three

[137] Richard Li-dar Wang, "Ancillary Orders of Compulsory Licensing and Their Compatibility with the TRIPS Agreement" (2015) 18 *Marquette Intellectual Property Law Review* 87-105.
[138] Eduardo Urias and Shyama Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence" (2020) 1 *Journal of International Business Policy* 1-18.
[139] Doha Declaration on the TRIPS Agreement and Public Health 2001.
[140] Stacey Lee, "Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?" (2013) 44 44 *Georgetown Journal of International Law* 1-12.
[141] Richard Li-dar Wang, "Ancillary Orders of Compulsory Licensing and Their Compatibility with the TRIPS Agreement" (2015) 18 *Marquette Intellectual Property Law Review* 92.

preconditions discussed in the paragraph above. At the same time, as stated above, the existence of this measure increases governments' chances of reaching an agreement with pharmaceutical companies that would help parties avoid such a radical measure as a compulsory license.

Ancillary orders may be used by host governments to increase effectiveness of compulsory licenses in case if some preconditions have not been met. Wang argues that know-how transfer orders could be utilized to make right holders share know-how with companies working on generic products, thus overcoming the problem described in the previous paragraph.[142] However, such a solution is hard to imagine in practice because of various reasons. First, it is unclear how the government could define specific aspects of know-how that should be shared. Second, the procedure for implementing the transfer of know-how is unclear. Wang argues that if right holders do not agree to transfer knowledge, the government could release people with access to know-how from their non-disclosure agreements, thus using them to gain this know-how.[143] At the same time, such a solution seems inherently problematic and contradictive; moreover, the TRIPS Agreement does not specify any exceptions from the trade secrete protection clause, thus implying that know-how ancillary orders might be incompatible with the TRIPS Agreement.

2.1.4. Criticism of the TRIPS Agreement

Whereas it may seem that the TRIPS Agreement improved poor nations' access to medicines, the available evidence provides a compelling reason to suggest otherwise. The document established a substantial level of IPR protection, extending it to all the WTO members. Despite certain flexibilities available for countries, the landscape of international relations with the evident inequality in terms of power prevents developing and least developed nations from using these flexibilities to a full extent. Abdelgawad argues that the Agreement introduced double standards of IPR protection, providing countries from the "global North" with an additional leverage for inserting their dominance over the "global South".[144] An interesting observation in this area was made by Dutfield, who noted that the TRIPS Agreement had adopted the Western model of IPR, thus ignoring any avenues for protecting IPRs related to traditional knowledge. A rhetorical question asked by the scholar captures the essence of this problem, "After all, if indigenous peoples in WTO member states are required to accept the existence of patents that they are economically prevented from availing themselves of (…), why should their own knowledge-related customary regimes including property rules not be respected by others?"[145] In accordance with Abdelwagad, the TRIPS Agreement protects only modern inventions from high-income countries, while empowering corporations from these states to engage in biopiracy

[142] Ibid.
[143] Ibid.
[144] Walid Abdelgawad, "TRIPS Agreement: From Minimum Standards to Double Standards of Intellectual Property Rights Protection in North-South Relations" (online at 2015) *HAL* <https://hal.archives-ouvertes.fr/hal-01131407/document>.
[145] Graham Dutfield, *Protecting Traditional Knowledge: Pathways to the Future* (Geneva, International Centre for Trade and Sustainable Development – ICTSD: 2006).

and exploit traditional knowledge due to the absence of a multilateral system protecting the misappropriation of traditional knowledge.[146] The example provided above brings additional evidence for suggesting that the TRIPS Agreement might benefit developed states more than developing and least-developed ones, thus violating the utilitarian principles of justice.

2.2. The Role of Bilateral Investment Treaties and Treaties with Investment Provisions in the Regulation of Health-Related Intellectual Property Rights

Bilateral investment treaties and treaties with investment provisions are an important source of regulations relevant for the regulation of health-related intellectual property rights. They are often cited in the literature as critical components of TRIPS-plus dimensions.[147] Detailed discussion of the possible areas of divergence between investment treaties and the TRIPS Agreement will be provided in the section 2.3. Simultaneously, it should be noted in this section that BITs and treaties with investment provisions are fundamentally different from the TRIPS Agreement because whilst the TRIPS Agreement sets minimum protection layers, bilateral investment treaties and treaties with investment provisions specify the instrument of protecting investors' rights, thus often building upon the standards offered by the TRIPS Agreement and, as a result, creating TRIPS-plus dimensions.

In order to ensure objective understanding of the implications of BITs and treaties with investment provisions for investment protection in relation to health-related intellectual property rights, it is important to carry out a brief overview of a sample investment treaty with an emphasis on those issues that are of interested from the perspective of the problem under investigation. Definitions of the main terms used in an agreement could be found in the first article of a bilateral investment treaty. A definition of investments is a critical matter in this sphere. In particular, in addition to using an asset-based or an enterprise-based definition, treaties might also impose limitations on investments' scope.[148] Whereas none of the exclusions specifically focus on assets that are related to pharmaceutical products, some of them could be relevant. In particular, the denial of benefits clause that is triggered based on the ownership requirement and the criterion of "substantive business activity" often becomes important arguments on which parties in investor-state dispute settlements rely.[149] Thus, its examination is relevant to the chosen research problem.

Definitions of investors are hardly a central point in BITs and treaties with investment provisions. Nonetheless, an emphasis on citizens or permanent residents and the exclusion of dual

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[146] Walid Abdelgawad, "TRIPS Agreement: From Minimum Standards to Double Standards of Intellectual Property Rights Protection in North-South Relations" (online at 2015) *HAL* <https://hal.archives-ouvertes.fr/hal-01131407/document>.

[147] Susy Frankel, "Challenging Tripls-Plus Agreements: The Potential Utility of Non-Violation Disputes" (2009) 12 *Journal of International Economic Law* 1023-1065.

[148] Catherine Yannaca-Small, *International Investment Law: Understanding Concepts and Tracking Innovations* (OECD Publishing 2008) 7-15.

[149] Loukas Mistelis and Crina Baltaq, "Denial of Benefits' Clause in Investment Treaty Arbitration" (2018) 293 *Queen Mary School of Law Legal Studies* 1-39.

nationals might be pertinent provisions.[150] A combination of these clauses may exclude certain investors from the scope of the treaty, thus preventing them from using investor-state dispute settlement mechanisms. As a rule, these limitations could be found in the treaties signed by countries with strong protectionist policies like Saudi Arabia.[151] The clause pertaining to dual nationals, at the same time, is primarily utilized to prevent citizens from taking a legal action against their own country.

The second article of a bilateral investment treaty might take different forms. In most situations, it starts with a clause related to the treaty's temporal scope. This clause is important since it determines whether an agreement applies to those investments and disputes that occurred before its signing.[152] The first three articles of bilateral investment treaties sometimes include a clause "in accordance with a host State's laws". A BIT signed between Morocco and Nigeria, for example, states that "Each Contracting Party shall ensure that measures and efforts are undertaken to prevent and combat corruption regarding matters covered by this Agreement in accordance with its laws and regulations".[153] Such a formulation provides a host state with substantive rights and, accordingly, reduces investors' ability to take a legal action against a state through the investor-state dispute settlement channel.[154] Thus, it might be relevant for discussing pharmaceutical companies' dispute settlement options.

One of the most important parts of investment treaties from the perspective of the problem under investigation is the standards of treatment. As it is known, investment treaties might include the provisions of national, most-favored-nation, and fair and equitable treatment and specify the manner in which this treatment is provided and the exceptions that are excluded from its scope.[155] All these three types of treatment play a major role in investor-state dispute settlement mechanisms, and many cases, such as *Bayer v. Union of India*, solely rely on the provisions related to a certain type of treatment.[156] Detailed discussion of the possible areas of divergence between the treatment regimens clarified in the TRIPS Agreement and in investment treaties will be offered in the section 2.3.

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[150] Chi-Chung Kao, "Definition of Investor and Related Issues in Investment Treaty Arbitration under the Proposed Taiwan-China Bilateral Investment Agreement" (2011) 4 *Contemporary Asia Arbitration Journal* 179-213.
[151] Ibid.
[152] Southern African Development Community, *SADC Model Bilateral Investment Treaty Template with Commentary* (SADC Press: 2012) 22.
[153] Reciprocal Investment Promotion and Protection Agreement between the Government of the Kingdom of Morocco and the Government of the Federal Republic of Nigeria 2016.
[154] Felix Antolin Martinez, "Re-thinking the Requirement of Making an Investment in Accordance with Domestic Laws as a Substantive Right and a Cause of Action for Host States under the BITs" (2018) 22 *Luris Dictio* 101-114.
[155] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.
[156] Bayer Corporation v. Union of India.

One of the most important sections of bilateral investment treaties and treaties with investment provisions from the perspective of the problem under investigation are those with expropriation clauses because their provisions are directly connected with the use of compulsory licenses. The main aspects of expropriation clauses are the type of situations that are excluded from the provision[157] and the ways in which a compensation is calculated and transferred.[158] For instance, the free trade investment treaty between Australia and the United States introduces four strict criteria for using the expropriation or nationalization mechanism, thus creating an important TRIPS-plus rule.

There are also many other issues related to TRIPS-plus dimensions that could be created with the help of BITs or treaties with investment provisions. An extension of the patent protection period is one of the most well-known issues in this sphere. While the TRIPS Agreement establishes a timeline after which a patent expires, some treaties with investment provisions, especially those signed by the United States, introduce the option of extending this timeline by triggering the "new use" clause.[159] Some treaties also explicitly prohibit performance requirements, which is one of the central implications of investment treaties for the protection of intellectual property rights. Other clauses that might be relevant to the discussion are the "umbrella" clause, the entry of personnel, transparency, the non-derogation clause, and the prohibition of lowering standards. The prohibition of lowering standards and the "umbrella clause" are the most important from the perspective of the problem under investigation. The former might help investors invoke treaty protection under the international law[160], while the latter provides investors with an additional layer of protection in case if a state introduces new unfavorable policies. Finally, it is also relevant to emphasize that some treaties include provisions that are directly connected to general public policy exceptions, including public health and environment.[161] Such clause might be used as a premise for invoking the derogation of treaty obligations based on international law.

A description of investor-state dispute settlement (ISDS) mechanisms usually takes a substantial part of investment treaties. The key areas of interests in articles related to ISDS are the availability of alternative options, such as conciliation and mediation[162], the scope and contest of

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[157] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.

[158] Carlos Correa, "Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights?" (online at 24 June 2020) *Grain* <https://www.grain.org/article/entries/125-bilateral-investment-agreements-agents-of-new-global-standards-for-the-protection-of-intellectual-property-rights#six>.

[159] Cynthia Ho, *An Overview of 'TRIPLS-Plus" Standards* (Oxford, OUP: 2011).

[160] OECD, *International Investment Law: Understanding Concepts and Tracking Innovations: A Companion Volume to International Investment Perspectives* (OECD Publishing 2008) 101-134.

[161] Lahra Liberti, "Intellectual Property Rights in International Investment Agreements" (Online at 2010) OECD <https://www.oecd.org/investment/internationalinvestmentagreements/WP-2010_1.pdf>.

[162] Chunlei Zhao, "Investor-State Mediation in a China-EU Bilateral Investment Treaty: Talking about Being in the Right Place at the Right Time" (2018) 17 *Chinese Journal of International Law* 111-135.

ISDS, the type of consent to arbitration, and the types of forums available to investors.[163] Bilateral investment treaties and treaties with investment provisions may provide investors with an option to take a legal action against a host state in domestic courts and through ICSID, UNCITRAL, and other forums. They also specify the relationship between these forums by using such approaches as the "fork in the road", waiver clause, or "local remedies first".[164] Finally, investment treaties provide general guidelines concerning the structure and functionality of an arbitration tribunal and the transparency of arbitral proceedings.

The list of issues reviewed above hardly encompasses all the matters related to the regulation of health-related intellectual property rights that could be affected by bilateral investment treaties and treaties with investment provisions. In dependence on the nature of a particular agreement, many other aspects of this field could be touched. For instance, the Trans-Pacific Partnership Agreement could have become the first agreement to introduce biologics as a relevant term related to IPRs. The TPPA's draft provided 8 years of protecting clinical trial data, thus preventing the development of "biosimilars".[165] Furthermore, the document also was supposed to use the clause from the WTO Agreement on Technical Barriers to Trade arguing that "technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create".[166] The clause would directly apply to health regulations, thus creating potential problems with using the "necessity test", which is a frequent cause of disputes between governments.[167] Finally, treaties might also affect the regulation of health-related intellectual property rights via indirect channels. For instance, Faunce voices concerns that a free trade treaty between the United States and Australia could adversely affect the Pharmaceutical Benefits Scheme in Australia by delegating policy choice to stakeholders with private interests without triggering public debates.[168] Such indirect effects should be discussed separately for each country with reference to a specific agreement.

2.3. An Overview of Possible Areas of Divergence between the TRIPS Agreement and Treaties with Investment Provisions in Regard to the Regulation of Health-Related Intellectual Property Rights

2.3.1. Introduction to Areas of Divergence

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[163] Southern African Development Community, *SADC Model Bilateral Investment Treaty Template with Commentary* (SADC Press 2012) 30-60.
[164] Guiguo Wang, *International Investment Law: The Chinese Perspective* (Routledge 2014) 204.
[165] Ronald Labonte, Ashley Schram and Arne Ruckert, "The Trans-Pacific Partnership Agreement and Health: New Gains, Some Losses, Many Risks" (2016) 12 *Globalization and Health* 2.
[166] The WTO Agreement on Technical Barriers to Trade.
[167] World Trade Organization, "Disputes by Agreement" (online at 2021) *WTO* <https://www.wto.org/english/tratop_e/dispu_e/dispu_agreements_index_e.htm?id=A22>
[168] Thomas Faunce, "Reference Pricing for Pharmaceuticals: Is The Australia-United States Free Trade Agreement Affecting Australia's Pharmaceutical Benefits Scheme?" (2007) 187 *The Medical Journal of Australia* 240-242.

As explained in the section 2.2, the TRIPS Agreement and treaties with investment provisions often overlap. However, the nature of their overlapping is based on the fact that the TRIPS Agreement serves as the minimum protection layer, while additional clauses inserted by bilateral investment treaties or treaties with investment provisions might create TRIPS-plus dimensions.[169] From the perspective of utilitarianism, investment treaties create more significant threats for violating the principles of justice because they might include clauses that were inserted in documents by powerful states using their high negotiating power. The current chapter discusses in detail possible areas of divergence between the TRIPS Agreement and investment treaties.

Limitations related to the scope of parallel importing and compulsory licensing, which are important flexibilities of the TRIPS Agreement, are one of the most evident areas of divergence. A Draft of the Free Trade Area of the Americas (FTAA) Agreement introduces a series of limitations on the compulsory licensing mechanism. In particular, it clarifies that if a Party plans to use a patent's subject matter without a patent owner's authorization, a license "shall be granted only for public non-commercial purposes or in situations of a declared national emergency or other situations of extreme urgency".[170] Moreover, a state would not be able to use a compulsory license until four years pass since the patent have been granted.[171] If the agreement had been signed, it would have significantly reduced the scope of compulsory licensing and, at the same time, constrain low-income nations' access to medicines even more.

2.3.2. Compulsory Licensing and Parallel Importing

Limitations of the compulsory licenses' scope could be also found in many bilateral investment agreements and free trade agreements. In particular, US agreements with Singapore, Jordan, and Australia determine a limited set of situations in which a compulsory could be issued, including "(a) to remedy a practice determined after judicial or administrative process to be anti-competitive; (b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government; or (c) on the ground of failure to meet working requirements, provided that importation shall constitute working".[172] These narrow specifications, which could be found in many BITs and treaties with investment provisions signed by the United States and the European Union, exemplify a TRIPS-plus provisions. They shift the balance of stakeholders' rights and interests, reducing the bargaining power of governments in negotiations with pharmaceutical companies.

In addition to limitations on compulsory licenses, BITs and treaties with investment provisions could also affect parallel importing. Considering that parallel importing is one of

[169] Cynthia Ho, *An Overview of 'TRIPLS-Plus" Standards* (Oxford, OUP: 2011).
[170] Third Draft of the Free Trade of the Americas Agreement 2003
[171] Ibid.
[172] Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area 2000

flexibilities allowing developing and underdeveloped countries to access medicines at lower prices, its prohibition by an agreement is a crucial issue reducing poor nations' access to medicines.[173] The free trade agreement between the United States and Australia prevents the parallel importation of generic drugs that are produced in Australia under a compulsory license.[174] A similar clause could be also found in a free trade agreement between the United States and Morocco. This document, in particular, states that "each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory".[175] A similar formulation could be also found in the US free trade agreement with Singapore. By limiting the scope of parallel importing or prohibiting it explicitly, bilateral investment treaties and treaties with investment provisions create a TRIPS-plus dimension that is against the spirit of the 2001 Doha Declaration and the Council's decision on Paragraph 6.

2.3.3. Patent Terms

An extension of patent terms is the next relevant feature that should be discussed in regard to the divergence between the TRIPS Agreement and investment treaties. For example, the free trade agreement between the United States and Morocco provides patent owners with additional five years of exclusive rights over test data as well as additional three years for "new clinical information", which extend even to those drugs that are not patented in a host state. As a result, companies producing generic versions of a drug might struggle with accessing data that is necessary in the production process. The proposed Trans-Pacific Partnership Agreement provided a clause on patenting the existing pharmaceuticals that already have been protected by patents "for new uses, new methods of using… or new processes". Labonte, Schram, and Ruckert explain that this is a TRIPS+ provision that eliminates one of flexibilities offered by the TRIPS Agreement.[176] Such clauses could translate into patents' "evergreening", thus delaying the manufacturing of generic versions of drugs. It is also important to emphasize that if the Trans-Pacific Partnership Agreement had been signed, companies would have been able to use the clause of "unreasonable delays" to extend the term of their patents, even though such a provision does not exist in the TRIPS Agreement.

Similar inconsistencies could be also found in some investment treaties, including those signed by the United States with Australia, Jordan, and Chile. For example, a free trade agreement signed by the USA with Chile states that "each party shall provide for the adjustment of the term of a patent, at the request of the patent owner, to compensate for unreasonable delays that occur in granting the patent", specifying that unreasonable delays should be interpreted as "a delay in the

[173] Sarah McKeith, "Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion" (2014) 6 *African Journal of Legal Studies* 287-314.
[174] Free Trade Agreement between Australia and the United States of America.
[175] Free Trade Agreement between the Kingdom of Morocco and the United States of America 2004.
[176] Ronald Labonte, Ashley Schram and Arne Ruckert, "The Trans-Pacific Partnership Agreement and Health: New Gains, Some Lessons, Many Risks" (2016) 12 *Globalization and Health* 2

issuance of the patent of more than five years from the date of filing of the application in the Party, or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays".[177] These agreements also include the "new use" clause, which provides an important leverage for pharmaceutical companies, while also reducing nations' access to medicines. It might take a significant amount of time to trigger the "new use" clause, especially if it is accompanied by a dispute related to a patent violation.[178] Procedures associated with this provision, which is not explicitly permitted under the TRIPS Agreement, slow down the process of manufacturing generic versions of a drug, thus undermining developing and least developed states' ability to alleviate a health crisis.

2.3.4. Data Exclusivity

Clauses on data exclusivity, which could be found in many treaties with investment provisions, also create TRIPS-plus dimensions. The aforementioned treaty with Chile clarifies that "if a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity… the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information".[179] The prohibition could be maintained "for a period of at least five years from the data of approval for a pharmaceutical product".[180] Article 39 of Section 7 of the TRIPS Agreement already includes provisions on the protection of undisclosed information[181], but clauses included in investment treaties specify instruments that should be triggered by states and extend the scope of this protection as well as its length. These clauses reduce the governments' ability to pursue "the greatest good" in addressing health crises.

Various agreements utilize different instruments to create additional layers of protection beyond those guaranteed by Article 39 of the TRIPS Agreement, including the granting of marketing procedures, extension of data protection beyond the patent expiration timeline, and prohibition of reliance on prior test data. This issue might have a dramatic effect on access to medicines because it reduces the compulsory licensing mechanism. The study carried out by Oxfam International clarifies that the data exclusivity clause in the US-Jordan free trade agreement delayed the production of

[177] Free Trade Agreement between the Government of the United States of America and the Government of the Republic of Chile.
[178] MSF, "Trips, R&D and Access to Medicines: A Guide to the Post 2005 World" (online at February 2005) *MSF* <https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_GuideToTRIPS_ENG_2005.pdf>.
[179] Free Trade Agreement between the Government of the United States of America and the Government of the Republic of Chile.
[180] Ibid.
[181] The TRIPS Agreement.

generic versions of 79% of medicines sold by 21 pharmaceutical companies during the period between 2002 and 2006 that would have been available if the agreement had not been signed.[182] Therefore, even though data exclusivity clauses have received much less attention than compulsory licenses, they could be also considered a crucial TRIPS-rule rule that dramatically affects the regulation of health-related intellectual property rights.

2.3.5. Performance Requirements

Prohibition of performance requirements is another pertinent aspect of the problem under investigation. Technically, such a clause does not contradict the TRIPS Agreement because this document does not mention performance requirements. However, Boie is under the impression that this prohibition is "at odds with the TRIPS Agreement's spirit on a number of points, particularly with regard to certain performance requirements such as technology transfer, which are to a certain extent encouraged by the TRIPS Agreement for development purposes".[183] Therefore, prohibitions of some performance requirements may lead to inconsistencies between the TRIPS Agreement and BITs or treaties with investment provisions.

The TRIPS Agreement explicitly encourages parties to facilitate knowledge transfer in order to "create a solid and viable technological base".[184] In contrast to this spirit, many BITs and treaties with investment provisions prohibit technology transfer. For instance, a Canada-Croatia BIT prohibits "to transfer technology, a production process or other proprietary knowledge to a person in its territory unaffiliated with the transferor, except when the requirement is imposed or the commitment or undertaking is enforced by a court, administrative tribunal or competition authority, either to remedy an alleged violation of competition laws or acting in a manner not inconsistent with other provisions of this Agreement".[185] Such language of treaties might be considered inconsistent with the TRIPS Agreement. Therefore, many recent treaties specify exceptions from the prohibition of performance requirements in case if a particular measure is in accordance with the Articles 31 or 39 of the TRIPS Agreement.

2.3.6. Standards of Treatment

Contradictions between the treatment regimens is a controversial yet topical aspect of the interaction between the TRIPS Agreement and BITs and treaties with investment provisions. The most-favored-nation treatment clause could be found both in the TRIPS Agreement and in most bilateral investment treaties and treaties with investment provisions. The main goal of the MFN

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[182] Rohit Malpani, "All Costs, No Benefits: How TRIPS-Plus Rules in the US-Jordan FTA Affect Access to Medicines" (2007) 102 *Oxfam Briefing Paper* 1-37.

[183] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.

[184] The TRIPS Agreement.

[185] Agreement between the Government of the Republic of Croatia and the Government of Canada for the Promotion and Protection of Investments.

treatment in the TRIPS Agreement is to "level the playing field" for parties, while the MFN clause in investment law focuses on setting a shared protection layer.[186] The MFN clause requires "like circumstances". However, even if these "like circumstances" are established, "no other rights can be claimed under an MFN clause than those falling within the subject-matter of the clause".[187] At the same time, a scenario in which investment treaties utilize the MFN clause to "borrow" provisions from IP conventions is highly unlikely because of the difference between the TRIPS Agreement and investment treaties' regulatory intents. Whereas the most-favored nation treatment is an important principle that plays an important role in the regulation of health-related intellectual property rights, it is described similarly in the TRIPS Agreement, BITs, and treaties with investment provisions and, thus, does not display any evident areas of divergence between the documents.

The concept of national treatment is much more challenging from this perspective. Boie argues that despite the absence of any insights into the substance of rules at issue, the national treatment clause implies a requirement of foreign investors' non-discriminatory treatment.[188] The national treatment provision is incorporated in many bilateral investment treaties and treaties with investment provisions, protecting parties both from *de jure* and from *de facto* discrimination based on their foreign status. Article 3 of the TRIPS Agreement establishes exceptions from the clause that are based on the Berne, Paris, and Rome Conventions as well as the Treaty on Intellectual Property in Respect of Integrated Circuits[189]; furthermore, it also specifies that broadcasters, performers, and phonograms' producers gain rights only in respect to those mentioned in the text of the Agreement.[190] These exceptions are not included in the text of most BITs and treaties with investment provisions; therefore, they could be used to overrule these exceptions.[191] Such a situation results in TRIPS-plus rules introduced by BITs and treaties with investment provisions based on their broader exceptions than those elucidated in the TRIPS Agreement.

Certain areas of divergence between the documents could also arise in relation to the fair and equitable treatment. This standard is described by the TRIPS Agreement exclusively in relation to the enforcement of IPRs, whilst investment treaties use it as an absolute standard of treatment.[192] The

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[186] Carolyn Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford, OUP: 2008).
[187] Carlos Correa, Bilateral Investment Agreements: Agents of a New Global Standard for the Protection of Intellectual Property Rights? (online at December 2004) *TDM* <https://www.transnational-dispute-management.com/article.asp?key=318>.
[188] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.
[189] The TRIPS Agreement
[190] Ibid.
[191] Andrew Newcombe and Lluis Paradell, *Law and Practice of Investment Treaties: Standards of Treatment* (Alphen aan den Rijn, Kluwer Law International: 2009).
[192] Katia Yannaca-Small, "Fair and Equitable Treatment Standards: Recent Developments," in *Standards of Investment Protection*, ed. August Reinisch (Oxford, Oxford University Press: 2008), 111.

essence of a possible area of divergence between the TRIPS Agreement and treaties using the fair and equitable treatment as an absolute standard is directly connected to the ways in which this standard could be tested. As it is known, the fair and equitable treatment clause must be considered violated after a claimant proves that "the treatment it has received fell below the 'floor' established by the international law standard (whether imposed under customary international law or by treaty)".[193] In practice, enforcement of the treatment implies not violating legitimate expectations of investors.[194] Such expectations constitute a controversial yet powerful line of argumentation because they could potentially provide investors with a layer of protection than is equivalent to those guaranteed by the TRIPS Agreement or even higher. In particular, one may imagine a situation in which investors engage in close interaction with local authorities of a least developed country and, thus, have legitimate expectations of a treatment that is at least compliant with the standards offered in the TRIPS Agreement, even though the Agreement is not directly mentioned in the text of investment treaties.

Another critical issue related to the interaction between the TRIPS Agreement and investment treaties is the option of demanding treatment that is guaranteed by the international law. In theory, such an opportunity might allow parties to invoke a wide set of different international law sources, although there have not been such precedents to date. The interpretation of minimum standards of treatment under the fair and equitable treatment is also a relevant issue in this sphere. Newcombe and Paradell believe that this term opens the path for incorporating the TRIPS Agreement into the IP protection under investment law because of the document's recognition as the most well-known "floor" of international IPR protection.[195] Nonetheless, in theory, a peculiar interpretation of the minimum standard of treatment might be used to extend the protection level beyond the one guaranteed by the TRIPS Agreement.

2.3.7. Dispute Settlement

Finally, the last crucial area in which BITs and treaties with investment provisions create a TRIPS-plus dimension is dispute settlement mechanisms. The TRIPS Agreement describes a state-to-state dispute settlement channel. In contrast, BITs and treaties with investment provisions also describe the investor-to-state mechanism, which offers certain advantages for the former.[196] Investor-to-state instruments provide investors with an opportunity to use TRIPS-plus provisions of investment treaties, which may sometimes test flexibilities of the TRIPS Agreement, such as those in regard to exceptions from compulsory licenses, the scope of parallel importing, or the exceptions from the

[193] Todd Grierson-Weiler and Ian A. Laird, "Standards of Treatment," in *The Oxford Handbook of International Investment Law*, ed. Peter Muchlinski, Federico Ortino, and Christoph Schreuer (New York, Oxford University Press: 2008), 262.
[194] Ibid.
[195] Andrew Newcombe and Lluis Paradell, L*aw and Practice of Investment Treaties: Standards of Treatment* (Alphen aan den Rijn, Kluwer Law International: 2009).
[196] United Nations, *Investor-State Dispute Settlement and Impact on Investment Rulemaking* (New York, UN: 2007).

national treatment clause.[197] Like in the case with provisions about compulsory licenses, the presence of TRIPS-plus ISDS clauses undermines the balance between the parties' rights and interests and reduces the negotiating capacity of governments in negotiations with pharmaceutical companies.

Simultaneously, it should be noted that different treaties offer various channels for the investor-to-state dispute settlement, such as the availability of such international forums as ICSID and UNCITRAL, the option of utilizing conciliation and mediation instruments, the use of the "fork in the road" principle, and requirements concerning the transparency in arbitral proceedings. Therefore, a decision on whether to use IPR protection under the TRIPS Agreement or investment protection under BITs and treaties with investment provisions is usually made based on the specifics of particular treaties.

2.4. The Role of BITs, Treaties with Investment Provisions, and the TRIPS Agreement in the Regulation of Health-Related IP Rights in Regard to Vaccine Manufacturing and Distribution

2.4.1. IPR Protection on the Vaccine Market

The TRIPS Agreement has become an important step in the evolution of the vaccine industry. Introduction of the Agreement essentially extended the Western paradigm of intellectual property rights to developing and underdeveloped countries, thus making these states comply with the established mechanisms protecting vaccine-related IPRs.[198] The instruments introduced by the TRIPS Agreement establish several mechanisms for protecting vaccine-related IPRs, including patents, trademarks, and know-how. In accordance with the Agreement, patents are subject to an expiration period of 20 years, while expiration of know-how is not mentioned.[199] Interestingly, despite a popular belief that product patents are the main layer of defense in the sector, process patents are usually preferred over product ones in the vaccine industry except for those vaccines that include purified components.[200] Thus, patent protection of products might be no longer the most important mechanism of protecting vaccine-related IPRs.

This statement could be confirmed with the help of empirical data. The number of biotech and chemical patents at the U.S. Patent and Trade Mark Office had increased from 30,000 to 45,000 annual cases during the period between mid-1990s and 2001; however, this number returned to its previous levels by 2006.[201] According to Kerry Flynn, the vice president of Shire Human Genetic Therapies Inc., "the landscape has changed recently because of higher standards in granting patent

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[197] Yetty Komalasari Dewi and Arie Afriansyah, "Dispute Settlement Mechanism in Bilateral Investment Treaties (BITs)" (2019) 34 *Yuridika* 153-174.
[198] Julie Milstien and Miloud Kaddar, "Managing the Effect of TRIPS on Availability of Priority Vaccines" (2006) 84 *Bulletin of the World Health Organization* 360-365.
[199] The TRIPS Agreement.
[200] World Health Organization, "Intellectual Property Rights and Vaccines in Developing Countries" (online at 20 April 2004) *WHO* <https://apps.who.int/iris/bitstream/handle/10665/68875/WHO_IVB_04.21_%28302KB%29.pdf?sequence=1&isAllowed=y>.
[201] Nuala Moran, "The Rise of Trade Secrets in Biotechnolgy," (online at 25 June 2008) *Science Business* <https://sciencebusiness.net/news/70454/The-rise-of-trade-secrets-in-biotechnology>.

rights… when we were a small biotech we were more aggressive in patenting… whether we could afford to protect these patents or not is another matter… now as a bigger company we think we can protect value better as trade secrets".[202] This sentiment is echoed in David Levine's arguments describing trade secrets as the main barrier to the distribution of COVID-19 vaccines.[203] Westby also points out that trade secrets are becoming an increasingly important layer of vaccine-related IP rights' defense because they do not have an expiration date.[204] The focus of vaccine patents has also shifted to manufacturing processes, as protection of industrial processes turned out to be more effective than the protection of antigens and most other ingredients of a vaccine. Plotkin, Robinson, Cunningham, Iqbal, and Larsen claim that "many vaccine patents protect the manufacturing process rather than the antigen that is produced by the process, which is not always the analogous case for small molecule pharmaceutical products".[205] The role of IP protection of industrial processes in the form of patents and trade secrets in vaccine regulations is supposed to become even more important in the nearest future due to the growing complexity of manufacturing processes associated with the production of COVID-19 vaccines. Such a radical shift in the mechanisms of vaccine-related IPRs' protection encourages scholars to reconsider the role of the existing IPR protection instruments, including those described in the TRIPS Agreement, in the regulation of vaccine-related IP rights.

2.4.2. The TRIPS Agreement and Access to Vaccines

There is currently no agreement among scholars concerning the effect of the TRIPS Agreement on the access to vaccines. While all of them agree that the document creates certain barriers to this access, they disagree on the barriers' significance. Milstien and Kaddar, in particular, believe that IP protection under the TRIPS Agreement is not a substantial barrier to vaccine manufacturing in developing and underdeveloped countries. They argue that Hib conjugate did not have an exclusive license limiting access to the product and did not use manufacturing secrets that were not available online, but no manufacturers from least developed and developing states managed to produce a Hib vaccine in 10 years after the introduction of Hib conjugate.[206] A similar opinion was expressed by Hannah, Scott, Trommer, and Harman in regard to the current debate of the TRIPS waiver's possible impact on equitable access to COVID-19 vaccines. The scholars emphasize that flexibilities in the TRIPS Agreement, specifically compulsory licenses, already provide a path for developing and least developed nations to start producing generic versions of COVID-19 vaccines.[207]

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[202] Ibid.

[203] David Levine, "Covid-19 Should Spark a Reexamination of Trade Secrets' Stranglehold on Information" (online at 10 July 2020) *Stat News* <https://www.statnews.com/2020/07/10/covid-19-reexamine-trade-secrets-information-stranglehold/>.

[204] Jody Westby, *International Guide to Privacy* (Chicago, 2004: American Bar Association).

[205] Stanlley Plotkin, James Robinson, Gerard Cunningham, Robyn Iqbal and Shannon Larsen, "The Complexity and Cost of Vaccine Manufacturing – An Overview" (2017) 35 *Vaccine* 4064-4071.

[206] Julie Milstien and Miloud Kaddar, "Managing the Effect of TRIPS on Availability of Priority Vaccines" (2006) 84 *Bulletin of the World Health Organization* 362.

[207] Erin Hannah, James Scott, Silke Trommer and Sophie Harman, "TRIPS Waiver: US Support Is a Major Step but No Guarantee of COVID-19 Vaccine Equity" (online at 12 May 2021) *The Conversation*

However, the lack of manufacturing capacity, the absence of adequate knowledge transfer channels, and the lack of access to industrial know-how prevent these countries from issuing a compulsory license to start producing generic versions of vaccines.[208] In other words, it is possible that other reasons rather than IP protection under the TRIPS Agreement might be a critical barrier to access to vaccines. If one agrees with this point of view, it would mean that the text of the TRIPS Agreement is aligned with the utilitarian interpretation of justice.

Despite these arguments, the available evidence provides a compelling reason to believe that patent protection guaranteed by the TRIPS Agreement still remains a relevant barrier to low-income nations' access to vaccines. The case of Gardasil exemplifies this pattern. According to Padmanabhan, Smin, Sampat, Cook-Deegan, and Chandrasekharan, there were 81 patents of Gardasil in the United States in 2010 that belonged to 18 entities.[209] Rutschman clarifies that it might be sometimes nearly impossible to develop a vaccine because different ingredients and technologies are patented by various pharmaceutical companies; as a result, none of them can use all the necessary ingredients and technology to develop a product.[210] Patents also extend market exclusivity, preventing generic completion of drugs and vaccines even if companies obtain compulsory licenses. For instance, Amin and Keselheim found that 108 patents that are related to 2 HIV vaccines could postpone generic completion until 2028.[211] Patent protection remains a substantial impediment in the area of new formulations of existent vaccines. In particular, in 2007, the University of Michigan at Ann Arbor has sold its royalties on payments from the use of the nasal-spray technology in the vaccine FluMist.[212] This example shows that the task of creating a vaccine in the modern world might require substantial investments due to patent barriers on different innovations related to vaccines.

2.4.3. TRIPS-Plus Barriers to Vaccine Access

TRIPS-plus rules introduced by bilateral investment treaties and treaties with investment provisions undoubtedly provide more serious barriers to vaccine access than the TRIPS Agreement. An extension of the patent expiration term beyond 20 years specified in the TRIPS Agreement, limitations on compulsory licenses, and other constraints slowing down or even preventing the introduction of generic products reduce the ability of developing and least developed countries to

<https://theconversation.com/trips-waiver-us-support-is-a-major-step-but-no-guarantee-of-covid-19-vaccine-equity-160638>.

[208] Ibid.

[209] Swathi Padmanabhan, Tahir Amin, Bhaven Sampat, Robert Cook-Deegan and Subhashini Chandrasekharan, "Intellectual Property, Technology Transfer and Manufacture of Low-Cost HPV Vaccines in India" (2010) 28 *Nature Biotechnology* 671-678.

[210] Ana Santos Rutschman "Property and Intellectual Property in Vaccine Markets" (2020) *Texas A&M University Journal of Property Law*, 2020 https://ssrn.com/abstract=3590912>.

[211] Amin Tahir and Aaron Kesselheim, "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades" (2012) 31 *Health Affairs* 2286-2294.

[212] Goldie Blumenstyk, "U. of Michigan Sells Patent Royalties from FluMist for as Much as $35 Million" (online at 12 July 2007) *The Chronicle of Higher Educatio*n <https://www.chronicle.com/article/u-of-michigan-sells-patent-royalties-from-flumist-for-as-much-as-35-million/>.

access high-quality vaccines at affordable prices.[213] Furthermore, it is important to emphasize that regulatory authorities might use provisions of investment treaties to block the export of materials that is necessary for conducting clinical trials in those situations when licenses are not present.[214] The data exclusivity clause upheld at the regional or national level requires generic producers to submit efficacy and safety data that were received from their own clinical trials rather than using the data of patent holders.[215] The clause creates additional challenges for generic producers in addition to delaying the introduction of generic vaccines, which might undermine a state's ability to resolve a health crisis. The data exclusivity provision is one of relevant areas of divergence between the TRIPS Agreement and investment treaties in regard to the vaccine industry. Whilst the former does not explicitly prevent disclosure of data in those situations when such disclosure is necessary to protect the nation, the latter might prevent it with the help of a TRIPS-plus rule. All these measures arguably violate the utilitarian principles of justice by undermining governments' ability to pursue actions that lead to "the greatest utility".

The arguments laid out above illustrate that the TRIPS Agreement does not create explicit barriers to access to vaccines except for the layer of patent protection and protection of trade secrets. Furthermore, patent protection could be successfully bypassed with the help of compulsory licensing. The fact that the use of compulsory licensing to obtain the right to produce generic vaccines is unlikely to succeed due to limited resources of most pharmaceutical companies in developing and least developed countries and the inability of compulsory licensing to regulate access to know-how, which is crucial for vaccine manufacturing, is hardly a result of the TRIPS Agreement's excessive regulation. The Agreement indeed provides a general framework for protecting IP rights related to vaccines; however, the most substantial barriers to accessing vaccines by generic manufacturers do not originate from restrictions introduced by the TRIPS Agreement.

2.4.4. Discussion of the TRIPS Waiver

The discussion provided in this chapter illustrates that a TRIPS waiver, which is currently a topic of intense debates among many stakeholders, cannot be viewed as a mechanism of eliminating all the barriers that currently prevent developing and least developed countries from manufacturing generic vaccines. The majority of instruments that could be used to facilitate this process are already present in the TRIPS Agreement. However, the attempts of developing or least developed countries to use most of these flexibilities often result in substantial pressure from developed countries. The case of a compulsory license that was issued by India for a cancer drug and resulted in a 97% decrease in

[213] Mohammed K El Said, *Public Health Related TRIPS-Plus Provisions in Bilateral Trade Agreements* (Geneva, WHO Press: 2010).
[214] Ibid.
[215] Karin Timmermans, "Monopolizing Clinical Trial Data: Implications and Trends" (2007) 4 *PLoS Med* 1-5.

its price exemplifies this pattern.[216] The proposed waiver, therefore, primarily aims not to eliminate the existing legislative barriers to equitable access to vaccines but rather to ensure that developed countries will not oppose other states' attempts to use the existing flexibilities guaranteed by the TRIPS Agreement. As Bosse, Kang, and Thambisetty explain, "support for the waiver… may give all trading partners… the confidence to boldly use those powers [flexibilities] to improve the supply of COVID-19 vaccines without fear of trade retaliation".[217] Such confidence, therefore, may become a crucial outcome of the waiver.

The proposed waiver, which was recently endorsed by the United States, also includes other measures besides reaffirming the existing flexibilities, including actions to facilitate access to trade secrets. Improved access to data from regulatory approval process as well as tacit know-how could be effectively utilized by generic manufacturers to facilitate production of vaccines.[218] It is also important to emphasize that the waiver would empower countries to use those flexibilities of the TRIPS Agreement that seemed impractical in the past. In particular, as it is known, an exception concerning the production of generic drugs for export was triggered only once; furthermore, even this case involved a multi-year delay.[219] The waiver could allow facilitating the implementation of this flexibility by eliminating numerous enduring processes that are currently required to obtain a permission to export drugs under a compulsory license to a country with insufficient manufacturing capacity. The idea of a TRIPS waiver is hardly aligned with the utilitarian understanding of justice, as it rather pursues the liberal interpretation of justice and its implications for the equitable access to vaccines by appealing to moral obligations of developed states and pharmaceutical companies. Nevertheless, if the scope of this waiver primarily revolves around an explicit permission and even encouragement to bypass patent protection without the fear of trade retaliation and enduring bureaucratic obstacles, such a measure could indeed encourage generic manufacturing of COVID-19 vaccines without disrupting the existing balance between the interests and rights of different stakeholders.

2.4.5. TRIPS-Plus Rules and Access to COVID-19 Vaccines

It was showed in the study that whereas the TRIPS Agreement could be considered an initial layer of protection of IP rights, bilateral investment treaties and treaties with investment provisions

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[216] Access Campaign, "A Timeline of U.S. Attacks on India's Patent Law & Generic Competition" (online at January 2015) *Medicine Sans Frontieres* <https://msfaccess.org/sites/default/files/2018-10/IP_Timeline_US%20pressure%20on%20India_Sep%202014_0.pdf>.
[217] Jocelyn Bosse, Hyo Yoon Kang and Sive Thambisetty, "Trips waiver: There's More to the Story than Vaccine Patents" (online at May 7 2021) <https://theconversation.com/trips-waiver-theres-more-to-the-story-than-vaccine-patents-160502>.
[218] Richard Li-dar Wang, "Ancillary Orders of Compulsory Licensing and Their Compatibility with the TRIPS Agreement" (2015) 18 *Marquette Intellectual Property Law Review* 92.
[219] International Centre for Trade and Sustainable Development, "Canadian Access to Medicine Bill Under Threat" (2011) 15 *Bridges* 1-5.

often create a TRIPS-plus dimension, extending protection beyond this initial layer.[220] Surprisingly, in case of COVID-19 vaccines, the majority of issues from this TRIPS-plus dimension are hardly relevant. Manufacturing of COVID-19 vaccines is an urgent matter that requires immediate actions; accordingly, such provisions as standards of treatment, dispute settlement mechanisms, and an extended patent protection periods are hardly pertinent to the problem under investigation. Furthermore, limitations on compulsory licenses also do not prevent states from issuing compulsory licenses on vaccines. The free trade agreement between the United States and Jordan clarifies that a compulsory license could be issued in three occasions, including "in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government".[221] Even though this agreement, as stated above, substantially limited the number of situations in which the mechanism of compulsory licensing could be triggered, the COVID-19 pandemic undoubtedly qualifies for a national emergency. Therefore, BITs and treaties with investment provisions hardly prevent states from issuing compulsory licenses on COVID-19 vaccines.

Certain complications could arise in regard to data exclusivity clauses. These provisions explicitly prohibit the use of ancillary orders or other instruments to help generic companies gain access to valuable information about vaccines and their manufacturing. The free trade agreement between the USA and Chile, in particular, states that "the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information".[222] Data exclusivity clauses could play a major role in reducing effectiveness of generic manufacturing. At the same time, this protection layer does not exist in all the countries. In particular, Heilliczer explains that Israel does not offer regulatory exclusivity for biological agents[223]; furthermore, unlike Jordan, Chile, and many other countries, Israel does not currently have a treaty with the USA that would provide for such data exclusivity period. This factor could substantially facilitate manufacturing of COVID-19 vaccines in Israel under compulsory license, especially considering that this country already had successful experience with compulsory licenses during the COVID-19 crisis.[224] Although Israel is unlikely to use this instrument given that the government has already successfully vaccinated almost the entire population by purchasing vaccines directly from

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[220] Susy Frankel, "Challenging Tripls-Plus Agreements: The Potential Utility of Non-Violation Disputes" (2009) 12 *Journal of International Economic Law* 1023-1065.
[221] Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area 2000
[222] Free Trade Agreement between the Government of the United States of America and the Government of the Republic of Chile.
[223] Ephraim Heilliczer, "How Will Pfizer and Moderna Protect Their Vaccine Patent Applications?" (online at 25 November 2020) *Calcalist* <https://www.calcalistech.com/ctech/articles/0,7340,L-3876233,00.html>.
[224] Aishani Singh and Arindam Purkayastha, "Worldwide: Israel Issuing Compulsory License during the Time of COVID-19 Pandemic" (online at 16 April 2020) *Mondaq* <https://www.mondaq.com/india/operational-impacts-and-strategy/917898/israel-issuing-compulsory-license-during-the-time-of-covid-19-pandemic>.

manufacturers, it is important to emphasize that Israel potentially had more chances than such countries as Chile, Jordan, or most others to launch manufacturing of generic vaccines because of the absence of a barrier pertaining to data exclusivity.

Finally, it is also important to state that limitations related to parallel importing and export of products manufactured under compulsory licenses also could be considered pertinent barriers to the use of compulsory licenses to facilitate equitable access to vaccines. In particular, the free trade agreement between the United States and Morocco explicitly prohibits parallel importing.[225] Such restrictive provisions in bilateral investment treaties and treaties with investment provisions complicate the use of relevant flexibilities in the TRIPS Agreement. In general, it seems justified to conclude that bilateral investment treaties and treaties with investment provisions create substantial barriers to equitable access to vaccines. TRIPS-plus dimensions do not prevent states with substantial manufacturing capacity from producing vaccines under compulsory licenses, but they often prevent governments from accessing know-how and other information that is crucial for launching the manufacturing process. Furthermore, TRIPS-plus clauses complicate export of vaccines to least developed and developing countries without substantial manufacturing capacity by preventing parallel importing or prohibiting export of products under compulsory licenses. At the same time, it is important to emphasize that the export of vaccines under compulsory licenses is a challenging process even without the TRIPS-plus dimensions because the procedure for triggering this flexibility of the TRIPS Agreement is complex and enduring.

2.5. Conclusion

The TRIPS Agreement plays a crucial role in the regulation of health-related IP rights. Its strict regulations created substantial restrictions that negatively affect equitable access to affordable drugs and vaccines. As a result, there is a popular opinion that developing and least developed countries are often at a disadvantage owing to the TRIPS Agreement. Nonetheless, the treaty introduced four flexibilities allowing these states to access medicines, including transitional periods, a five-year term for recognizing patents in those areas that had not been covered by patent protection before, the "exhaustion of rights" clause, and compulsory licenses.

Investment treaties also strongly affect the regulation of health-related IP rights. Such provisions as the "in accordance with a host State's laws" clause, standards of treatment, expropriation clauses, the "umbrella clause", and investor-state dispute settlement mechanisms are relevant instruments protecting investors' rights. Treaties with investment provisions as well as some BITs could also introduce certain TRIPS-plus rules, such as prohibition of parallel importing, limitations related to the scope of compulsory licenses, avenues for patent term extensions, additional data exclusivity clauses, prohibition of performance requirements, and new layers of protection originating from the standards of treatment. Some of these TRIPS-plus rules inhibit equitable access

[225] Free Trade Agreement between the Kingdom of Morocco and the United States of America 2004.

to vaccines. In particular, data exclusivity clauses, patent term extensions, and limitations on compulsory licenses damage generic competition, while prohibition of performance requirements prevents generic manufactures from accessing valuable know-how. Restrictions that are put on parallel importing are also relevant from this perspective, as they force developing and least developed countries to engage in direct negotiations with vaccine manufacturers, thus reducing their negotiating power. Most of these restrictions negatively affect equitable access to COVID-19 vaccines, encouraging the international community to discuss the option of the TRIPS waiver in line with the liberal interpretation of justice. However, the available evidence provides a compelling reason to believe that even if this waiver is negotiated, it could hardly eliminate all the barriers to technology transfer, thus failing to ensure equitable access of all the nations to COVID-19 vaccines.

CHAPTER 3. THE TRIPS AGREEMENT, BILATERAL INVESTMENT TREATIES, AND TREATIES WITH INVESTMENT PROVISIONS IN THE KINGDOM OF SAUDI ARABIA

3.0. Introduction

The chapter presents an analysis of the regulation of health-related intellectual property rights in Saudi Arabia in light of the TRIPS Agreement, bilateral investment treaties, and treaties with investment provisions. It starts with reviewing the system of IPRs' protection in the country and outlining the key weaknesses of the state in this area. The section also reviews the main clauses of most investment treaties signed by Saudi Arabia with the focus on standards of treatment, compulsory licensing clauses, and dispute settlement mechanisms. The last section of the chapter highlights the key areas of congruence between the TRIPS Agreement and Saudi investment treaties as well as the key discrepancies between them.

3.1. The System of Intellectual Property Rights' Protection in Saudi Arabia

The Kingdom of Saudi Arabia has recently turned into an attractive country for foreign investors. The country's population has around 34.27 million people, displaying the annual growth of 2%.[226] Most of these people have high levels of income, and the GDP per capita in the Kingdom is currently at $23,140, which is a relatively high figure that puts Saudi Arabia on the same level with some developed states, such as Portugal.[227] The country secures the 62nd place in the Ease of Doing Business rating, swiftly improving its business environment with the help of various reforms, such as those related to obtaining construction permits, accessing electricity, and enforcing contracts.[228] The state is still governed by conservative traditions and policies; however, it has been gradually opening its markets for foreign investors. The opening of TADAWUL for foreign investors and the recent IPO of Saudi Aramco exemplify this pattern.[229] Such radical changes are accompanied by the growing interest of foreign investors in Saudi markets, including not only the petroleum industry but also other sectors, such as transportation, construction, and many others.

The available evidence provides a compelling reason to believe that the country is still in the process of updating its regulatory framework to meet common standards of IP rights' protection. In 2018, the state was placed on the Priority Watch List by the Office of the United States Trade Representative. The 2019 report voiced concerns "regarding the lack of IP protection for innovative pharmaceutical products, including the lack of adequate and effective protection against unfair

[226] The World Bank, "Population, total – Saudi Arabia" (online at 2019) *The World Bank* <https://data.worldbank.org/indicator/SP.POP.TOTL?locations=SA>.
[227] The World Bank, "GDP per Capita (current US$) – Saudi Arabia" (online at 2020) *The World Bank* <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?locations=SA>.
[228] The World Bank, "Ease of Doing Business 2020," (online at 2020) *The World Bank: Open Knowledge* <https://openknowledge.worldbank.org/bitstream/handle/10986/32436/9781464814402.pdf>.
[229] Samantha Gross, "The Saudi Aramco IPO Breaks Records, but Falls Short of Expectations" (online at 11 December 2019) *Brookings* <https://www.brookings.edu/blog/order-from-chaos/2019/12/11/the-saudi-aramco-ipo-breaks-records-but-falls-short-of-expectations/>.

commercial use, as well as unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval".[230] The document also criticized the state for failing to address the issue of online piracy, specifically the one that was demonstrated by the service BeoutQ.[231] From the perspective of health-related IPRs, it is crucial to emphasize that the report highlights the failure of the Kingdom to ensure protection against unfair commercial use and unauthorized disclosure, as pharmaceutical companies received a marketing approval in 2016 and 2017 to produce generic versions of innovative pharmaceutical products with the help of test and other data that were provided by innovators to receive a marketing approval; moreover, a national tender was reportedly given to a generic manufacturer in 2018 to produce a product that was covered by patent protection.[232] These cases were not accompanied by the use of compulsory licenses and, therefore, situations were considered by the USTR as violations of IP rights.

The Kingdom has been taking measures to improve the system of IPR protection. Significant changes were made in Trademark, Copyright, and Patent laws in 2002, 2003, and 2004 respectively. The Saudi Authority for Intellectual Property was established under the Ministry of Commerce and Investment to reshape the entire framework of IPR protection.[233] This authority has recently created a convenient platform for providing services in areas related to the regulation of intellectual property rights.[234] Unfortunately, there is currently no evidence of significant progress in IPR protection in the Kingdom. The number of disputes related to this matter has been swiftly increasing. In 2018, the firm "beuoutQ" has gained its momentum in the country by providing an unauthorized access to sports and entertainment content.[235] Despite the efforts of stakeholders to draw the attention of the government to this case, the provider's set-top boxes could be purchased in Saudi public markets. U.S. software providers reported another example of IPR violations. As the companies' representatives explain, some government computer systems in the KSA continue using under-licensed or even unlicensed software.[236] Moreover, it seems that the Ministry of Commerce and Investment experiences problems with entering residential areas in which the use of unlicensed software has been detected. Even if officials are aware of the fact that people in specific residential areas violate the intellectual property law, it might be hard from the juridical perspective to gain an authorization to enter these areas with the purpose of stopping the use of pirated content. The case of beoutQ as well as the aforementioned issues related to the protection of health-related IP rights remain the most important reasons behind

[230] The United States Trade Representative, "2019 Special 301 Report" (online at April 2019) *USTR* <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf>.
[231] Ibid.
[232] Ibid.
[233] Saudi Authority for Intellectual Property, "About SAIP" (online at 2020) Saudi Authority for Intellectual Property <https://www.saip.gov.sa/en/about/>.
[234] Ibid.
[235] Sam Carp, "BeIN Seeks US$1bn from Saudi Arabia over BeoutQ 'privacy plague'" (online at 2 October 2018) SportsPro https://www.sportspromedia.com/news/bein-sports-saudi-arabia-beoutq-piracy.
[236] Mohammed El Said, Intellectual Property Law in Saudi Arabia (Kluwer Law International B.V., 2018).

the fact that Saudi Arabia remains in the Priority Watch List of the Office of the United States Trade Representative.

The system of IPR protection in the health care industry is weak. The existing laws in regard to trademarks[237] and patents[238] are adequate and do not include any unusual clauses that could limit the scope and effectiveness of IPR protection. Simultaneously, the enforcement of these laws remains problematic because the state's judicial system is often lenient to parties violating IP rights. For example, courts rarely award a substantial amount of compensation in infringement cases due to the fact that Shariah requires a significant burden of proof.[239] Moreover, sometimes courts rule that a plaintiff is supposed to take an administrative action before filing an infringement case, even though this requirement could not be found in the Trademark Law.[240] Alleged infringement of patent law remains a disturbing problem for the Kingdom. The Saudi Food and Drug Authority has recently allowed local manufacturers to produce their own versions of patent-pending drugs; furthermore, in 2017, the authority granted a license to a local firm for the innovative treatment model that had been designed by the U.S. firm which had filed for patent protection under the GCC patent office.[241] All these issues illustrate that Saudi Arabia is still unable to create and maintain a consistent system of IPR protection and sometimes fails to ensure protection of IP rights in the health care industry.

The legal system of the Kingdom of Saudi Arabia is fully compliant with the TRIPS Agreement. Cullen argues that IP rights in a form described in the TRIPS Agreement have a place under Sharia.[242] Malkawi clarifies that IP rights may be interpreted under Sharia as a constituent of private property rights; therefore, basic provisions of the TRIPS Agreement are fully compliant with Sharia.[243] Certain tension exists in regard to the restricting access to patented medicines and vaccines because an inability of people in need to access necessary medications violates the principle of Maslahah.[244] Therefore, TRIPS flexibilities play an important role in the legal systems of Muslim countries.

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[237] Mohammad Jomoa and Asif Iqbal, "Saudi Arabia: Trade Marks 2020" (online at 3 April 2020) *ICLG* <https://iclg.com/practice-areas/trade-marks-laws-and-regulations/saudi-arabia>.
[238] A Royal Decree No. M/38 issued by King of the Kingdom of Saudi Arabia
[239] Mohammad Jomoa and Tariq Zain, "Litigation Procedures and Strategies: Saudi Arabia" (online at 28 January 2019) *World Trademark Review* <https://www.worldtrademarkreview.com/enforcement-and-litigation/litigation-procedures-and-strategies-saudi-arabia>.
[240] Mohammad Jomoa and Asif Iqbal, "Procedures and Strategies for Pharmaceutical Brands: Saudi Arabia" (online at 1 October 2019) *World Trademark Review* <https://www.worldtrademarkreview.com/brand-management/procedures-and-strategies-pharmaceutical-brands-saudi-arabia>.
[241] Fitch Solutions, "Ineffective Patent Enforcement Continues Pose Risks to Innovative Drugmakers in Saudi Arabia" (online at 11 Match 2019) *Fitch Solutions* <https://www.fitchsolutions.com/corporates/healthcare-pharma/ineffective-patent-enforcement-continues-pose-risks-innovative-drugmakers-saudi-arabia-11-03-2019>.
[242] Chad Cullen, "Can TRIPS Live in Harmony with Islamic Law – An Investigation of the Relationship between Intellectual Property and Islamic Law" (2011) 14 *Science and Technology Law Review* 45-68.
[243] Bashar Malkawi, "The Alliance between Islamic Law and Intellectual Property: Structure and Practice" (2013) 10 *University of St. Thomas Law Journal* 618-649.
[244] Sami Awad and Mohamed Hassan, "The Alliance between Islamic Law and TRIPS Agreement: Structure and Practice" (2019) 5 *International Journal of Management and Applied Science* 113-118.

All the TRIPS flexibilities are integrated in the Saudi legislation. Articles 24 and 25 of Patent Law empower the King Abdulaziz City for Science and Technology to grant compulsory licenses via a set of steps.[245] None of the criteria specified in Article 24 and Article 25 is inconsistent with provisions of the TRIPS Agreement. In general, experts note that companies that plan to invest in the Saudi market should be concerned not with the Kingdom's IP laws but with their inconsistent and sometimes ineffective enforcement.[246] Therefore, Saudi national laws do not indicate any surprising patterns that could undermine investment treaties and the TRIPS Agreement's role in protecting IP rights in the Kingdom.

3.2. Standards of Treatment in Saudi BITs

The majority of bilateral investment treaties signed by Saudi Arabia include explicit post-establishment national treatment obligations. For instance, Article 2 of the Saudi BIT with Japan states that "each Contracting Party shall accord to investors of the other Contracting Party and to their investments treatment no less favorable than the treatment it accords in like circumstances to its own investors and their investments with respect to investment activities".[247] Similar clauses could be also found in many treaties with investment provisions. For instance, the free trade agreement between GCC states and Singapore includes specific clauses related to national treatment in regard to trade in goods, trade in services, and government procurement.[248] It seems justified to assume that the main reason behind the inclusion of the national treatment clause in Saudi BITs and treaties with investment provisions is poor enforcement of IPR protection laws in the country, which is evident in recent cases of alleged discrimination in which the government and the judiciary provided preferential treatment to local pharmaceutical firms.[249] The inclusion of national treatment clauses in most BITs and treaties with investment provisions is an important issue from the perspective of the problem under investigation.

The most-favored nation treatment provisions could be also found in Saudi treaties. The BIT with Belarus, for instance, claims that parties "shall accord the investors of the other Contracting Party in connection with the management, maintenance, use, enjoyment or disposal of investments or with the means to assure their rights to such investments like transfers and indemnification or with any other activity associated with this in its territory, treatment not less favorable than the treatment it

[245] Somto Kizor-Akaraiwe, "Saudi Arabia Compulsory Licensing" (online at 28 June 2021) *Kluwer Patent Blog* <http://patentblog.kluweriplaw.com/2021/06/28/saudi-arabia-compulsory-licensing/>.
[246] International Trade Administration, "Saudi Arabia – Protecting Intellectual Property" (online at 22 January 2020) *Export.gov* <https://www.export.gov/apex/article2?id=Saudi-Arabia-Protecting-Intellectual-Property>.
[247] Agreement between Japan and the Kingdom of Saudi Arabia for the Promotion and Protection of Investment.
[248] Free Trade Agreement between the Cooperation Council for the Arab States of the Gulf and the Republic of Singapore 2008.
[249] Fitch Solutions, "Ineffective Patent Enforcement Continues Pose Risks to Innovative Drugmakers in Saudi Arabia" (online at 11 Match 2019) *Fitch Solutions* <https://www.fitchsolutions.com/corporates/healthcare-pharma/ineffective-patent-enforcement-continues-pose-risks-innovative-drugmakers-saudi-arabia-11-03-2019>.

accords to its investors or to the investors of a third state, whichever is more favorable".[250] The inclusion of this clause in investment treaties as well as the exclusion of taxation and economic integration treaties from its scope is a typical practice in international law[251]; therefore, Saudi Arabia hardly displays any unique patterns in this field.

The fair and equitable treatment clause could be found in the majority of Saudi BITs and treaties with investment provisions, although this provision is formulated differently in various documents. For instance, the BIT with Singapore indicates that "Each Contacting Party… shall in any case accord such investments [investments by investors of the other Contacting Party] fair and equitable treatment"[252], whilst the BIT with Japan states that "each Contracting Party shall accord to investments of investors of the other Contracting Party treatment in accordance with international law, including fair and equitable treatment and full protection and security".[253] The treaty with Japan is among the few treaties containing an explicit reference to international law, which potentially provides investors with an opportunity to use protection layers guaranteed by international law, including provisions of the TRIPS Agreement, in investment disputes. This issue is especially crucial for Saudi Arabia, which, as stated above, still struggles with ensuring a favorable legislative environment for foreign investments.

In general, Saudi bilateral investment treaties and treaties with investment provisions provide investors with a relatively high level of protection. The majority of BITs except for the ones signed with China and Belarus include both the national and the most-favored-nation treatment clauses, which could be rarely found in most BITs signed by developed countries. Therefore, in theory, investment law provides foreign pharmaceutical companies with beneficial standards of treatment, which are higher than those that exist in most other countries. Unfortunately, as stated above, protection of IP rights, especially those related to the health care sector, is not adequately ensured in the Kingdom not because of weak legislation but rather because of inconsistency of the judiciary and difficulties with law enforcement.

3.3. Compulsory Licensing in Saudi BITs

3.3.1. Requirements for Expropriation

Bilateral investment treaties signed by Saudi Arabia include indirect expropriation clauses, although they hardly provide clear definitions of this term. It is important to emphasize that causes falling under general regulatory measures and compulsory licenses are not carved out from the expropriation clause. Accordingly, pharmaceutical companies in Saudi Arabia that represent a

[250] Agreement between the Government of the Republic of Belarus and the Government of the Kingdom of Saudi Arabia on Promotion and Reciprocal Protection of Investments 2009.
[251] Tomy Cole, "The Boundaries of Most Favored Nation Treatment in International Investment Law" (2012) 33 *Michigan Journal of International Law* 537-586.
[252] Agreement between the Republic of Singapore and the Kingdom of Saudi Arabia concerning the Promotion and Reciprocal Protection of Investments 2006.
[253] Agreement between Japan and the Kingdom of Saudi Arabia for the Promotion and Protection of Investment.

Contracting Party in some BITs could take an indirect expropriation action against the host state for the improper authorization of a compulsory license. The fact that the clause about compulsory licenses is absent in all the bilateral investment treaties that are analyzed in this thesis illustrates that compulsory licenses are apparently covered by the clause of indirect expropriation. Accordingly, it is of paramount importance to analyze acceptable conditions listed in the indirect expropriation clause of BITs and compare them with the respected provisions of the TRIPS Agreement. An analysis of the Saudi BITs with Japan, Singapore, Turkey, Sweden, Belarus, Czech Republic, China, and Malaysia illustrates that all of them cite the same requirements towards indirect expropriation:

- It should be conducted in "public interest" or/and to pursue an important "public purpose";
- It should be implemented in a non-discriminatory manner;
- It should be conducted in accordance with relevant local laws;
- An investor whose assets are expropriated is entitled to an "adequate" compensation that is calculated on the basis of the investment's value before the date when it was conducted or announced.

None of these criteria create TRIPS-plus dimensions in regard to compulsory licenses. It is also important to emphasize that Saudi Arabia signed only a small number of treaties with investment provisions, and none of them introduced any TRIPS-plus clauses related to indirect expropriation. Whereas the United States managed to sign free trade agreements limiting the scope of compulsory licenses with many countries, it has not signed such a treaty with the Kingdom yet, which could be probably explained by the perceived unpreparedness of Saudi Arabia to ensure enforcement of strict IPR protection clauses. Therefore, the majority of treaties with investment provisions signed by Saudi Arabia formulate general principles of investment and trade promotion without introducing TRIPS-plus provisions. For instance, an agreement with the United States pertains to "the development of trade and investment relations" and primarily revolves around the creation of a Joint Council on Trade and Investment that could monitor investment and trade relations, hold consultations between the countries, guide removal of impediments to trade and investment, facilitate contacts between stakeholders, and promote an attract investment and trade climate.[254] This agreement could be rather considered a necessary background for further negotiations than a final document regulating investment and trade.

Unlike the agreement with the United States, a recent treaty with EFTA states includes several relevant provisions related to the protection of intellectual property rights. However, all these provisions are general and comprise either definitions of terns or standards of treatment.[255] In general,

[254] Agreement between the Government of the United States of America and the Government of the Kingdom of Saudi Arabia Concerning the Development of Trade and Investment Relations 2003.
[255] Free Trade Agreement between the EFTA States and the Member States of the Co-Operation Council for the Arab States of the Gulf 2009.

an analysis of bilateral investment treaties and treaties with investment provisions signed by the Kingdom of Saudi Arabia shows that BITs rather than other investment treaties are the main source of investment law regulating the use of compulsory licenses as a part of the expropriation mechanism.

3.3.2. Calculation of the Amount of Compensation

Whereas all the Saudi BITs cite the same criteria justifying the use of compulsory licenses without introducing any TRIPs-plus provisions, they offer different avenues for calculating the amount of "fair compensation" that should be given to holders of IP rights on products or services that are subject to expropriation. All the Saudi bilateral investment treaties use the term "fair market value of expropriated investments" when referring to this compensation. The majority of treaties describe a timeline for determining the amount of this "fair market value" based on two alternative events: the date of expropriation and the date of its announcement. For instance, the BIT with the Belgo-Luxemboug Economic Union argued that "such compensation shall be equivalent to the value of the expropriated investment immediately before the date on which the actual or threatened expropriation, nationalization or comparable measure has become publicly known".[256] A similar choice is given in most other Saudi BITs, such as those that were signed with Japan, Singapore, Turkey, Czech Republic, and Belarus. The BITs with Malaysia and China use a different formulation in this clause. The BITs with China, in particular, states that "compensation… shall be equivalent to the value of the expropriated investment at the time of the declaration of expropriation".[257] However, there is no evidence to claim that such formulation might result in any problems related to the calculation of the amount of compensation given that the sole fact of expropriation could be interpreted as the time of its declaration.

The rate of return in compensations is mostly calculated in Saudi BITs based on the prevailing market rate of return until the time of payment. Simultaneously, some other documents offer alternative interpretations of this clause. The agreement with China, in particular, does not include any provision in regard to the interest rate at all, whilst the one signed with Turkey refers to an interest rate that should be applied exclusively in those situations when the payment of a compensation is delayed.[258] As a result, Chinese and Turkish investors are at a disadvantage in Saudi Arabia as compared to investors from such countries as Sweden, Czech Republic, or Japan. Some BITs do not clarify the period during which this return rate should be applied. Some of them emphasize that the prevailing time period should be calculated for the period between the expropriation and the time of payment. At the same time, some others, such as the one with Belarus[259], includes a vague

[256] Agreement between the Kingdom of Saudi Arabia and the Belgo-Luxemburg Economic Union (B.L.E.U.) concerning the Reciprocal Promotion and Protection of Investments 2001.
[257] Agreement between the People's Republic of China and the Kingdom of Saudi Arabia on the Reciprocal Promotion and Protection of Investments 1995.
[258] Agreement between the Government of the Republic of Turkey and the Government of the Kingdom of Saudi Arabia Concerning the Reciprocal Promotion and Protection of Investments 2006.
[259] Agreement between the Government of the Republic of Belarus and the Government of the Kingdom of Saudi Arabia on Promotion and Reciprocal Protection of Investments 2009.

formulation "until the time of payment", which does not indicate whether the period should be calculated starting from the moment when expropriation has been declared or from the moment when it has actually happened.

Finally, the last important issue that should be discussed in regard to compensations in expropriation cases is the use of the term "freely usable currencies as defined by the International Monetary Fund" in the recent BIT with Japan.[260] This new formulation was apparently added to the text of the treaty in order to promote transparency in payments. Despite certain slight distinctions like the one highlighted above, there is no premise to believe that there are substantial differences between the ways in which compensations should be calculated and paid in expropriation clauses under various Saudi BITs. Therefore, investment treaties do not provide different frameworks for using the compulsory licensing mechanism. Application of this instrument is governed by the same rules in accordance with all the BITs and treaties with investment provisions that were reviewed in this study.

3.4. Dispute Settlement Mechanisms in Saudi BITs and Treaties with Investment Provisions

3.4.1. Mediation and Conciliation Options

All the Saudi bilateral investment treaties offer the mechanism of investment-state dispute settlement. Simultaneously, there are significant differences between various BITs in regard to this issue. In particular, the BITs with Japan and Singapore introduce mediation or conciliation instruments that could be triggered on the initial stages of dispute settlement. Simultaneously, the term "conciliation" does not even appear in the text of the BIT with Indonesia.[261] The fact that most BITs do not include mediation and conciliation clauses could be considered a negative issue from the perspective of both states and investors. The literature argues that mediation alternatives to arbitration enable parties to address problematic issues that negatively influence the investment climate in a more effective way without disrupting the business environment and creating additional tension.[262] Such a mechanism is especially valuable in the health care sector because of the sensitive and politicized nature of some critical issues related to the protection of health-related intellectual property rights, such as compulsory licenses and parallel importing.

Without an opportunity to settle disputes through mediation or conciliation, holders of intellectual property rights might be discouraged from taking any legal action at all due to the fear of potential retaliation from the state, which is especially topical in developing countries like Saudi Arabia. The example of Roche in Taiwan shows that compromises between parties can ensure a more effective and swift solution of problems related to the protection of intellectual property rights in the

[260] Agreement between Japan and the Kingdom of Saudi Arabia for the Promotion and Protection of Investment 2013.
[261] Agreement between the Government of the Kingdom of Saudi Arabia and the Government of the Republic of Indonesia concerning the Promotion and Reciprocal Protection of Investments 2003.
[262] Chunlei Zhao, "Investor-State Mediation in a China-EU Bilateral Investment Treaty: Talking about Being in the Right Place at the Right Time" (2018) 17 *Chinese Journal of International Law* 111-135.

health care industry.[263] Thus, mediation and conciliation options, which are absent in most Saudi BITs, are an important enabler of a fair and just dispute settlement procedure.

3.4.2. Availability of Dispute Settlement Forums

An analysis of Saudi BITs does not indicate any substantial differences between them in terms of the scope of dispute settlement. The treaties do not limit the scope of investor-state dispute settlement. At the same time, certain peculiarities exist in regard to the type of consent that is required to trigger the arbitration process. A certain form of consent is required by all the treaties. The treaty between Saudi Arabia and Japan, for instance, explicitly points at the need to provide "written consent of the parties to a dispute".[264] Many others, at the same time, require the case-by-case consent, which is a more favorable option for investors.

One of the most important aspects of dispute settlement as per Saudi BITs and treaties and treaties with investment provisions is the choice of forums for investor-state dispute settlement. All the BITs signed by the Kingdom of Saudi Arabia allow using domestic courts and the Convention on the Settlement of Investment Disputes between States and Nationals of Other States (the ICSID Convention). The ICSID Convention, which is mentioned in all the Saudi BITs, is known as the key forum for settling disputes between investors and states. The majority of well-known cases, such as *Bridgestone v. Panama*, have been taken in front of this body.[265] Therefore, it is natural that an option to use this forum is available to investors in accordance with all the bilateral investment treaties discussed above.

The United Nations Commission of International Trade Law (UNCITRAL) framework of arbitration rules, at the same time, is mentioned only in some Saudi BITs. In particular, it is available under the Saudi BITs with Turkey, Belarus, and Czech Republic but absent in BITs with Japan, Singapore, France, Malaysia, Germany, and China. Availability of the UNCITRAL framework is a crucial issue because it provides parties with an opportunity to settle their disputes in a completely new environment that is independent from both of them.[266] An Arbitral Tribunal might be considered as a less beneficial option because at least one of its members is appointed by a party that allegedly violates a treaty's terms, which might negatively affect transparency of decision making.

A relationship between domestic courts, the ICSID Convention, and the UNCITRAL framework is described differently in various Saudi BITs. Whereas some of them allow parties to

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[263] Neil George Cherian, *Using Compulsory Licenses to Access Pharmaceuticals: A Cross Case Analysis of Outcomes* (Unpublished Master's Thesis) (University of Oslo, 2016) 42.
[264] Agreement between Japan and the Kingdom of Saudi Arabia for the Promotion and Protection of Investment 2013.
[265] Neil Wikof, "Investment Disputes, Trademarks and Licenses, and ICSID Tribunals – "Bridgestone v. Panama" (online at March 23, 2018) *The IPKat* <http://ipkitten.blogspot.com/2018/03/investment-disputes-trademarks-and.html>.
[266] Andrew Tuck, "Investor-State arbitration Revised: A Critical Analysis of the Revisions and Proposed Reforms to the ICSID and UNCITRAL Arbitration Rules" (2007) 13 *Law and Business Review of the Americas* 885-922.

settle their disputes through different forums simultaneously, others establish a clear procedure for choosing specific mechanisms. Saudi BITs that were signed with Japan, Turkey, Belarus, Singapore, France, and Malaysia establish a "fork in the road" principle, prohibiting the use of domestic and international forums at the same time. The treaty with Japan indicates that "if the investment dispute is submitted to a competent court of the disputing Party, the disputing investor may not resort to arbitrations set forth in paragraph 4 concurrently for the settlement of the same investment dispute… the final decision on the merits of the aforementioned competent court shall be binding and shall not be appealed by any means, other than what is provided for in the legislation of the Contracting Party".[267] Ebrahimgol and Haghighian describe the "fork in the road" clause as a natural safety measure to prevent possible conflicting decisions of different forums and corresponding confusion and ambiguous interpretations.[268] However, regardless of its intent, this principle undoubtedly limits investors' options in regard to dispute settlement.[269] Such a conclusion appears to be especially relevant in the case of Saudi Arabia, which, as stated above, still struggles with ensuring consistency in its judicial system.

Another important aspect of dispute settlement that should be mentioned in this study is the availability of other frameworks besides the ICSID Convention, domestic courts, and the UNCITRAL arbitration rules. Some BITs, such as those signed with Japan, Turkey, Belarus, and Singapore allow parties to use other frameworks. For example, the treaty with Belarus specifies that a dispute could be at the investor's request filed to the domestic court, the ICSID, an ad hoc tribunal under the UNCITRAL framework, or "any other forum of arbitral settlement agreed upon by parties to the dispute".[270] At the same time, the treaty with the Czech Republic lists the three forums mentioned above without including the "other forums" clause. In theory, the absence of alternative options in around a half of Saudi BITs might be considered a negative sign for investors, but this issue is hardly crucial given that any forums or arbitral settlement mechanisms besides domestic courts and the UNCITRAL and ICSID frameworks have to be agreed upon by both parties in advance under the BITs' terms.

3.5. The Key Areas of Congruence and Discrepancies between the TRIPS Agreement and Saudi BITs and Treaties with Investment Provisions

An analysis of the BITs signed by Saudi Arabia illustrates that they are in harmony with the text of the TRIPS Agreement from the perspective of regulating health-related intellectual property rights. Saudi BITs do not include exhaustive lists of investments' required characteristics;

[267] Agreement between Japan and the Kingdom of Saudi Arabia for the Promotion and Protection of Investment 2013
[268] Alireza Ebrahimgol and Mahdi Haghighian, "Fork in the Road Clause in International Trade Arbitration Practice by Focusing on ICSID Verdicts" (2019) 7 *Journal of Private Law* 9-34.
[269] Markus Petsche, "The Fork in the Road Revisited: An Attempt to Overcome the Clash between Formalistic and Pragmatic Approaches" (2019) 18 *Washington University Global Studies Law Review* 391-428.
[270] Agreement between the Government of the Republic of Belarus and the Government of the Kingdom of Saudi Arabia on Promotion and Reciprocal Protection of Investments 2009.

furthermore, there is no test of "substantive business activity" in these documents. None of the BITs or treaties with investment provisions that were signed by the Kingdom introduces restrictions on the compulsory licensing mechanism, and none of them prohibits performance requirements. BITs' expropriation clauses could be considered complementary provisions of the TRIPS Agreement, as they provide clear paths towards calculating the amount of compensation that should be paid to holders of intellectual property rights in case if the government issues a compulsory license on their products. Saudi BITs use the "fair market value" to determine the amount of compensation. In case of pharmaceutical companies, such an approach might result in a lower compensation than the one that could be calculated with the help of the royalty rate-based approach established in the TRIPS Agreement. The existence of alternative paths for establishing the amount of necessary compensation in BITs and in the TRIPS Agreement, which are sometimes described as complementary rather than contradictory approaches, is a common feature that could be observed in the majority of countries.[271] Therefore, Saudi BITs are hardly unique from this perspective.

Slight areas of divergence between BITs and the TRIPS Agreement could be found in the field of treatment standards. Saudi BITs establish the standards of national treatment in addition to the most-favored-nation and fair and equitable treatment. A relatively high level of protection given to investors by the Kingdom is supposed to compensate for their risks that are connected with the weak legislative environment and inconsistent law enforcement in regard to the protection of intellectual property rights. The treaty with Japan provides an even more significant level of protection by inserting an explicit reference to international law in its fair and equitable treatment clause. At the same time, contradictions BITs and the TRIPS Agreement in terms of standards of treatment do not apply to the problem under investigation. For instance, the Agreement includes exceptions related to the Paris, Berne, and Rome Conventions[272], but none of them is relevant to the health care sector. In general, it could be concluded that standards of treatment described in Saudi BITs do not contradict treatment standards specified in the TRIPS Agreement.

The "umbrella clause" and the "in accordance with the host state's laws" provision might become potential sources of ambiguity. The "umbrella clause", which is present in the BIT between Saudi Arabia and Germany, could potentially provide German investors with an opportunity to argue that the provision expands the Kingdom's obligations under the TRIPS Agreement to the protection of individual investments and investors.[273] The "in accordance with host State's laws" provision, which is present in most Saudi BITs except for the ones signed with Japan and Belarus, is pertinent from the perspective of the problem under investigation. A tribunal might reject a particular case on the

[271] Lahra Liberti, "Intellectual Property Rights in International Investment Agreements" (Online at 2010) OECD <https://www.oecd.org/investment/internationalinvestmentagreements/WP-2010_1.pdf>.
[272] TRIPS Agreement.
[273] Jarrod Wong, "Umbrella Clauses in Bilateral Investment Treaties: Of Breaches of Contact, Treaty Violations, and the Divide between Developing and Developed Countries in Foreign Investment Disputes" (2006) 137 *Geo. Mason L. Rev*. 137-179.

grounds of a party's alleged failure to comply with some local law or even tradition. A refusal of domestic courts to take a legal case because a pharmaceutical company had not filed an administrative action before exemplifies such risk. It should be also emphasized that the legislative system of Saudi Arabia is unique. Saudi courts used to refer to uncodified Sharia before 2018 without applying legal principles and precedents.[274] In this situation, the "in accordance with host State's laws" provision may be regarded as a disruptive factor that could potentially empower the Kingdom to violate IP rights based on local traditions. Such a risk is especially significant given that none of the Saudi BITs except for the one with Japan obliges the government to publish recent laws and regulations that affect investors' operations in the country. The two provisions reviewed in this paragraph negatively affect the IPR protection that is guaranteed to investors under BITs.

3.6. Conclusion

The system of IPR protection in the health care industry of Saudi Arabia is weak. Despite recent progress in this area, the state is still in the Priority Watch List of the Office of the U.S. Trade Representative as a result of the government's failure to prevent unauthorized disclosure of test data, ensure patent protection for innovative pharmaceutical products, and eliminate online piracy. Investment treaties signed by the country guarantee post-establishment national, most-favored-nation, and fair and equitable treatment for investors, which offers a relatively high level of protection. Compulsory licenses are regulated in Saudi investment treaties by expropriation clauses. These provisions are standard and do not introduce any TRIPS-plus rules.

Different investment treaties offer diverse dispute settlement mechanisms. Whereas these treaties do not elaborate on mediation and conciliation options, there are significant differences between them in terms of the availability of forums and a relationship between them. The chapter does not illustrate a significant number of areas of divergence between the TRIPS Agreement and investment treaties in the field of regulating health-related intellectual property rights. Slight discrepancies exist in relation to standards of treatment, the "umbrella clause", and the "in accordance with a host State's laws" provision, but none of them refers to significant contradictions between the documents. There is no evidence to believe that investment treaties signed by Saudi Arabia could undermine the government's ability to pursue "the greatest utility" in solving health care crises or weaken its position in negotiations with pharmaceutical companies.

[274] Jan Michiel Otto, *Sharia Incorporated: A Comparative Overview of the Legal Systems of Twelve Muslim Countries in Past and Present* (Leiden 2010) 161

CHAPTER 4. THE TRIPS AGREEMENT, BILATERAL INVESTMENT TREATIES, AND TREATIES WITH INVESTMENT PROVISIONS IN AUSTRALIA

4.0. Introduction

While the previous section of the thesis sought to explore the regulation of health-related IPRs in Saudi Arabia, the current chapter shifts the focus of the discussion to Australia. Its first subsection briefly reviews the main pillars of the system of IPR protection in Australia, explaining how its maturity protects the interests of investors. Considering that the role of the TRIPS Agreement in the regulation of health-related IPRs was covered in the previous chapter, this section proceeds with the overview of the main clauses of Australian investment treaties. In particular, the chapter provides valuable insights into the standards of treatment, compulsory licenses, and dispute settlement mechanisms. The chapter's last subsection presents a detailed analysis of the most important areas of congruence and divergence between the TRIPS Agreement and Australian investment treaties in light of the regulation of health-related IPRs.

4.1. The System of Intellectual Property Rights' Protection in Australia

Australia is a mature country with a robust legislative system. The state's regulatory framework is liberal and encourages sectors to apply self-regulatory instruments whenever possible and create specific codes of conduct for maintaining explicit rules. The country has a stable political environment making Australia the 18th most stable state in the world as opposed to the 133rd place that is secured by Saudi Arabia.[275] Australia also has the 18th largest GDP per capita at $55,057.2.[276] The World Bank places the country within top-15 states with the most favorable business environment, praising the government for creating favorable conditions in regard to starting a business, dealing with construction permits, getting credit, and enforcing contracts but criticizing it for limiting trade across borders and failing to overcome difficulties with getting electricity and protecting minority investors.[277] Problems with trade across borders could be explained by recent changes introduced by the Foreign Investment Review Board addressing tense relations with China.[278] The data reviewed above indicate that Australia remains an attractive country for investors.

Unlike the Kingdom of Saudi Arabia, Australia has a mature and effective system of IPR protection. The Assembly of the World Intellectual Property Organization (WIPO) notes that the Australian government "expresses its strong and ongoing commitment to working with WIPO and its membership to ensure that the international IP system promotes global growth and development and

[275] The World Bank, "Political Stability – Country Rankings" (online at 2020) *The Global Economy* <https://www.theglobaleconomy.com/rankings/wb_political_stability/>.
[276] The World Bank, "GDP per Capita (current US$)" (online at 2021) *The World Bank* <https://data.worldbank.org/indicator/NY.GDP.PCAP.CD?most_recent_value_desc=true>.
[277] The World Bank, "Ease of Doing Business 2020," (online at 2020) *The World Bank: Open Knowledge* <https://openknowledge.worldbank.org/bitstream/handle/10986/32436/9781464814402.pdf>.
[278] Melissa Clarke, "Foreign Investment Review Board to be Given Greater Approval Powers amid Increasing National Security Risk," (online at 5 June 2020) *ABC* <https://www.abc.net.au/news/2020-06-05/foreign-investment-restrictions-tighten-australian-businesses/12324276>.

serves out innovators, creators, and businesses to meet existing needs and be responsive to emerging challenges and opportunities".[279] According to MinterEllison, the legislative system of the country provides "comprehensive protection for intellectual property, including copyright, patents for inventions, trade names and trademarks, domain names, trade secrets and confidential information, and registered designs".[280] The Australian system of IPR protection is generally regarded as consistent and effective.[281] From this perspective, Australia differs favorably from Saudi Arabia.

Administration of the country's responsibilities under the WIPO is conducted by IP Australia, whilst the Department of Home Affairs oversees the enforcement of counterfeit and pirated goods laws. The state is a member of many treaties under WIPO.[282] Simultaneously, the regulation of IP rights also highly depends on investment treaties and treaties with investment provisions. A free trade agreement with the United States has become a source of heavy criticism from local and international experts arguing that it creates TRIPS-plus dimensions prohibiting equitable access to medicine and limiting the government's ability to address public health crises.[283] The implications for IPR protection that are connected with this agreement will be discussed in detail in the current study.

Australia has a robust framework of patent protection allowing pharmaceutical firms to prevent manufacturing, utilization, and sales of its products in the country. Certain provisions of the Australian law are beneficial for these companies. For example, pharmaceutical substances could enjoy patent protection for the period of up to 25 years from the date of the application's filing, which is much more than the duration of patent protection covering any other invention.[284] There are no known inconsistencies between the trademark and design protection in the country's legislative system, as the law clarifies a difference between the trademarks and design, elucidating that the shape of a bottle with drugs should be considered as an element of design, whereas the original packaging could be protected by trademark law. In particular, the law explains that signs "include the following or any combination of the following, namely, any letter, word, name, signature, numeral, device, brand, heading, label, ticket, aspect of packaging, shape, color, sound or scent".[285] Such a formulation helps prevent possible misunderstandings and reduce confusion pertaining to certain aspects of the regulation of health-related IP rights.

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[279] WIPO, "General Statement – Australia" (online at 24 September 2018) *WIPO* <https://www.wipo.int/edocs/mdocs/govbody/en/a_58/a_58_stmt_australia.pdf>.
[280] MinterEllison, "Doing Business in Australia – Intellectual Property" (online at 2 December 2018) *MinterEllison* <https://www.minterellison.com/articles/doing-business-in-australia-intellectual-property>.
[281] Mark Davison, Ann Monotti and Leanne Gaye Wiseman, *Australian Intellectual Property Law* (Cambridge University Press, 2016).
[282] IBP, *Australia: Oil, Gas, Resources, and Exploration Handbook, Volume 3 South Australia – Strategic Information and Regulations* (Lulu 2013) 42.
[283] Medicines Australia, "Intellectual Property Law Amends Will Add to Business Uncertainty" (online at 26 July 2019) *Medicines Australia* <https://medicinesaustralia.com.au/media-release/intellectual-property-law-amends-will-add-to-business-uncertainty/>.
[284] Australian Government, "Types of patents" (online at 3 Match 2020) *Australian Government: IP Australia* <https://www.ipaustralia.gov.au/patents/understanding-patents/types-patents>.
[285] Trade Marks Act 1995 No. 119, 1995.

The enforcement of IP rights primarily occurs via civil action. The pursuit of criminal actions in such cases is rare. In case if the offending conduct takes place within the context of parallel importing, the Australian regulator readily brings cases to trial.[286] There is no evidence to believe that the enforcement of IPR laws is ineffective or insufficient in the country. At the same time, there is a popular opinion that the recent IP Laws Amendment has weakened the state's attractiveness as a destination for investors in the pharmaceutical sector.[287] Medicines Australia, which is a credible entity that engages in academic research in the Australian medicines industry, recommended retaining innovation patents, adding an unambiguous objects clause that would harmonize with international obligations, granting compulsory licenses only when it is prescribed by the international law, and applying the Crown use provisions in a way that they would not contradict the country's obligations under international agreements.[288] Since the amendment did not cover most of these recommendations, there is a certain possibility that an inconsistency between the new law and the obligations taken by Australia under international treaties might cause confusion among investors and negatively influence the state's investment climate.

The legal system of Australia is fully compliant with the TRIPS Agreement. The Department of Foreign Affairs and Trade not only claims that Australia ensures the adherence of its laws to the TRIPS Agreement but also states that the country "supports the development of TRIPS-consistent IP systems in developing countries".[289] Australia has a dualist system; thus, provisions of the TRIPS Agreement alone could not protect IP rights if they are not supported by domestic laws. All the flexibilities of the TRIPS Agreement are adequately addressed by the local legislation. For instance, provisions concerning compulsory licenses are present in Section 87 of the Patents Act 1903.[290]

The Australian legal system also offers crown use provisions that might be considered an alternative to the compulsory license clause in Section 87. A separate right to exploitation by the government reflects the history of English patent law as a monopoly granted by the crown. In *Feather v The Queen*[291], it was recognized that the Crown may retain rights to exploit inventions for which a patent had been granted. The justifications for crown use provisions are (a) the crown should not be impeded from acting in the public interest by patents, which are crown grants; and (b) the crown, through its departments and authorities is ordinarily engaged in public service, rather than commercial

[286] Nicholas Tyacke et al., "Pharmaceutical IP and Competition Law in Australia: Overview" (online at 1 July 2019) *Thomson Reuters Practical Law* <https://uk.practicallaw.thomsonreuters.com/9-565-4226?__lrTS=20200527190720991>.
[287] Medicines Australia, "Medicines Australia Angry over IP Law Amends" (online at 26 July 2019) *The Pharma Letter* <https://www.thepharmaletter.com/article/medicines-australia-angry-over-ip-law-amends>.
[288] Medicines Australia, "Intellectual Property Law Amends Will Add to Business Uncertainty" (online at 26 July 2019) *Medicines Australia* <https://medicinesaustralia.com.au/media-release/intellectual-property-law-amends-will-add-to-business-uncertainty/>.
[289] Department of Foreign Affairs and Trade, "Intellectual Property" (online at 2021) *Australian Government: Department of Foreign Affairs and Trade* <https://www.dfat.gov.au/trade/organisations/wto/intellectual-property/Pages/intellectual-property>.
[290] Patents Act 1903 (NO. 21, 1903)
[291] *Feather v The Queen* (1865) 6 B & S 257

activities, and therefore should be in a special position in regard to the use of patented inventions.[292] The ALRC noted that "The Crown use provisions involve significant interference with the rights that patent holders otherwise have under the patent system… it is arguable that the Crown use provisions should not be relied upon too readily and should be invoked only in exceptional circumstances if confidence in the patent system is to be preserved".[293] Thus, the threat of the crown use remains a disrupting factor for the Australian patent system.

However, this provision is rarely used, as there have been only two reported cases of disputes involving its utilization: patented inventions in water meters by local government in *Stack v Brisbane City Council* and patented central bearing structures for railway carriage construction in *General Steel Industries Inc v Commissioner for Railways.*[294] It remains unclear whether crown use provisions could be used to trigger compulsory licenses or they present an alternative avenue for the authorized use of patented subjects.

The use of IPR protection in Australia has recently attracted the attention of stakeholders. In particular, the plain packaging case is described in the literature as a landmark case demonstrating that public health concerns could be used by governments as a justification for introducing trade-restrictive measures.[295] The Panel ruled that tobacco plain packaging measures introduced by the Australian government were reasonable, while also emphasizing that these measures did not violate Articles 2.2., 2.1, 15.4, 16.1, 16.3, 20, 2.1, 22.2, and 24.2 of the TRIPS Agreement.[296] One of the most important implications of this case is connected with the fact that the Australian government preserved its right to use public health concerns to introduce trademark restrictions in line with the paragraph 5 of the Doha Declaration. The Panel found that plain tobacco packaging measures did not prevent trademarks from acquiring or maintaining a "well-known" status and did not encumber the use of trademarks in trade. According to Voon, such a ruling has crucial IP implications.[297] At the same time, there is no premise to believe that this landmark decision is indicative of the Australian IPR protection framework's breaches. This decision was rather an important stage in the evolution of international IPR clarifying a context in which trade-restricting measures could be made based on public health concerns of national governments without violating the existing provisions related to IP rights in investment treaties, the TRIPS Agreement, and other legal sources.

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[292] Advisory Council on Intellectual Property, "Review of Crown Use Provisions for Patents and Designs" (online at 2005) *Australian Government* <https://www.ipaustralia.gov.au/sites/default/files/acip_final_report_review_of_crown_use_provisions_archived.pdf>.
[293] Ian Freckelton, *Disputes and Dilemmas in Health Law* (Federation Press, 2006), p. 293.
[294] *General Steel Industries Inc v Commissioner for Railways (NSW)* (1964) 112 CLR 125
[295] Cheryl Kirschner, "Australia's Tobacco Plain Packaging Law: An Analysis of the TRIPS Article 20 Challenge at the WTO," 32 *Pace Law School* 247-313.
[296] Ibid.
[297] Tania Voon, "Inside Views: WTO Panel on Australia's Tobacco Plain Packaging: A Fact Dependent Analysis of TRIPS Art 20," (online at 3 July 2018) *Intellectual Property Watch* <https://www.ip-watch.org/2018/07/03/wto-panel-australias-tobacco-plain-packaging-fact-dependent-analysis-trips-art-20/>.

The case involving Philip Morris is another example providing valuable information about the system of IPR protection in Australia. Despite the company's attempt to take advantage of investment law and use the instrument of investor-state dispute settlement, it was established that Philip Morris relocated its office to Hong Kong specifically to use the ISDS channel.[298] As a result, the case was thrown away on the basis of process abuse. Recent evidence suggests that Australia had to spend approximately A$24 million on arbitration costs and external legal fees in this case.[299] The fact that the Australian government is willing to spend such money on protecting its right to introduce trade-restricting measures implies that investors could hardly use the threat of ISDS suits in negotiations with the government, which could be sometimes observed in other countries.

The contemporary justice system of Australia prioritizes public health concerns. The recent thalidomide case shows that a failure to report proved side effects of pharmaceutical products, such as drugs or vaccines, could result in immense financial losses for pharmaceutical companies. Diageo, a company that purchased Distillers, which used to distribute thalidomide to Australia, agreed to pay $89 million to thalidomide victims as a compensation for their physical disabilities induced by the drug.[300] This example illustrates that maturity of the Australian justice system allows protecting the nation from adverse effects of pharmaceutical products, thus increasing risks for pharmaceutical companies that enter the Australian market with new products. Such a scenario is especially relevant for the problem under investigation because, as it is known, unprecedentedly short periods of COVID-19 vaccine testing leave stakeholders wonder whether all the possible long-term effects of vaccine usage had been considered by vaccine manufacturers during Phases 2 and 3. The arguments laid out above illustrate that the Australian legal system pursues the principles of utilitarian justice, using a variety of instruments to protect the health of its population and, thus, achieving "the greatest good" by taking radical measures that might be considered as those that violate the spirit of free trade.

4.2. Standards of Treatment in Australian BITs and Treaties with Investment Provisions

Australian BITs and treaties with investment provisions do not display any unique features in most spheres related to the problem under investigation. All of them use asset-based definitions of investments, include clear definitions of investors, and comprise definitions of ownership and control without the test for "substantive business activity". Clauses pertaining to the treaties' temporary scope differ, as whereas certain BITs, such as the ones with Turkey, Uruguay, and Argentina carve out pre-existing disputes, most others do not offer conclusive information on this matter.

[298] Patricia Ranald, "When Even Winning Is Losing. The Surprising Cost of Defeating Philip Morris over Plain Packaging," (online at 26 March 2019) *The Conversation* <https://theconversation.com/when-even-winning-is-losing-the-surprising-cost-of-defeating-philip-morris-over-plain-packaging-114279>.
[299] Ibid.
[300] Mark Russel, "Thalidomide Victims Receive $89 Compensation," (online at 7 February 2014) *The Sydney Morning Herald* <https://www.smh.com.au/national/thalidomide-victims-receive-89m-compensation-20140207-325pf.html>.

Only a few BITs signed by Australia include the national treatment clause. Such a provision, in particular, could be found in the treaties with Argentina, Turkey, and Sri Lanka. In line with the common practice, Australia includes the most-favored-nation treatment clause in all its BITs, while also excluding taxation and economic integration treaties from its scope.[301] Some Australian BITs and treaties with investment provisions seem to shift the focus from international to local legislation with the help of the "in accordance with host State's laws" provision and the clause of ensuring the security and protection of investments. BITs with Lithuania, Uruguay, Argentina, and Pakistan exemplify this pattern. Simultaneously, most treaties signed by the country offer only basic standards of most-favored-nation treatment. None of Australian BITs prohibit performance requirements, thus confirming to the "majority traditional approach" as per Nikiema's definition.[302] All the Australian BITs except for the one with Poland do not include the "umbrella case". Therefore, investors from most countries cannot invoke treaty protection within the framework of international law while elevating their claims of contracts' breaches.[303] In general, an analysis of the standards of treatment and other general clauses pertaining to them illustrates that Australia usually provides investors with a lower level of protection under investment law than the one provided by the Kingdom of Saudi Arabia.

4.3. Compulsory Licensing in Australian BITs

Clauses related to expropriation in most BITs and treaties with investment provisions signed by Australia are similar with expropriation clauses in Saudi BITs. For instance, a recent investment agreement with Hong Kong clarifies that "neither Party shall expropriate a covered investment either directly or indirectly through measures equivalent to expropriation, except: a) for a public purpose; b) in a non-discriminatory manner; c) on payment of compensation in accordance with paragraph 2, paragraph 3 and paragraph 4; and d) in accordance with due process of law".[304] Such a formulation is typical and could be found in the majority of BITs and treaties with investment provisions.

At the same time, while none of the Australian BITs examined in this study limit the scope and application of compulsory licenses, the free trade agreement with the United States introduces unprecedented restrictions on this mechanism. Article 17.9 of the Agreement indicates that "a party shall not permit the use of the subject matter of a patent without the authorization of the right

[301] Tony Cole, "The Boundaries of Most Favored Nation Treatment in International Investment Law" (2012) 33 *Michigan Journal of International Law* 537-586
[302] Suzy Nikiema, 'Performance Requirements in Investment Treaties' (online at December 2014) *International Institute for Sustainable Development* <https://www.iisd.org/sites/default/files/publications/best-practices-performance-requirements-investment-treaties-en.pdf>.
[303] OECD, *International Investment Law: Understanding Concepts and Tracking Innovations: A Companion Volume to International Investment Perspectives* (OECD Publishing 2008) 101-134.
[304] Investment Agreement between the Government of Australia and The Government of the Hong Kong Special Administrative Region of the People's Republic of China 2019.

holder"[305]. The treaty includes only two exceptions from this clause: the one pertaining to actions against anti-competitive practices and the one related to "national emergency or other circumstances of extreme urgency".[306] The Agreement formulates three requirements for using compulsory licenses in such cases, including the following: "(i) the Party shall limit such use to use by the government or third persons authorised by the government; (ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and (iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph".[307] The quotations above are bright examples of TRIPS-plus clauses since they narrow down the situations in which compulsory licenses could be issued and offer strict restrictions concerning the disclosure of know-how, which might effectiveness of the compulsory licensing mechanism. This issue will be discussed in more detail in the last section of the chapter.

Certain differences between the Australian BITs and treaties with investment provisions could be found in regard to the calculation of compensation. Australian BITs use a fair market of expropriated investments as a basis for calculating the amount of compensation and suggest calculating this value at the moment of the actual or threatened expropriation. Most BITs, such as the ones signed with Lithuania, Pakistan, Poland, Sri Lanka, and Uruguay base the calculation of a rate of return on the prevailing market rate of return during the period between the expropriation and payment dates. The agreement with China offers a relatively unusual approach calculation technique, recommending parties to calculate the interest rate on the basis of "the average of the daily exchange rates… over the six months immediately prior to the taking of the measures".[308] At the same time, such a path could hardly translate into fundamentally different amounts of compensation as compared to the traditional one.

In comparison with Saudi BITs, Australian BITs and treaties with investment provisions offer a more flexible model for calculating investments' value. For instance, the BIT with Argentina states that "where that value [value of expropriated investments] cannot be readily ascertained, the compensation shall be determined in accordance with generally recognized principles of valuation and equitable principles taking into account the capital invested, depreciation, capital already repatriated, replacement value, currency exchange rate movements and other relevant factors".[309] In theory, such a vague formulation empowers investors to demand recalculation of the fair market value of their expropriated investments based on the grounds that "generally recognized principles of valuation" had

[305] Free Trade Agreement between Australia and the United States of America 2004.
[306] Ibid.
[307] Ibid.

[308] Agreement between the Government of Australia and the Government of the People's Republic of China on the Reciprocal Encouragement and Protection of Investments 1988.
[309] Agreement between the Government of Australia and the Government of the Argentine Republic on the Promotion and Protection of Investments 1995.

not been adequately applied. Investors are also provided with an opportunity to choose a freely convertible currency in which they would like to receive their compensation. In case if they do not request a new currency, a compensation shall be paid in the investment's original currency.

4.4. Dispute Settlement Mechanisms in Australian BITs

Australian BITs and treaties with investment provisions do not offer a consistent dispute settlement system. An analysis of different bilateral investment treaties signed by this state shows that availability of the ICSID Convention is one of the few common features of all these documents. Investors are encouraged to use this forum to settle their disputes with a host State in case if previous attempts to find a common ground fail. In order to minimize the likelihood of legal actions, many BITs provide parties with a chance to trigger conciliation and mediation options. For instance, the treaty with Sri Lanka highlights that parties "… may refer the dispute to the International Centre for Settlement of Investment Disputes ("the Centre") for conciliation or arbitration pursuant to Articles 28 or 36 of the Convention…".[310] The BITs with Indonesia, Viet Name, Argentina, Egypt, and China, at the same time, do not include the conciliation clause, referring parties to arbitration in case if they fail to resolve their disputes via negotiations. It could be inferred from the analysis of Australian BITs that most recent treaties usually include conciliation provisions except for the one signed with Egypt, whereas almost all the older ones mention only arbitration options.

While the ICSID Convention is described as an available dispute settlement forum in all the Australian BITs, there is no consistency between these documents in regard to other forums. The UNCITRAL framework is mentioned in the treaties with Indonesia, Argentina, and Turkey; simultaneously, it is absent in most other BITs, such as the ones with Poland, Uruguay, and Pakistan. Almost all the BITs refer to domestic courts as one of possible dispute settlement mechanisms. The treaty with Philippines, for instance, clarifies that "if the dispute in question cannot be resolved through consultations and negotiations, either party to the dispute may: (a) in accordance with the law of the Party which admitted the investment, initiate proceedings before that Party's competent judicial or administrative bodies".[311] Surprisingly, the BIT with Turkey does not allow investors to use domestic courts for settling their disputes, which is a highly uncommon practice in investment law.[312] An inability of investors to use these forums could be regarded as a restrictive factor since it limits their dispute settlement options.

There is no consistency between Australian BITs in terms of the priority of forums and their interaction with each other. The BITs with Argentina and Uruguay offer a "fork in the rode" principle,

[310] Agreement between the Government of Australia and the Government of the Democratic Socialist Republic of Sri Lanka for the Promotion and Protection of Investments 2002.
[311] Agreement between the Government of Australia and the Government of the Republic of the Philippines on the Promotion and Protection of Investments 1995.
[312] Agreement between the Republic of Turkey and Australia on the Reciprocal Promotion and Protection of Investments 2005.

requiring parties to choose either domestic or international forums in order to reduce ambiguity.[313] The treaty with Poland is highly unusual from this perspective. Whereas it allows investors to use both domestic and international forums to settle disputes in relation to expropriation and nationalization, it specifies that "where the dispute arises otherwise than under Article 7 of this Agreement [expropriation and nationalization], action pursuant to paragraph (3) of this Article may be taken where local remedies available pursuant to paragraph (2) of this Article have been exhausted".[314] Naturally, this provision could be considered as highly restrictive since it extends the duration of dispute settlement and creates additional barriers for investors.

A controversial provision in regard to dispute settlement could be found in the free trade agreement with the United States. In particular, Article 11.16 of the Agreement emphasizes that "if a Party considers that there has been a change in circumstances affecting the settlement of disputes on matters within the scope of this Chapter and that, in light of such change, the Parties should consider allowing an investor of a Party to submit to arbitration with the other Party a claim regarding a matter within the scope of this Chapter, the Party may request consultations with the other Party on the subject, including the development of procedures that may be appropriate".[315] It could be inferred from this statement that the United States preserves a right to pressure the Australian government into the establishment of new investor-state dispute settlement mechanisms in case if a U.S. firm has a complaint about the Australian government's approach.[316] Thus, even though U.S. investors currently do not enjoy preferential treatment in regard to dispute settlement, the USA has an option to continue the discussion of investment-state dispute settlement with the Australian government that is included in the free trade agreement's text.

4.5. The Key Areas of Congruence and Discrepancies between the TRIPS Agreement and Australian BITs and Treaties with Investment Provisions

Areas of congruence and discrepancies between the TRIPS Agreement and Australian treaties should be discussed separately for the case of Australian BITs and most treaties and for the case of the free trade agreement with the United States. Australian bilateral investment treaties and most treaties with investment provisions hardly create substantial TRIPS-plus dimensions. They use standard definitions of investors and investments, do not include exhaustive lists of investments' required characteristics, do not apply "substantive business activity" tests, do not limit the scope of compulsory licenses, and do not narrow down the list of situations in which they could be triggered. It is also

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[313] Agreement between the Government of Australia and the Government of the Argentine Republic on the Promotion and Protection of Investments 1995.
[314] Agreement between Australia and the Republic of Poland on the Reciprocal Promotion and Protection of Investments 1992.
[315] Free Trade Agreement between Australia and the United States of America 2004.
[316] David Richardson, "Foreign Investment and the Australia United States Free Trade Agreement" (online at 8 March 2004) *Parliament of Australia* <https://www.aph.gov.au/About_Parliament/Parliamentary_Departments/Parliamentary_Library/Publications_Archive/CIB/cib0304/04cib07>.

important to emphasize that none of the Australian BITs prohibit performance requirements. Certain peculiarities in regard to the calculation of a "fair market value" of expropriated investments hardly constitute a significant area of divergence between treaties and the TRIPS Agreement.

Standards of treatment described in Australian BITs and treaties with investment provisions do not contradict corresponding clauses of the TRIPS Agreement. Such treaties as those signed with Sri Lanka and Argentina, which introduce the national treatment clause, might create a TRIPS-plus dimension because similarly with the national treatment provisions of most other BITs, they do not address exceptions from the TRIPS Agreement's national treatment clause.[317] However, none of the Australian BITs introduces any uncommon treatment provisions that would be inconsistent or contradictory with the corresponding provisions of the TRIPS Agreement. In general, an analysis of Australian BITs and most treaties with investment provisions shows the absence of significant areas of divergence between them and the TRIPS Agreement from the perspective of the regulation of health-related intellectual property rights.

The free trade agreement with the United States is fundamentally different from Australian BITs and treaties with investment provisions reviewed above because it could be regarded a typical example of a document that creates a substantial number of TRIPS-plus layers of protection for investors, including those that directly apply to pharmaceutical companies. First, as stated above, the application of compulsory licenses under this agreement is restricted to only two cases: anti-competitive practices and the case of "national emergency or other circumstances of extreme urgency".[318] Second, the agreement offers flexibility in terms of extending patent terms. While they are not as significant as those that could be found in some other U.S. free trade agreements, such as the one with Morocco, they could still help pharmaceutical companies extend the patent terms of their products beyond the timeline stipulated in the text of the TRIPS Agreement. For example, Article 17.9 of the treaty states that "with respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process".[319] Such a clause may be regarded as an extension of the standard patent protection layer offered by the TRIPS Agreement.

Third, the treaty prohibits parallel importing. Article 17 states that "each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means".[320] Whereas, as stated above, parallel

[317] Andrew Newcombe and Lluis Paradell, *Law and Practice of Investment Treaties: Standards of Treatment* (Alphen aan den Rijn, Kluwer Law International: 2009).
[318] Free Trade Agreement between Australia and the United States of America 2004.
[319] Ibid.
[320] Ibid.

importation is not explicitly permitted by the TRIPS Agreement, its prohibition is "at odds" with the Agreement, eliminating an important flexibility available for countries.[321] All these arguments point at substantial TRIPS-plus dimensions that were created by the free trade agreement between the United States and Australia.

One of the most important clauses of the treaty from the perspective of the problem under investigation is connected with the protection of data that could be used to manufacture generic versions of pharmaceutical products. As stated above, the free trade highlights that parties "may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention".[322] The treaty establishes strict measures for protecting test data concerning safety or efficacy of products. It is emphasized in Article 17.10 that such data and the corresponding marketing approval cannot be used by third parties "to market the same or a similar product… for at least five years from the data of marketing approval by the Party".[323] Similarly, evidence of the marketing approval of a pharmaceutical product in another territory also could not be used to market a new or similar product for the period of at least five years.[324] Moreover, in case if a third person requests marketing approval for a product claiming the product or approved use during the patent term, Parties are supposed to notify patent holders of such requests and even disclose the identity of these "third persons".[325] None of these provisions could be found in the text of the TRIPS Agreement.

The available evidence provides a premise to believe that while the free trade agreement between Australia and the United States introduces many TRIPS-plus clauses, the ones protecting know-how and test data are the most significant ones from the perspective of the problem under investigation. The treaty allows Parties to continue using compulsory licenses, although the number of situations in which they could be issued is limited under the free trade agreement. However, generic manufacturers are unlikely to succeed in producing generic versions of pharmaceutical products since they are required to submit their own test data for the marketing approval, which, requires a substantial amount of time and financial resources. In this situation, the use of compulsory licenses by Parties could be considered as a highly unlikely scenario. Restrictive clauses significantly weaken the position of Australia in negotiations with pharmaceutical companies from the United States and undermine the government's ability to balance the rights and interests of stakeholders in accordance with the utilitarian principles of justice.

Clauses related to the protection of test data and know-how have received a significant amount of attention in the literature. Drahos and Henry argue that an obligation to comply with U.S. standards of test data protection is one of the most important implications of the agreement that could

[321] Ibid.
[322] Ibid.
[323] Ibid.
[324] Ibid.
[325] Ibid.

potentially undermine the Australian system of public health.[326] Faunce describes extended data exclusivity as an important disrupting issue that could affect the Australian medicines policy.[327] The importance of data exclusivity is also highlighted in the studies by Tully[328] and Xiong.[329] In light of the arguments laid out above, it seems justified to conclude that the free trade agreement with the United States has significantly affected the regulation of health-related IP rights in Australia, essentially limiting flexibilities that are provided under the TRIPS Agreement. TRIPS-plus clauses related to the prohibition of parallel importing and extension of data exclusivity provisions exemplify this pattern. In general, it seems justified to argue that unlike all the other investment treaties, the free trade agreement with the United States significantly affects the regulation of health-related IP rights and has important implications for utilitarian justice in the regulation of vaccine-related IP rights.

4.6. Conclusion

Australia has a mature system of IPR protection. Its robust patent protection framework, an effective system of law enforcement, and consistent regulations contribute to attractiveness of the country's investment climate. Its bilateral investment treaties, at the same time, do not provide such a high level of protection for investors as the ones signed by Saudi Arabia. These treaties rarely include national treatment provisions, mostly focusing on the standards of most-favored-nation and fair and equitable treatment. Like in the case with Saudi investment treaties, most BITs signed by Australia do not introduce substantial TRIPs-plus rules, even though the rights of investors are limited to a certain extent owing to the limited range of available dispute settlement forums. Simultaneously, it should be noted that the free trade agreement with the United States introduces unprecedented TRIPS-plus provisions that significantly limit TRIPS flexibilities related to parallel importing, compulsory licenses, patent protection terms, and performance requirements. Detailed discussion of these TRIPS-plus rules could be found in Chapter 7.

[326] Peter Drahos and David Henry, "The Free Trade Agreement between Australia and the United States" (2004) 328 *BMJ* 1271-1272.
[327] Thomas Faunce, "Reference Pricing for Pharmaceuticals: Is The Australia-United States Free Trade Agreement Affecting Australia's Pharmaceutical Benefits Scheme?" (2007) 187 *The Medical Journal of Australia* 240-242..
[328] Stephen Tully, "Free Trade Agreements with the United States: 8 Lessons for Prospective Parties from Australia's Experience" (2016) 5 *British Journal of American Legal Studies* 395-418.
[329] Ping Xiong, "Patents in TRIPS-Plus Provisions and the Approaches to Interpretation of Free Trade Agreements and TRIPS: Do They Affect Public Health?" (2012) 46 *SSRN Electronic Journal* 155-186.

CHAPTER 5. ARRANGEMENTS RELATED TO VACCINE SUPPLIES

5.0. Introduction

The current thesis seeks to explore the regulation of vaccine-related IP rights in light of the areas of divergence between the TRIPS Agreement and investment treaties. The study is conducted in the context of the COVID-19 pandemic; therefore, it seems natural that a specific chapter is devoted to the examination of vaccine arrangements related to vaccine supplies. The chapter starts with the examination of a typical vaccine from the perspective of IP rights. It presents the distinctive features of vaccines as pharmaceutical products and investments, reviews the basics of their patent protection, reviews vaccines' components, and discusses IPR protection of different components of vaccines. The subsection that focuses on vaccine development and licensing reviews vaccine development stages, investigates differences between vaccine licensing in different countries, and presents barriers to vaccine licensing. The third subsection, at the same time, introduces the existing arrangements related to COVID-19 vaccine supplies, including COVAX arrangements, international organizations' assistance, and direct negotiations between governments and vaccine manufacturers.

5.1. Examination of a Typical Vaccine from the Perspective of Intellectual Property Rights

5.1.1. Vaccines as Pharmaceutical Products and as Investments

A vaccine is fundamentally different from most other products manufactured by pharmaceutical companies. First, their preventative nature complicates calculation of savings generated by vaccine deployment.[330] Second, most vaccines before the pandemic offered long-term immunity based on administration of a single dose. Such a feature substantially limited monetization opportunities that were available for vaccine developers.[331] Third, preservation of many vaccines requires specific conditions, which might be hard to maintain in some developing and least developed countries. When discussing COVID-19 vaccination in developing nations, Sheikh, Pal, Javed, and Shekhar pointed out that Moderan and Pfizer vaccines, which require temperatures of -20°C and -60°C respectively, could be hardly used for vaccinating most developing nations due to the lack of equipment and reliable power supply that are necessary for maintaining such ultra-cold storage conditions.[332] Considering the fact that hotbeds of pandemics are often located in developing and least developed countries, problems with maintaining necessary temperature conditions might substantially reduce vaccine developers' profit expectations.

Fourth, confidence of customers in vaccines started decreasing even before the COVID-19 pandemic. The rejection of vaccines by certain communities resulted in the outbreaks of measles and

[330] Rino Rappuoli, Henry Miller and Stanley Falkow, "The Intangible Value of Vaccination" (2002) 297 *Science* 937-939.
[331] Patricia Danzon, Nuno Pereira and Sapna Tejwani, "Vaccine Supply: A Cross-National Perspective" (2005) 24 *Health Affairs* 706-717.
[332] Abu Baker Sheikh, Suman Pal, Nismat Javed and Rahul Shekhar, "COVID-19 Vaccination in Developing Nations: Challenges and Opportunities for Innovation" (2021) 13 *Infectious Disease Reports* 429-436.

pertussis cases in the USA in 2014.[333] More than 90% of people diagnosed with these diseases in 2014 had not been vaccinated, which implies that low vaccination rates became the main reason behind these local outbreaks.[334] Fifth, it is also important to emphasize that the costs of vaccine development and approval had been steadily growing in the beginning of the 21st century.[335] All these factors contributed to the perceived unprofitability of vaccines as compared to other pharmaceutical products. Rutschman illustrates this regularity by comparing the sales of anti-diabetic medication Januvia and MMR vaccines. Merck & Co., which manufacturers both Januvia and MMR vaccines, reported $675 million in revenue from selling its MMR vaccines in the wake of the outbreak of measles in 2018 and 2019, whilst its annual revenues generated from Januvia reached an impressive number of $6 billion.[336] Gardasil, which is among the most successful vaccines in the world, generated only $3 billion in 2018, which is still significantly less than the revenues from Januvia.[337] These examples illustrate that development of vaccines used to be a less profitable niche than development of drugs before the pandemic.

The conclusion above is crucial because considering the low profitability of vaccine manufacturers, the protection of their products by IPR mechanisms is becoming increasingly important. In the opinion of many experts, IPR protection mechanisms serve as an important factor stimulating research and development in the vaccine market[338]; accordingly, the removal of this incentive might completely discourage stakeholders from investing in the industry. The use of such measures as a proposed TRIPS waiver that would temporarily cancel patent protection on vaccines, therefore, may be regarded as an unwise decision from the perspective of pragmatism. It could weaken the position of pharmaceutical companies even more, discouraging them from engaging in vaccine R&D activities. Eventually, such a course of events could be barely conducive to the achievement of "the greatest good", as the world's population would be less likely to have necessary vaccines during the next pandemic. The available evidence provides a compelling reason to believe that IPR protection is more important for the vaccine market than it is for any other segment of the pharmaceutical industry.

5.1.2. Patent Protection of Vaccines

Recent debates concerning the TRIPS waiver might imply that patent protection is the major instrument of IPR protection on the vaccine market. However, as explained in the previous parts of the thesis, patent protection is only one layer of IPR protection that is relevant to the vaccine market,

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[333] Tara Smith, "Vaccine Rejection and Hesitancy: A Review and Call to Action" (2017) 4 *Open Forum Infectious Diseases* 1-7.
[334] Ibid.
[335] Ana Santos Rutschman, "IP Preparedness for Outbreak Diseases" (2018) 5 *UCLA Law Review* 1201-1266.
[336] Ana Santos Rutschman, "The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks" (2020) 119 Michigan Law Review Online 170-186.
[337] Ibid.
[338] Sara Eve Cragerm, "Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways" (2018) 108 *American Journal of Public Health* 414-420.

whereas a typical vaccine also enjoys protection based on other instruments of IPR. According to Durell, "just as there are many forms of vaccines and components to vaccines – particular compositions, delivery systems, components, and distribution networks – there are a variety of intellectual property protections applicable to vaccines".[339] Copyright, trademarks, patents, know-how, rights of plant breeders, and trade secrets are examples of IPR instruments that are used by vaccine manufacturers to protect IP rights related to their products.

All the mechanisms described above are described explicitly in the text of the TRIPS Agreement. A patent could be defined as "the legal right of an inventor to exclude others from making or using a particular invention".[340] The TRIPS Agreement clarifies that patents are available for all the inventions, including both products and processes in any industry, in case if they meet the following criteria: novelty, inventive steps, and industrial application capability.[341] It is further clarified in the Agreement that the term "inventive step" may be interpreted as "non-obvious", whilst the term "capability of industrial application" is synonymous to "useful".[342] Patents provide their owners with substantial exclusive rights under the TRIPS Agreement. In particular, a patent on a product allows parties "to prevent third parties not having the owner's consent from the acts of making, using, offering for sale, selling, or importing for these purposes that product"[343], and a patent on a process allows owners "to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process".[344] In comparison with other instruments of IPR protection, patents have received a significant amount of attention among scholars and stakeholders.[345]

A patent may be granted only when an invention successfully passes through several tests. In particular, as stated above, this invention is supposed to be new, useful, and non-obvious. In addition to these three criteria, it is also important to ensure that the subject of an invention is patentable. Patentability of a particular subject matter might be a controversial issue in certain situations, such as in the case with computer algorithms and business methods. The European Patent Convention excludes four groups of subject matters from the scope of patentable inventions: "(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information".[346] The European Patent Office clarified in 2000 that "having technical

[339] Karen Durell, "Vaccines and IP Rights: A Multifaced Relationship" (2016) 2 *Vaccine Design* 791-811.
[340] Bronwyn Hall, "Patents and Patent Policy" (2007) 23 *Oxford Review of Economic Policy* 568-587.
[341] TRIPS Agreement, Article 27.
[342] Ibid.
[343] Ibid.
[344] Ibid.
[345] See the articles written by Hall (2007), Bosse, Kang, and Thambisetty (2021) and Bonadio and Baldini (2020) for more information about patent protection.
[346] The European Patent Convention.

character is an implicit requirement of the EPC to be met by an invention to be an invention within the meaning of Article 52(1) EPC".[347] In the United States, a patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof".[348] Whilst specific laws differ in various countries, laws of most states essentially indicate that all the subject matters should be technical in their nature in order to be considered patentable.

Despite the existence of certain differences between the interpretations of various tests that should be passed by inventions in order to receive a patent, these differences hardly apply to vaccines. Jonas Salk, who invented the first polio vaccine, responded to a journalist's question about its patentability with a rhetorical question to the public asking whether one could patent the sun, further clarifying that he did not patent the vaccine in an attempt to make it available to everyone.[349] However, a dominant opinion on vaccines' patentability changed in the middle of the 20th century. The Supreme Court's decision in *Funk Bros* reaffirmed that the nature indeed could not be patented[350]; however, its decision in *Diamond v. Chakrabarty* established that the scope of patentable inventions could include "anything under the sun that is made by man".[351] Even though such a broad interpretation of subject matters' patentability was limited with the help of criteria discussed in the previous paragraphs, most components of the vaccines as well as most processes related to their creation certainly meet all the four stages of the patentability test.

5.1.3. Components of Vaccines

From the perspective of IP rights, a vaccine includes a variety of separate inventions that are patentable in the field of biotechnology. In most situations, vaccines' patents include separate patents for the active ingredient, elements of the ingredient and their combinations, the production method, and the product formulation and administration.[352] Active ingredients are arguably the most important element of most pharmaceutical products. At the same time, companies often use a variety of patents to cover other components of their vaccines, including antigens, stabilizers, adjuvants, preservatives, and antibiotics, which are all protected separately under patent law.[353] Thambisetty believes that such a practice often aims to overcome traditional limitations of patent protection.[354] Under the TRIPS Agreement, owners of patents that were issued on novel products and processes could enjoy a patent

[347] T 931/95.
[348] The Code of Laws of the United States of America.
[349] Siang Yong Tan and Nate Ponstein, "Jonas Salk (1914-1995): A Vaccine against Polio" (2019) 60 *Singapore Medical Journal* 9-10.
[350] 7 Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).
[351] Diamond v. Chakrabarty 447 U.S. 303 (1980).
[352] Enrico Bonadio and Andrea Baldini, "COVID-19 Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health" 1 *Eur J Risk Regul* 1-6.
[353] Centers for Disease Control and Prevention, "What's in Vaccines" (online at 5 August 2019) *CDC* <https://www.cdc.gov/vaccines/vac-gen/additives.htm>.
[354] Siva Thambisetty, "Vaccines and Patents: How Self-Interest and Artificial Scarcity Weaken Human Solidarity" (online at 9 February, 2021) *LSE British Politics and Policy* <https://blogs.lse.ac.uk/politicsandpolicy/vaccines-and-patents/>.

monopoly preventing other parties from "making, using, offering for sale, selling, or importing for these purposes that product"[355]. However, it is important to note that any patent monopoly is limited by a series of time, geographical, and subject matter constraints. In the opinion of Thambisetty, the use of multiple patents on different components of pharmaceutical companies provides companies with an opportunity to overcome some geographical and time limitations of patent protection. For instance, she explains that even though the patent on the active ingredient of Imbruvica was exhaustive, its inventors issued 154 other patent applications associated with the drug in an attempt to complicate and delay competition, such as three patents that aimed to specify aspects of the main patents after its submission.[356] Whereas scholars might engage in intense debates over the purpose of various vaccine-related patents, the fact that a typical pharmaceutical product is protected by numerous patents covering various products and processes related to it illustrates the need for reviewing the key components of a vaccine in this study.

As stated above, active components, which are also referred to as antigens, are the most popular subject matter that is protected by vaccine-related patents. They derive from disease-causing organisms that are supposed to trigger an immune response.[357] Adjuvants are another important component of a typical vaccine. These ingredients are supposed to facilitate an organism's immune response by stimulating the production of antibodies. Aluminum, mineral oil, cytokines, and squalene are bright examples of popular adjuvants.[358] At the same time, it is important to emphasize that some vaccines, such as the chickenpox and measles ones, do not have any adjuvants. Adjuvants are widely used in COVID-19 vaccines. For instance, the Sinopharm vaccine contains aluminum salt, whilst Pfizer and Moderna vaccines include polymer-based or lipid nanoparticles aiming to enhance the uptake of mRNA by humans' immune cells.[359] Preservatives, which are sometimes used in multidose vaccines, prevent the fungal and bacterial growth, which prevents unwanted contamination of a vaccine.[360] However, none of the COVID-19 vaccines that have been licensed to date contain preservatives; therefore, this ingredient is irrelevant from the perspective of the problem under investigation.

Stabilizers are present in all the modern vaccines. These ingredients are responsible for ensuring the components' integrity and preventing the occurrence of unwanted chemical reactions in a vaccine.[361] Such features play a critical role during the transportation and storage of vaccines. All the

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[355] Ibid.
[356] Ibid.
[357] Ibid.
[358] Public Health, "What Goes into a Vaccine?" (online at 2020) *Public Health* <https://www.publichealth.org/public-awareness/understanding-vaccines/goes-vaccine/>.
[359] Anita Milicic, "Adjuvants: The Unsung Heroes of Vaccines" (online at 24 March 2021) *The Conversation* <https://theconversation.com/adjuvants-the-unsung-heroes-of-vaccines-156548>.
[360] Ibid.
[361] Centers for Disease Control and Prevention, "What's in Vaccines" (online at 5 August 2019) *CDC* <https://www.cdc.gov/vaccines/vac-gen/additives.htm>.

known COVID-19 vaccines that have been licensed to date include acid stabilizers (Tromethamine & Tromethamine hydrochloride).[362] Finally, antibiotics are also included in vaccines in order to ensure effective storage of these products through prevention of their contamination by bacteria and germs that penetrate vaccines from external sources.[363] Even though antigens are commonly considered the most important element of a vaccine, other ingredients and the ways in which they are combined with each other are also often crucial for ensuring a vaccine's effectiveness.

In most situations, adjuvants, antibiotics, stabilizers, and preservatives that are used in vaccines are not subject to patent protection because companies use traditional ingredients and processes. At the same time, an analysis of the literature reveals certain exceptions from this trend. For instance, PCI Biotech has patented the use of fimaVacc in combination with Toll like receptor agonists, which act as a new type of adjuvants.[364] Patent protection of adjuvants has also become a popular instrument in relation to HIV vaccines. In particular, the number of patents on immunostimulatory adjuvants has been steadily growing.[365] Preservatives are also subject to patent protection in case if they meet all the four criteria of patentability. In particular, Assunta S. Ng, Ralph J. Mancinelli, and John P. Hennesey have successfully registered a patent for "novel combinations of methyl and propyl parabens, benzyl alcohol, and 2-phenoxyethanol that were put into vaccines using L-histidine as a buffer to keep pH at 7.0".[366] Developers of vaccines might also use the system of patent protection to protect stabilizers and antibiotics that are integrated in their products in case if they use novel substances or engage in novel processes.

Despite the arguments laid out above, it seems justified to claim that the majority of patents protecting vaccine-related IP rights revolve around active ingredients, their combinations, and technologies that are used to manipulate them. For example, BNT162 developed by Pfizer and BioNTech is protected by a series of patents that are mostly related to such fields as RNA, combinations of lipid nanoparticles with mRNA, and pharmaceutical compositions that include combinations of lipid nanoparticles and mRNA.[367] Patentability of active ingredients is a challenging

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[362] Juan Ravell, "A Simple Breakdown of the Ingredients in the COVID Vaccines" (online at 11 January 2021) *Hackensack Meridian Health* <https://www.hackensackmeridianhealth.org/HealthU/2021/01/11/a-simple-breakdown-of-the-ingredients-in-the-covid-vaccines/>.
[363] Ibid.
[364] PCI Biotech Holding ASA, "PCI Biotech: US patent for the Vaccine Technology (fimaVacc) with a New Important Class of Adjuvants" (online at 26 March 2020) *Globe News Wire* <https://www.globenewswire.com/news-release/2020/03/26/2006763/0/en/PCI-Biotech-US-patent-for-the-vaccine-technology-fimaVacc-with-a-new-important-class-of-adjuvants.html>.
[365] Jon Cavicchi and Stanley Kowalski, "Franklin Pierce Law Center Educational Report: Patent Landscape of Adjuvant for HIV Vaccines" (online at 2009) *International Technology Transfer Institute* <https://www.ipmall.info/sites/default/files/hosted_resources/PatentLandscape/itti_patent_ls_hiv_vaccine_adjuvants.pdf>.
[366] United States Patent Ng et al. (online at 14 September 2004) *Patent Images Storage* <https://patentimages.storage.googleapis.com/34/03/f5/3f88949da9d120/US6790445.pdf>.
[367] Mario Gaviria and Burcu Kilic, "BioNTech and Pfizer's BNT162 Vaccine Patent Landscape" (online at 16 November 2020) *Public Citizen* <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>.

issue that is subject to varied interpretations and disputes. The Supreme Court's decision in *Molecular Pathology v. Myriad Genetics, Inc.*[368] became a landmark decision that dramatically changed the dominant approaches towards patentability of active ingredients related to human genes. The Court asserted that genes are not subject to patents because they are a "product of nature"; accordingly, a company discovering a particular gene does not make any invention and merely reports the existence of genes.[369] This ruling invalidated approximately 4,300 patents of human genes that had been issued before; simultaneously, the Supreme Court allowed inventors to patent those DNA sequences that were manipulated in their labs since these sequences could not be found in their current form in nature.[370] It could be inferred from this decision that a vaccine's antigen may be patentable if it is genetically modified and cannot be patentable if it uses a naturally occurring virus form. Simultaneously, even if a developer is unable to ensure patent protection of its antigen, it could still patent other components of a vaccine, such as stabilizers, adjuvants, antibiotics, and preservatives.

5.1.4. IPR Protection of Different Components of Vaccines

Patent protection is currently the key barrier to the manufacturing and distribution of vaccines. The case of Gardasil exemplifies this pattern. According to Padmanabhan, Smin, Sampat, Cook-Deegan, and Chandrasekharan, there were 81 patents of Gardasil in the United States in 2010 that belonged to 18 entities.[371] Rutschman clarifies that it might be sometimes nearly impossible to develop a vaccine because different ingredients and technologies are patented by various pharmaceutical companies; as a result, none of them can use all the necessary ingredients and technology to develop a product.[372] Patents also extend market exclusivity, preventing generic completion of drugs and vaccines even if companies obtain compulsory licenses. For instance, Amin and Keselheim found that 108 patents that are related to 2 HIV vaccines could postpone generic competition until 2028.[373] Patent protection remains a substantial impediment in the area of new formulations of existent vaccines. In particular, in 2007, the University of Michigan at Ann Arbor has sold its royalties on payments from the use of the nasal-spray technology in the vaccine FluMist.[374] This example shows that the task of creating a vaccine in the modern world might require substantial investments due to patent barriers on different innovations related to vaccines.

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[368] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589–90 (2013).
[369] Ibid.
[370] Lara Cartwright-Smith, "Patenting Genes: What Does Association for Molecular Pathology v. Myriad Genetics Mean for Genetic Testing and Research?" (2014) 129 *Public Health Reports* 289-292.
[371] Swathi Padmanabhan, Tahir Amin, Bhaven Sampat, Robert Cook-Deegan and Subhashini Chandrasekharan, "Intellectual Property, Technology Transfer and Manufacture of Low-Cost HPV Vaccines in India" (2010) 28 *Nature Biotechnology* 671-678.
[372] Ana Santos Rutschman "Property and Intellectual Property in Vaccine Markets" (2020) *Texas A&M University Journal of Property Law*, 2020 https://ssrn.com/abstract=3590912>.
[373] Amin Tahir and Aaron Kesselheim, "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended for Decades" (2012) 31 *Health Affairs* 2286-2294.
[374] Goldie Blumenstyk, "U. of Michigan Sells Patent Royalties from FluMist for as Much as $35 Million" (online at 12 July 2007) *The Chronicle of Higher Educatio*n <https://www.chronicle.com/article/u-of-michigan-sells-patent-royalties-from-flumist-for-as-much-as-35-million/>.

The term "know-how" is another instrument of IP rights protection that is applicable to vaccines. The TRIPS Agreement indicates that parties could prevent information disclosure without their consent in case if this information meets three criteria of a secret in a sense that it is not generally known, has a commercial value, and is subject to evident efforts to keep it secret by a party who lawfully controls this information.[375] Considering that the development of a vaccine is a challenging process that requires substantial expertise, developers have the right to protect know-how related to the production process. The presence of this know-how is important because it could inhibit the development of a vaccine even in case if a compulsory license allows parties to bypass patent protection for separate components.[376] The importance of know-how in the regulation of vaccine-related IP rights has been increasing.

Under certain circumstances, the protection of vaccine-related IP rights could also cover delivery devices. This issue might be especially important for a COVID-19 vaccine given the fact that some specialists advocate for the use of innovative aerosol devices to spread a vaccine rather than use a standard method.[377] Some scholars also argue that the protection of clinical trials' results might be a relevant protection mechanism; however, most experts believe that parties could use bio-equivalence techniques to compare originator and organic vaccines without an access to clinical trials' data.[378] The arguments laid out above show that although the chosen research area is subject to many different interpretations and re-interpretations, patent protection of a vaccine's elements and delivery devices as well as protection of trade secrets related to pertinent know-how are at the heart of the regulation of vaccine-related IP rights.

In addition to a vaccine itself, the regulation of vaccine-related IP issues also covers production methods and the product formulation and administration. The discussion of these matters is hardly present in the existing research on vaccines because active ingredients and their combinations capture that attention of the public. Nonetheless, the literature indicates that there are also many other relevant areas of vaccines besides active ingredients that could be protected under IPR law.[379] For instance, patent protection extends to innovative manufacturing delivery methods, such as adenoviral vectors, and novel packaging technologies, such as two-dimensional barcodes or blow-fill-seal.[380] Naturally, the ways in which various ingredients are combined with each other and

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[375] Ibid.
[376] David Levine, "Covid-19 Should Spark a Reexamination of Trade Secrets' Stranglehold on Information" (online at 10 July 2020) *Stat News* <https://www.statnews.com/2020/07/10/covid-19-reexamine-trade-secrets-information-stranglehold/>.
[377] Fraiser Kansteiner, "Iowa State Taps Device Maker Zeteo for Early Work on Nasal Spray COVID-19 Vaccine" Fierce Pharma" (online at 24 November 2020) *Fierce Pharma* <https://www.fiercepharma.com/drug-delivery/iowa-state-taps-device-maker-zeteo-for-early-work-nasal-spray-covid-19-vaccine>.
[378] Christophere Garrison, "Intellectual Property Rights and Vaccines in Developing Countries" (online at 13 April 2004) *WHO* <https://www.who.int/intellectualproperty/events/en/Background_paper.pdf?ua=1>.
[379] Karen Durell, "Vaccines and IP Rights: A Multifaceted Relationship" (2016) 1404 *Methods in Molecular Biology* 791-811.
[380] Benoit Haymann and Sonia Pagliusi, "Emerging Vaccine Manufacturers Are Innovating for the Next Decade" (2020) 5 *Vaccine: X* 1-11.

the specifics of a vaccine's administration are also among important aspects of vaccine-related IP rights protection.[381] It seems justified to claim that every vaccine should be analyzed separately from the perspective of IP rights because of the presence of many issues that could add new layers to the existing system of know-how and patent protection relevant to a vaccine.

5.2. Vaccine Development and Licensing

5.2.1. An Overview of Vaccine Development Stages

Development of a new vaccine is a complex process that comprises many procedures and operations that could last for a significant amount of time. It might seem that there is currently no single approach towards distinguishing between various stages of vaccine development. The Centres for Disease Control and Prevention claims that a new vaccine passes through an exploratory stage, a pre-clinical stage, and the phases of clinical development, regulatory review and approval, manufacturing, and quality control.[382] Specialists from the Aimst University use a similar classification, outlining exploratory, preclinical, clinical, and approval stages as well as the pharmacovigilance phase that implies monitoring the vaccine after its delivery to the public.[383] The article written by Levine, which is based on the interview with representatives of Johnson & Johnson, mentions the preclinical stage, safety evaluation during Phases 1 and 2, effectiveness evaluation during Phase 3, regulatory approval and licensure, and continuous monitoring during the post-approval period.[384] At the same time, a detailed analysis of various classifications that are outlined in the literature shows that all of them revolve around the same stages but use different terms to denote them.

Exploratory and pre-clinical stages, which might be sometimes combined into a single phase, include laboratory testing of antigens, their compounds, and other components of a vaccine. The main goal of the exploratory stage is to identify a particular antigen that will be used in a vaccine and find a suitable mechanism for combining this antigen with other components, such as adjuvants, antibiotics, and stabilizers. The pre-clinical stage, in turn, is necessary to conduct required experiments on cells, tissues, and animals in order to evaluate a vaccine's efficacy, find an optimal method of vaccine administration, determine the optimal dosage of a vaccine, and estimate an immune response that is stimulates. According to Sharma, Sultan, Ding, and Triggle, exploratory and pre-clinical stages are relatively long and may take up to 3 years.[385] The scholars emphasize that a significant number of

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[381] Sameer Sharma and Lyn Hinds, "Formulation and Delivery of Vaccines: Ongoing Challenges for Animal Management" (2012) 4 *Journal of Pharmacy & BioAllied Sciences* 258-266.
[382] Centers for Disease Control and Prevention, "Vaccine Testing and the Approval Process" (online at 1 May 2014) *CDC* <https://www.cdc.gov/vaccines/basics/test-approve.html>.
[383] Aimst University, "How Do Vaccines Work?" (online at 2021) *Aimst University* <https://www.aimst.edu.my/event-news/5-stages-vaccine-development/>.
[384] Hallie Levine, "The 5 Stages of COVID-19 Vaccine Development" (online at 23 September 2020) *Innovation* <https://www.jnj.com/innovation/the-5-stages-of-covid-19-vaccine-development-what-you-need-to-know-about-how-a-clinical-trial-works>.
[385] Omna Sharma, Ali Sultan, Hong Ding and Chris Triggle, "A Review of the Progress and Challenges of Developing a Vaccine for COVID-19" (2020) 11 *Frontiers in Immunology* 1-17.

vaccine candidates fail to pass through these first stages. The study by Khuroo, Khuroo, Khuroo, Sofi, and Khuroo cites even higher numbers. The researchers mentioned the average duration of 2-5 years and the average cost of approximately $20 million.[386] They also clarify that only approximately 33% of vaccines successfully pass these two stages.[387] The figures reported in both studies reviewed above show that the exploratory and pre-clinical stages are usually relatively long and expensive.

Clinical development is the next stage of vaccine development following successful exploratory and pre-clinical trials. This stage usually comprises three phases that entail gradually increasing the number of individuals on whom the vaccine candidate is being tested as well as broadening their groups. Phase 1 typically implies administering a vaccine to a relatively small number of volunteers in order to analyze its efficacy, evaluate an immune response, and detect possible side effects. Approximately three out of five vaccines successfully pass through this phase, meeting necessary safety criteria and demonstrating a considerable immune response in volunteers. Phase 2 of vaccine development implies testing vaccines' safety, immunity response, efficacy, administration schedule, and delivery methods on a larger group of volunteers that might include up to several hundreds of individuals. Volunteers are usually divided into the two groups in which the first one receives vaccine doses, while the second one receives a placebo, adjuvants, or established vaccines.[388] This stage is significantly longer than the first one and might take up to two years; furthermore, more than a half of vaccine candidates fail to pass Phase 2. Finally, Phase 3 seeks to evaluate vaccine safety and efficacy on the basis of a research on a large target audience including thousand of people. In comparison with the previous phase, this stage entails administering a vaccine in field conditions that resemble those that could be observed during future vaccine use. This phase might take up to 4 years and cost around $87 million; simultaneously, it should be noted that the majority of vaccine candidates that succeeded during Phase 2 also successfully pass Phase 3 trials. A completion of Phase 3 allows pharmaceutical companies to start the process of regulatory approval and licensure.

Developers usually launch the stage of regulatory review and approval after their vaccine successfully passes Phase III, but some countries allow medical companies to enter this stage earlier. In particular, as it is known, the vaccine Sputnik V had been registered in the Russian Federation before Phase III trials were completed.[389] The country had registered the first Coronavirus case on

[386] Mohammad Khuroo, Mohammad Khuroo, Mehnaaz Khuroo, Ahmad Sofi and Naira Khuroo, "COVID-19 Vaccines: A Race against Time in the Middle of Death and Devasation!" 10 *Journal of Clinical and Experimental Hepatology* 610-621.
[387] Ibid.

[388] Mohammad Khuroo, Mohammad Khuroo, Mehnaaz Khuroo, Ahmad Sofi and Naira Khuroo, "COVID-19 Vaccines: A Race against Time in the Middle of Death and Devasation!" 10 *Journal of Clinical and Experimental Hepatology* 610-621.
[389] Talka Khan Burki, "The Russian Vaccine for COVID-19" (2020) 8 *The Lancet: Respiratory Medicine* 85-86.

January 31, clinical trials started on June 17, and the vaccine was approved on August 11.[390] Such a rapid pace raised concerns among scholars, making them doubt that the vaccine was indeed safe and effective. Simultaneously, it should be noted that such a fast regulation of the vaccine could be explained by the Russian government's attempt to register the vaccine as fast as possible, thus re-inventing the existing licensing procedures. Both Moderna and Pfizer/BioNTech started their Phase 3 trials in a little more than a week after the developers of the Sputnik vaccine; however, none of the vaccines had been registered and approved until the completion of Phase 3.[391] The example of Sputnik confirms that while the exploratory, pre-clinical, and clinical development stages occur similarly in various countries and for different vaccines, the stage of a regulatory review and approval strongly depends on country-specific regulations and, therefore, is unique for each particular country.

A typical vaccine development process is enduring and may take up to 15 years. A smallpox vaccine, which is known as the first vaccine in the human history, was invented in 1798.[392] However, the guidelines for its production and quality control were adopted in 1959, and the smallpox was completely eradicated only in 1978.[393] The first clinical trials on an influenza vaccine started in the 1930s, the vaccines' safety and efficacy was being studied between 1942 and 1944, and the vaccine was eventually licensed in the United States only in 1945.[394] In 1954, Thomas Peebles isolated the measles virus and developed a vaccine, but it took four years to license it.[395] All the examples above illustrate that the development of a vaccine in less than a year, which could be observed in the case of a COVID-19 vaccine, is an unprecedented achievement.

5.2.2. Vaccine Licensing in Different Countries

There are substantial differences between regulatory review and approval stages of vaccine development in various states. In the European Union, the evaluation of vaccines is within the responsibilities of the European Medicines Agency (EMA). After successfully completing Phase III trials, medical companies submit a marketing authorization application to the EMA that includes information about the vaccine's manufacturing and quality control and data from all the pre-clinical and clinical trials.[396] The EMA conducts a vaccine's evaluation in a series of steps, such as the initial assessment, clock stop 1, a further assessment, clock stop 2, further consultations, final discussion, and a possible re-examination, which may take up to 210 days.[397] The European Commission then

[390] Kristyna Foltynova, "Sputnik V: The Story of Russia's Controversial COVID-19 Vaccine" (2021) *Radio Free Europe* <https://www.rferl.org/a/sputnik-v-vaccine/31133608.html>.
[391] Steven Joffe, "Evaluating SARS-Cov-2 Vaccines after Emergency Use Authorization or Licensing of Initial Candidate Vaccines" 325 *JAMA* 221-222.
[392] Stefan Riedel, "Edward Jenner and the History of Smallpox and Vaccination" (2005) 18 *Baylor University Medical Center Proceedings* 21-25.
[393] Ibid.
[394] Alexandra Minna Stern and Howard Markel, "The History of Vaccines and Immunization: Familiar Patterns, New Challenges" 24 *Health Affairs* 611-621.
[395] Ibid.
[396] European Medicines Agency, "The Evaluation of Medicines, Step-by-Step" (online at 18 August 2020) *EMA* <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/evaluation-medicines-step-step>.
[397] Ibid.

makes a final decision on whether to allow a medical company to market the vaccine in the European Union. Finally, national authorities make necessary decisions on integrating a vaccine into their immunization programs.[398] Due to the complex relationship between EU and national authorities, the process of licensing a vaccine to market it in an EU country might be time consuming.

The process of vaccine licensing in the United Kingdom includes four different procedures that should be followed depending on whether a medical company plans to market a vaccine only in the UK or in the UK and some EU countries. Due to the fact that the formal withdrawal of the UK from the EU will be completed only on 31 December 2020, the EMA is still responsible for granting the marketing authorization for vaccines in the United Kingdom; however, after that, these functions will be transferred to the Medicines and Healthcare products Regulatory Agency.[399] A typical duration of the application process in line with the national procedure also comprises around 210 days[400]; at the same time, the example of the Pfizer/BioNTech vaccine showed that this process can be significantly accelerated. Under special regulations by the government, the MHRA approved the vaccine after only several months of clinical trials.[401] Apparently, traditional timelines of vaccine regulatory approval processes might be not relevant to the case of a COVID-19 vaccine due to the unprecedented demand on this product.

Specifics of the regulatory review and approval process of new vaccines in the United States are not fundamentally different from the specifics of this process in the United Kingdom and the European Union. Medical companies that pass Phase III trials submit an application to the Food and Drug Administration (FDA) that should meet the criteria of a Biologics License Application.[402] The FDA then is supposed to inspect the factory and approve a vaccine's labeling. Clinical trials conducted by FDA's specialists, which are sometimes supported by the inputs of the Vaccines and Related Biological Products Advisory Committee (VRBPAC), determine whether a vaccine will be approved to use in the United States.[403] Similarly to the United Kingdom and the European Union, the United States has a procedure of emergency approval. Such procedure, in particular, was used by Pfizer.[404] The process of regulatory review is not finished after the approval because FDA can continue monitoring the effectiveness and safety of a vaccine through such instruments as Phase IV

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[398] Ibid.
[399] Cristiana Vagnoni and Sarah Barber, "Regulatory Approval of COVID-19 Vaccines in the UK," (online at 2 December 2020) *UK Parliament* <https://post.parliament.uk/regulatory-approval-of-covid-19-vaccines-in-the-uk/>.
[400] Ibid.
[401] Sarah Boseley and Josh Halliday, "UK Approves Pfizer/BioNTech Covid Vaccine for Rollout Next Week" (online at 2 December 2020) *The Guardian* < https://www.theguardian.com/society/2020/dec/02/pfizer-biontech-covid-vaccine-wins-licence-for-use-in-the-uk>.
[402] Centers for Disease Control and Preventionm "Vaccines & Immunizations" (online at 2020) *CDC* <https://www.cdc.gov/vaccines/basics/test-approve.html>.
[403] Ibid.
[404] Noah Weiland and Katie Thomas, "Pfizer Applies for Emergency F.D.A. Approval for Covid-19 Vaccine" (online at 20 November 2020) *The New York Times* < https://www.nytimes.com/2020/11/20/health/pfizer-covid-vaccine.html>.

trials, the Vaccine Safety Datalink, and the Vaccine Adverse Event Reporting System.[405] Similar post-approval mechanisms also exist in most other countries.

Unfortunately, even though the general framework for regulatory review and approval of vaccines is similar in most countries, their legislations sometimes display slight differences pertinent to certain stages. According to Dekkepiane and Pagliusi, this issue complicates the licensing of vaccines in emerging countries, turning into a substantial barrier to the distribution of vaccines to vulnerable groups in developing states.[406] The initiative of Japan, the United States, and the European Union in 1990 has led to the creation of a Common Technical Document that provides a list of recommendations concerning regulatory submissions for the regulatory review of vaccines in various countries.[407] This initiative was supposed to lead to the standardization of vaccine regulatory review and approval processes in different countries. Unfortunately, specific regulatory processes in various states still display fundamental differences. In the study conducted by Dekkepiane and Pagliusi, it was found that the level of similarity between a Common Technical Document and specific lists of requirements in Australia, ASEAN states, China, India, GCC countries, the EU, the United States, Thailand, Jordan, PAHO states, and Tanzania was only 62%.[408] A difference between specific requirements pertinent to the regulatory review and approval of vaccines in various countries undermines the ability of developing states to receive sufficient amounts of necessary vaccines in a timely manner, thus violating the utilitarian principles of justice.

While the existing literature argues that the alignment of vaccine licensing requirements in various countries with the Common Technical Document is mandatory for ensuring that people from various corners of the globe have an equal access to vaccines, it is important to emphasize that this discussion might be not applicable to the case of a COVID-19 vaccine. The development of a COVID-19 vaccine as well as its licensing has been occurring in line with an unprecedented scenario, as governments of various countries consider the fastest possible distribution of vaccines as a matter of foreground priority. Due to such urgency, many countries have simplified their regulatory frameworks or even allowed medical companies to bypass some requirements. In Russia, as stated above, Sputnik V had been licensed before Phase III trials.[409] In the United States, the FDA triggered the procedure of emergency approval, forcing a large team of specialists to analyze a Biologics

[405] Grace Lee, Jose Romero and Beth Bell, "Postapproval Vaccine Safety Surveillance for COVID-19 Vaccines in the US" (2020) 324 *JAMA* 1937-1938.
[406] Nora Dellepiane and Sonia Pagliusi, "Challenges for the Registration of Vaccines in Emerging Countries: Differences in Dossier Requirements, Application and Evaluation Processes" (2018) 36 *Vaccine* 3389-3396.
[407] The International Council for Harmonization, "Common Technical Document" (online at 2019) *ICH* <https://www.ich.org/page/ctd>.
[408] Nora Dellepiane and Sonia Pagliusi, "Challenges for the Registration of Vaccines in Emerging Countries: Differences in Dossier Requirements, Application and Evaluation Processes" (2018) 36 *Vaccine* 3389-3396.
[409] Talka Khan Burki, "The Russian Vaccine for COVID-19" (2020) 8 *The Lancet: Respiratory Medicine* 85-86.

License Application that has thousands of pages in only several weeks.[410] Furthermore, the U.S. has introduced the Vaccine Administration Management System to facilitate the vaccine's tracking.[411] In this situation, it seems justified to conclude that traditional vaccine licensing policies and regulations may be no longer applicable since countries are likely to alter them to accelerate the distribution of a COVID-19 vaccine.

5.2.3. Barriers to Vaccine Licensing

Substantial regulatory constraints are among the most important barriers to vaccine development discouraging medical companies from entering this field. Some regulatory requirements contribute to high costs of vaccines. In particular, licensing entails approving the manufacturing process and inspecting facilities. Documentation of the current good manufacturing processes often leads to increased manpower due to the need to ensure that quality assurance personnel constitutes around a half of the total number of production workers; furthermore, vaccine developers are also supposed to use low-risk techniques and approaches in manufacturing, which also requires the use of expensive technologies.[412] Plotkin, Robinson, Cunningham, Iqbal, and Larsen explain that vaccine developers must conduct "routine monitoring of adverse event data and annual reporting of specific manufacturing information (e.g., data trends, change management, stability review, critical investigations of any process failures or unexpected trends)".[413] Meeting all these requirements demands essential financial resources from vaccine developers, which may be available only in large enterprises.

While licensing of a vaccine for a home market is an enduring and complex process, a vaccine producer seeking to export its vaccine to other countries might find even more significant barriers. A company is supposed to license its vaccine in each country separately; furthermore, many of them require country-specific clinical trials and set additional monitoring and reporting constraints requirements, thus further complicating and slowing down the process of vaccine importing.[414] In addition to the need to obtain licenses in each country and to pass diverse regulatory processes, vaccine developers also have to adhere to WHO Pre-Qualification requirements in case if they are interested in using this sales channel to distribute a vaccine.[415] While meeting WHO PQ requirements might increase the time needed to export a vaccine, it may also accelerate this process because some

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[410] Noah Weiland and Katie Thomas, "Pfizer Applies for Emergency F.D.A. Approval for Covid-19 Vaccine" (online at 20 November 2020) *The New York Times* < https://www.nytimes.com/2020/11/20/health/pfizer-covid-vaccine.html>.
[411] Darius Tahir and Rachel Roubein, "Trump Officials Rush to Introduce Untested Vaccine Tracking System," (online at 13 September 2020) *Politico* < https://www.politico.com/news/2020/09/12/trump-vaccine-tracking-system-412968>.
[412] Stanlley Plotkin, James Robinson, Gerard Cunningham, Robyn Iqbal and Shannon Larsen, "The Complexity and Cost of Vaccine Manufacturing – An Overview" (2017) 35 *Vaccine* 4064-4071.
[413] Ibid.
[414] Ibid.
[415] World Health Organization, "Considerations for Evaluation of COVID-19 Vaccines" (online at 24 September 2020) *WHO* <https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/WHO_Evaluation_Covid_Vaccine.pdf?ua=1>.

countries might accept WHO approvals.[416] The role of WHO PQ requirements in the licensing of vaccines, therefore, is controversial and could be analyzed from different perspectives.

5.3. Arrangements Related to COVID-19 Vaccine Supplies

5.3.1. COVAX Arrangements

As explained in the previous sections of the chapter, IPR protection is critical for vaccine manufacturers because it acts as an important incentive of their research and development activities. Considering the critical importance of IPR protection for vaccine developers, a proposal to waive IPR protection on COVID-19 vaccines during the pandemic used to be unpopular among most stakeholders until recently. Simultaneously, it seems justified to state that the existing IPR protection indeed prevents many developing and least developed nations from accessing critically important COVID-19 vaccines, thus not only endangering the lives of their residents but also exposing people from other countries to the virus following the lifting of travelling restrictions. In this situation, it is crucial to find an optimal valance between preserving the existing system of IPR protection as an incentive for R&D activities on the vaccine market and creating favorable conditions for providing vulnerable populations with access to vaccines.

Debates concerning an optimal balance between these two priorities have been intensifying since the start of the pandemic. The instrument of pooled procurement is one of options that provide a balanced approach towards facilitating the distribution of vaccines without violating the existing framework of intellectual property and without utilizing the mechanism of compulsory licensing.[417] The mechanism called COVAX is currently the most well-known pooled procurement model that is used to provide populations of all the countries with access to considerable amounts of vaccine doses that are sufficient for protecting the most vulnerable population groups. A decision to launch the COVAX Facility was inspired by stakeholders' attempt to prevent the H1N1 scenario in which developed nations hoarded vaccine supplies, leaving least developed nations unable to counter the growth of influenza cases.[418] The COVID-19 Vaccine Global Access (COVAX) Facility was created by the World Health Organization in coordination with Gavi and CEPI. [419]

The project's main goal is to use the mechanism of pooled procurement to secure around 2 billion vaccine doses that could cover at least 20% of populations of each state, thus administering vaccines to the most vulnerable population groups that are exposed to especially high virus-related risks.[420] COVAX is funded by governments of different countries and non-government organizations. The COVAX Facility pools the purchasing power of all the stakeholders and uses it to "equitably

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[416] Ibid.
[417] Anthony So, "Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross-Sectional Analysis" (2020) 371 *BMJ* 1-8.
[418] Supriya Kumar, Sandra Crouse Quinn, Kevin Kim and Karen Hilyard, "US Public Support for Vaccine Donation to Poorer Countries in the 2009 H1N1 Pandemic" (2012) 7 *PLoS One* 1-17.
[419] World Health Organization, "COVAX: Working for Global Equitable Access to COVID-19 Vaccines" (online at 2020) *World Health Organization* <https://www.who.int/initiatives/act-accelerator/covax>.
[420] Ibid.

distribute vaccine doses to help protect the most at-risk groups in all participating countries".[421] In accordance with the terms offered by the program, high-income states could purchase their COVID-19 doses at around $11 per dose, whilst the price for low-income countries could be as low as $1.6-$2.0 per dose.[422] Such an approach allows developing and least developed states to purchase a substantial number of vaccine doses without bypassing the existing IPR protection systems or engaging in direct negotiations with vaccine developers.

The dominant approach used by COVAX is based on the idea that vaccination campaigns should be completed through a series of steps. In particular, vaccines should be primarily administered to the elderly, people working in the health care industry, and other individuals who are exposed towards increased risks related to COVID-19.[423] The intent behind COVAX arrangements is to ensure equitable access to vaccines and link distribution of vaccines to populations' needs rather than wealth possessed by states.[424] In line with the overarching logic behind the COVAX project, countries should gradually expand the scope of their vaccination campaigns once the majority of nations vaccinate at least 20% of their residents. Whereas it might seem that the proposal behind COVAX is idealistic, it offers practical instruments for ensuring equitable access to at least small amounts of vaccines for all the participating countries, which illustrates substantial advantages of the program in comparison with most other proposals aimed at ensuring equitable access to vaccines, such as the ones proposed by Emanuel et al.[425] and Liu, Salwi, and Drolet.[426] Because of this reason, COVAX arrangements remain the most successful alternative approach towards securing COVID-19 vaccines other than direct negotiations between governments and vaccine manufacturers.

The number of vaccine doses secured by the project had been swiftly growing in 2020. By the end of August 2021, the COVAX Facility managed to secure 251 million doses as well as funding that could cover 1 billion doses in total.[427] The United States, at the same time, was supposed to receive 800 million doses from vaccine manufacturers, whilst agreements of Japan, Canada and Australia secured more than a billion doses for these three countries combined. These numbers illustrate that the COVAX Facility indeed has limited capacity as compared to developed states. By

[421] Gavi, "COVAX" (online at 2020) *Gavi* <https://www.gavi.org/covax-facility>.
[422] Seth Berkley, "COVAX Explained" (online at 3 September 2020) *Gavi* <https://www.gavi.org/vaccineswork/covax-explained>.
[423] World Health Organization, "Fair Allocation Mechanism for COVId-19 Vaccines through the COVAX Facility" (online at 9 September 2020) *WHO* <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>.
[424] Ibid.
[425] Ezekiel Emanuel, Govind Persad, Adam Kern, Allen Buchanan, Cecile Fabre, Daniel Halliday, Joseph Heath, Lisa Herzog, Ephrem Lemango, Florencia Luna, Matthew McCoy, Ole Norheim, Trygve Ottersen, Owen Schaefer, Kok-Chor Tan, Christophere Wellman, Jonathan Wolff and Henry Richardson, "An Ethical Framework for Global Vaccine Allocation" (2020) 369 *Science* 1309-1312.
[426] Yangzi Liu, Sanjana Salwi and Brian Drolet, "Multivalue Ethical Framework for Fair Global Allocation of a COVID-19 Vaccine" (2020) 46 *Journal of Medical Ethics* 499-501.
[427] Anthony So, "Reserving Coronavirus Disease 2019 Vaccines for Global Access: Cross-Sectional Analysis" 371 *BMJ* 1-8.

December 18, COVAX managed to establish agreements to access 2 billion doses of several vaccines for 190 participating countries in the first half of 2021, and donors agreed to fund 1.3 billion doses for 92 countries.[428] By August 31, 2021, the COVAX Facility delivered approximately 251 million vaccines to 141 countries.[429] The delivery of German-funded vaccines to Mauritania is currently the last update on the organization's official website.[430] The use of COVAX could be regarded as one of the most effective instruments to date to secure a substantial number of COVID-19 vaccine doses without violating the existing IPR protection frameworks.

Simultaneously, COVAX has a number of flaws that predetermine its low effectiveness in comparison with the common approach of developed states that have pre-ordered a substantial number of vaccine doses. First, the targeted coverage of 20% of populations might seem desirable for low-income countries; however, it is hardly a suitable option for most developed states. Low amounts of doses guaranteed by the program predetermine a relatively low interest of many developed countries in COVAX. Second, the program's implementation is relatively slow. While the United States and the United Kingdom had started vaccinating their populations based on their own programs, most countries had not received vaccines under COVAX until the first quarter of 2021.[431] Such timeline is unacceptable for many states given that quarantine measures that control the spread of the virus hurt their economies and constrain the scope and effectiveness of recovery measures. Significant differences between developed and developing countries in terms of the pace of vaccination campaigns illustrate that COVAX indeed is a relatively slow mechanism. For example, while some developed countries are already close to finishing their vaccination campaigns, Pakistan, which has the population of more than 220 million, received only 9,051,862 doses to date.[432] Such a low number shows deficiencies of the COVAX mechanism.

It might seem that the emergence of the COVAX mechanism was a culmination of the stakeholders' appeals to the moral obligations of developed countries and wealthy entrepreneurs. However, another point of view describes COVAX as a pragmatic instrument that was launched by the international community in the pursuit of "the greatest good". As explained above, the inability of developing and least-developed states to vaccinate their populations would prolong the COVID-19

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[428] World Health Organization, "COVAX Announces Additional Deals to Access Promising COVID-19 Vaccine Candidates: Plans Global Rollout Starting Q1 2021," (online at 18 December 2020) *WHO* <https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021>.
[429] Gavi, "COVAX Vaccine Roll-Out," (online at 31 August 2021) *Gavi* <https://www.gavi.org/covax-vaccine-roll-out>.
[430] Ibid.

[431] World Health Organization, "COVAX Announces Additional Deals to Access Promising COVID-19 Vaccine Candidates: Plans Global Rollout Starting Q1 2021," (online at 18 December 2020) *WHO* <https://www.who.int/news/item/18-12-2020-covax-announces-additional-deals-to-access-promising-covid-19-vaccine-candidates-plans-global-rollout-starting-q1-2021>.
[432] Gavi, "COVAX Vaccine Roll-Out," (online at 31 August 2021) *Gavi* <https://www.gavi.org/covax-vaccine-roll-out>.

crisis, causing substantial financial losses for all the parties. Therefore, the emergence of this pooled procurement mechanism could be viewed as a result of the growing realization of the fact that the world could only overcome the pandemic by vaccinating the majority of the populations of all the countries, including both high-income and low-income ones.

5.3.2. Assistance of International Organizations within the Existing Frameworks of the Regulation of Vaccine-Related IP Rights

An expectation that international organizations would become an important driver of equitable access to vaccines used to be popular at early stages of the Coronavirus. Even though stakeholders did not agree on specific measures that these organizations had to take in order to contribute to this equitable access, their role was expected to be significant. However, over time, international organizations barely made an important contribution to vaccine arrangements. Except for the COVAX project initiated by the World Health Organization and supported by other entities, international organizations hardly initiated new programs that could allow developing and least developed countries to secure a sufficient number of vaccine doses for their populations.

A review of the literature illustrates that most projects of international organizations operate at the local level and aim to support countries' efforts to control the spread of the Coronavirus rather than introducing any alternative approaches towards obtaining vaccines. In particular, the WHO conducted programs in the Philippines, Bangladesh, Bolivia, Guatemala, Lebanon, and many other developing and least developed states that implied donating medical equipment, providing essential supplies, setting workplace safety systems, and launching other initiatives that could strengthen states' resilience towards the crisis.[433] The International Organization for Migration donated vaccine refrigerators and other cold chain equipment to Indonesia to support its vaccination campaigns.[434] The World Bank, at the same time, offers extensive financing packages to developing and least developed states to help them purchase vaccines via the COVAX Facility or through other channels. The overall funding of the program that is currently implemented by the World Bank is $4.6 billion.[435] Whereas all these projects could be undoubtedly considered useful for supporting vaccination campaigns, none of them could serve as an instrument of empowering low-income nations to secure a substantial number of vaccine doses.

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[433] World Health Organization, "WHO Continues to Support Countries to Fight COVID-19" *WHO* <https://www.who.int/news-room/feature-stories/detail/who-continues-to-support-countries-to-fight-covid-19>.
[434] International Organization for Migration, "IOM Delivers Vaccine Refrigerators, Cold Chain Equipment to Support Indonesia's COVID-19 Vaccination Drive" (online at 7 April 2021) *IOM* <https://indonesia.iom.int/news/iom-delivers-vaccine-refrigerators-cold-chain-equipment-support-indonesia%E2%80%99s-covid-19>.
[435] The World Bank, "World Bank Support for Country Access to COVID-19 Vaccines" (online at 31 August 2021) *The World Bank* <https://www.worldbank.org/en/news/press-release/2021/04/20/world-bank-financing-for-covid-19-vaccine-rollout-reaches-2-billion>.

The World Trade Organization became a platform for intense debates over the use of IPR frameworks in regard to COVID-19 vaccines. In October, India initiated a waiver at the WTO indicating that "an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need".[436] This waiver became a logical continuation of enduring discussions of the "fairness" of IP frameworks regulating vaccine development and distribution. In spite of the support of many developing nations, members of the WTO rejected the waiver. In particular, a spokesperson for the EU emphasized that "there is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID-19 related medicines and technologies".[437] As a result, most large pharmaceutical companies supported by governments of developed countries "continued with their business-as-usual approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19".[438] Developed countries have been approaching the well-known "vaccine nationalism" approach, reserving significant amounts of both vaccines and technologies that are necessary for their manufacturing and distribution for themselves.[439] Therefore, even though the WTO announced its plans to revisit the question of the waiver in 2021, it did not make any essential changes in the field of vaccine arrangements. The TRIPS waiver remains a controversial issue to date with different countries expressing diverse opinions on its relevance.[440] There is no premise to expect that this waiver will be introduced in the nearest future despite the surprising support of this measure by the new presidential administration of the United States.

In general, it seems justified to claim that efforts of international organizations are currently not sufficient for supporting low-income countries in their attempts to obtain necessary amounts of vaccine doses. Projects initiated by the WHO, UNICEF, and most other international organizations are unable to address problems related to the lack of equitable access to vaccines. Some of these organizations, primarily the UN and the WTO, currently serve as platforms empowering states to find

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[436] Council for Trade-Related Aspects of Intellectual Property Rights, "Waiver from Certain Provisions of the TRIPS Agreement" (online at 16 December 2020) *WTO* <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?&Language=ENGLISH&SourcePage=FE_B_009&Context=Script&DataSource=Cat&query=@Symbol=IP/C/W/*&DisplayContext=popup&languageUIChanged=true>.

[437] James Bacchus, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines" (2020) 78 *Free Trade Bulletin* 1-5.

[438] Biswajit Dhar and Kemal Gopakumar, "India – South Africa Proposal for a Waiver from Certain Obligations under the TRIPS Agreement," (online at December 2020) *Third World Network* <https://twn.my/title2/briefing_papers/twn/TRIPS%20waiver%20TWNBP%20Dec2020%20Dhar&Gopakumar.pdf>.

[439] Ana Santos Rutschman, "The Intellectual Property of COVID-19," (2020) *Saint Louis University School of Law* <https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1537&context=faculty>.

[440] King & Spalding, "Update on the Proposed TRIPS Waiver at the WTO: Where It Is Headed, and What to Expect?" (online at 8 June 2021) *JD Supra* <https://www.jdsupra.com/legalnews/update-on-the-proposed-trips-waiver-at-8411942/>.

new strategies towards ensuring equitable access to vaccines. In particular, as it is known, discussions over the TRIPS waiver have been intensifying along with the growing amount of pressure that is put on a few developed states that continue opposing the waiver.[441] Simultaneously, projects that are initiated and implemented by international organizations alone could hardly serve as an effective mechanism of ensuring equitable access to vaccines.

5.3.3. Direct Negotiations between Governments and Vaccine Manufacturers

Facilitation of direct negotiations between governments of various countries and pharmaceutical companies remains the most popular mechanism of providing nations with access to COVID-19 vaccines. In July, Pfizer managed to reach an agreement with the United States that obliged the company to supply 100 million doses of its vaccine for the total price of $1.95 billion once it is approved in the country.[442] The company also negotiated arrangements with the European Union and China for 200 million and 100 million doses respectively.[443] Israel reached a deal with Pfizer in November, agreeing to purchase 2 million two-shot doses for $56 each.[444] On April 20, 2021, the state also announced a deal with Moderna for the supply of 10 million doses.[445] Other developed countries, such as Canada, the United Kingdom, Australia, and Switzerland, also engaged in direct negotiations with vaccine manufacturers, making pre-orders of substantial amounts of prospective vaccines and signing deals on the delivery of approved vaccines.

At a certain point, a misbalance between developed and developing states in terms of their vaccine orders became obvious. By the end of November 2020, Canada, Japan, the United Kingdom, the United States, and Australia have already pre-ordered enough vaccines from AstraZeneca, Moderna, and Pfizer to cover 127.7%, 114.6%, 108.7%, 106.6%, and 87.6% of their population respectively.[446] In contrast, the majority of developing and least developed states relied exclusively on COVAX for obtaining vaccine doses or tried to engage in negotiations with China and Russia concerning the supply of those vaccines whose efficacy had not been proved yet.

Direct negotiations between governments and vaccine manufacturers are a controversial solution that has been heavily criticized by different stakeholders. First, it negatively affects access to

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[441] Nadine Schmidt, Rob Pincheta and Schams Elwazer, "Germany Resists Calls to Waive Patents on COVID-19 Vaccines" (online at 7 May 2021) *CNN* <https://edition.cnn.com/2021/05/06/europe/germany-us-covid-vaccine-patents-intl/index.html>.

[442] Katie Shonk, "Government Negotiations: Pfizer's Rocky Road to U.S. Covid-19 Vaccine Deals" (online at 25 January 2021) *Harvard Education* <pon.harvard.edu/daily/business-negotiations/government-negotiations-pfizers-rocky-road-to-u-s-covid-19-vaccine-deals/>.

[443] Ibid.

[444] Stuart Winer, "Israel Will Reportedly Pay Much More than US, EU for Pfizer Coronavirus Vaccine" (online at 16 November 2020) *Times of Israel* <https://www.timesofisrael.com/israel-will-reportedly-pay-more-than-us-eu-for-pfizer-coronavirus-vaccine/>.

[445] Moderna, "Moderna Announces New Supply Agreement with Israel for 2022" (online at 20 April 2021) *Investors Moderna* <https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-new-supply-agreement-israel-2022>.

[446] Katherine Ellen Foley, "The Countries that Have Already Ordered enough Vaccines for Their Entire Population" (online at 24 November 2020) *Quartz* <The countries that have already ordered enough Covid-19 vaccines — Quartz (qz.com)>.

vaccines for most residents of developing and least developed nations due to the prevalence of "vaccine hoarding" and "vaccine nationalism" tendencies in developed states' strategies.[447] Second, such a mechanism provides pharmaceutical companies with a high bargaining power and empowers them to set higher prices on their products. The fact that Israel agreed to pay $56 per a Pfizer's two-shot dose, while the European Union pays only $39 for the same product, exemplifies this tendency.[448] A leader of the Indian Congress recommends countries to engage in joint negotiations with vaccine manufacturers in order to set uniform prices.[449] However, as stated above, developed countries hardly utilize this option, as their negotiations are primarily driven by vaccine nationalism narratives.

The mechanism of direct negotiations described above is aligned with the existing system of international law and does not violate any IPR provisions. Simultaneously, it is important to note that some TRIPS-plus rules contribute to the vaccine hoarding trends by limiting states' opportunities to export vaccine doses that they obtain via contracts with pharmaceutical companies to third countries. As a result, it seems justified to assume that these direct negotiations might be a controversial measure that threatens vaccination campaigns in developing and least developed countries.

5.4. Conclusion

The chapter showed that vaccines are fundamentally different from other pharmaceutical products because of difficulties with calculating savings, limited monetization opportunities, the need for specific storage and distribution conditions, low confidence of customers in many vaccines, and high development costs. A typical vaccine consists of an active ingredient, elements of the ingredient, antigens, stabilizers, adjuvants, preservatives, and antibiotics. All these components as well as the production method and product formulation and administration techniques are usually protected by patents. Whereas patents remain the most well-known layer of protection of vaccine-related IPRs, recent research suggests that the protection of know-how constitutes a more significant barrier to equitable access to vaccines. Even if competitors use compulsory licenses to bypass patent protection, they might find themselves unable to produce vaccines due to the absence of necessary know-how.

The vaccine development processes includes the preclinical stage, safety evaluation during Phases 1 and 2, effectiveness evaluation during Phase 3, regulatory approval and licensure, and continuous monitoring during the post-approval periods. A typical vaccine development process lasts around 15 years. Specific requirements for regulatory approval differ in various countries; therefore,

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[447] Ana Santos Rutschman, "The Intellectual Property of COVID-19," (2020) *Saint Louis University School of Law* <https://scholarship.law.slu.edu/cgi/viewcontent.cgi?article=1537&context=faculty>.
[448] Stuart Winer, "Israel Will Reportedly Pay Much More than US, EU for Pfizer Coronavirus Vaccine" (online at 16 November 2020) *Times of Israel* <https://www.timesofisrael.com/israel-will-reportedly-pay-more-than-us-eu-for-pfizer-coronavirus-vaccine/>.
[449] The Economic Times, "States Must Jointly Negotiate Uniform Vaccine Price with Manufacturers: Chidambaram" (online at 24 August 2021) *Economic Times* <https://economictimes.indiatimes.com/news/politics-and-nation/states-must-jointly-negotiate-uniform-vaccine-price-with-manufacturers-chidambaram/articleshow/82212191.cms>.

companies are supposed to meet requirements of every country in which they plan to sell their vaccines. Substantial regulatory constraints and the need to license vaccines in each country separately are essential barriers to vaccine distribution.

The manufacturing and distribution of COVID-19 vaccines remain topical challenges for the international community. COVAX arrangements are currently the only instrument that allows providing residents of all the countries with access to vaccines. The system is based on the pooled procurement model and implies creating a pool of vaccines that are distributed between all the member states. Due to the fact that high-income countries make donations to the fund and purchase their vaccines at a higher price than other countries, Gavi attempts to contribute to equitable access to COVID-19 vaccines. The COVAX Facility has delivered around 251 million vaccines to 141 countries by 31 August 2021, but the program has a number of flaws, including its inability to cover more than 20% of populations and a relatively long timeline. Except for supporting the COVAX Facility, international organizations' contributions to vaccination campaigns remain limited. They provide targeted assistance to certain countries by sending supplies of medical equipment and supporting local projects, but their role in fueling vaccination campaigns is hardly crucial. Finally, direct negotiations between governments and vaccine manufacturers are currently the most effective and popular method of obtaining vaccine supplies. Many developed countries have already managed to negotiate deals for the delivery of vaccine doses in the amount that is sufficient for a vaccination campaign covering the entire population.

CHAPTER 6. OBTAINING VACCINE SUPPLIES IN SAUDI ARABIA: RECENT DEVELOPMENTS AND THE IPR PERSPECTIVE

6.0. Introduction

This chapter reviews recent developments in obtaining vaccine supplies in Saudi Arabia and presents the IPR perspective of this process. Its first subsection reviews current results of the country's vaccination campaign, while the next one discusses the state's participation in the COVAX program. The third subsection of the chapter scrutinizes the government's negotiations with vaccine developers in an attempt to uncover the effect of political, economic, and legal factors on agreements signed by the country. The main part of the chapter analyzes Saudi investment treaties that could affect the regulation of vaccine-related IP rights. In particular, it reviews such treaties as the BITs with China, Germany, Switzerland, South Korea, and the Belgium-Luxembourg Economic Union as well as the free trade agreement with the United States. The focus of this analysis is put on the agreements' scope and definitions, standards of treatment, and dispute settlement mechanisms. The last subsection of the chapter briefly reviews the key difficulties in implementation of the system of IPR protection in Saudi Arabia that could be relevant for the regulation of vaccine-related IP rights during the COVID-19 crisis.

6.1. An Overview of Recent Developments in Obtaining Vaccine Supplies in the Kingdom of Saudi Arabia

The vaccination campaign in Saudi Arabia is hardly different from the vaccination campaigns in most other Gulf countries. By August 31, 2021, the country administered 105.07 doses per 100 people, which is significantly more than the average figure for the world (67.82 doses) yet substantially less than the number of doses in many other countries, such as the United Arab Emirates, China, the United Kingdom, France, Germany, and the United States (181.75, 143.16, 133.41, 130.44, 121.62, and 110.08 doses respectively).[450] According to the state's officials, the country vaccinated all the vulnerable groups[451] by March 2021 and started expanding its vaccination campaign to the entire society.[452] In general, it could be assumed that whereas Saudi Arabia hardly achieved such a substantial progress in its vaccination program as the United Arab Emirates or Israel, its campaign is being implemented at an adequate pace considering a large size of the Saudi population and institutional and social barriers to vaccination.

Saudi Arabia entered into negotiations with many different developers of prospective vaccines in 2020. On 29 November 2020, the government signed an agreement with CureVac for the

[450] Our World in Data, "Coronavirus (COVID-19) Vaccinations" (online at 31 August 2021) *Our World in Data* <https://ourworldindata.org/covid-vaccinations>.
[451] It could be inferred from the context that the elderly, people with chronic diseases, and health care workers constitute groups, although the article does not provide any clarifications concerning this matter.
[452] Arab News, "Saudi Arabia Expanding COVID-19 Vaccination Camapgin" (online at 10 March 2021) *Arab News* <https://www.arabnews.com/node/1823451/saudi-arabia>.

supply of its vaccines.[453] The Kingdom became the first Gulf country to sign such an agreement with the German company. The government also allegedly agreed to allow the conduction of a Phase 3 study of the Russian vaccine in Saudi Arabia, even though such plans were revised later.[454] However, over time, the government focused on partnerships with AstraZeneca and Pfizer/BioNTech as the main sources of vaccine supplies. The state engaged in direct negotiations with these pharmaceutical companies in an attempt to fuel vaccination campaigns of vulnerable population groups. For example, in January 2021, the Kingdom signed an agreement with the Serum Institute of India for the supply of 3 million doses at the price of $5.25.[455] Despite the fact that arrangements concerning AstraZeneca vaccines promised a swift delivery of a sufficient number of doses, the country's cooperation with the Serum Institute of India remains a controversial matter. In addition to paying $5 for AstraZeneca vaccines as opposed to $3.5 that is paid by the European Commission[456], the country often suffers from delays in the supply of these vaccines.[457] Delays in supply were linked to the growing local demand on vaccines in India and insufficient production capacity of the facility.[458] Such problems illustrate that a partnership with the Serum Institute of India alone could hardly satisfy the nation's needs in vaccine supplies.

Products delivered by Pfizer/BioNTech became the basis of the state's vaccine campaign. The country signed an agreement to receive approximately 100,000 of vaccine doses on a weekly basis; however, like in the case with AstraZeneca vaccines, the delivery of Pfizer vaccines faced substantial delays at a certain point.[459] Despite these occasional problems, the state managed to secure a substantial number of vaccine doses both from Pfizer/BioNTech and from AstraZeneca.

The available evidence provides a compelling reason to believe that the main barriers to the vaccination campaigns in Saudi Arabia are currently connected not with supply chain delays and vaccine shortages but rather with the unwillingness of the remaining part of the society to be vaccinated. The growing popularity of vaccine hesitancy posts in social media discourages many Saudis from making vaccination appointments; accordingly, health care officials are forced to carry

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[453] Mehak Srivastava, "Saudi Signs Agreement for German Vaccine" (online at 30 November 2020) *Meed* <https://www.meed.com/saudi-pharma-firm-signs-agreement-with-german-vaccine-provider>.
[454] Jumana Al-Tamimi, "Arab Region Prepares for Prompt COVID-19 Vaccine Distribution" (online at 25 August 2020) *Arab News* < https://www.arabnews.com/node/1724526/middle-east (arabnews.com)>.
[455] Reuters, "Saudi Arabia to Receive 3 Million Doses of Vaccine from Serum Institute in a Week" (online at 26 January 2021) *Business Today* <https://www.businesstoday.in/latest/world/story/saudi-arabia-to-receive-3-million-doses-of-vaccine-from-serum-institute-in-a-week-285546-2021-01-26>.
[456] Jason Beaubien, "Price Check: Nations Pay Wildly Difference Prices for Vaccines" (online at 19 February 2021) *NPR* <https://www.npr.org/sections/goatsandsoda/2021/02/19/969529969/price-check-nations-pay-wildly-different-prices-for-vaccines?utm_campaign=storyshare&utm_source=twitter.com&utm_medium=social&t=1614345696192>.
[457] Oliver Holmes, "Brazil, Saudi Arabia and Morocco 'told of delay in Covid jabs from India'" (online at 21 March 2021) *The Guardian* <https://www.theguardian.com/world/2021/mar/21/brazil-saudi-and-morocco-told-of-delay-in-covid-jabs-from-india>.
[458] Ibid.
[459] Varun Godinho, "Saudi Arabia Acknowledges Delays in Receiving Pfizer-BioNTech Covid-19 Vaccine" (online at 21 January 2021) *Gulf Business* <https://gulfbusiness.com/saudi-arabia-acknowledges-delays-in-receiving-pfizer-biontech-covid-19-vaccine/>.

out large-scale information campaigns in order to refute false claims related to vaccines.[460] Although the instrument of direct negotiations with vaccine suppliers helped the Kingdom to secure a sufficient number of vaccine doses for its population, the pace of its vaccination campaign remains moderate due to vaccine hesitancy patterns. The rise of vaccine hesitancy as well as occasional supply chain disruptions of the existing vaccine suppliers might be an important reason behind the country's willingness to negotiate agreements with other vaccine manufacturers besides Pfizer and AstraZeneca

In particular, in addition to products from AstraZeneca and Pfizer, the country also recently authorized the use of Moderna vaccines. This company signed a contract with Tabuk Pharmaceutical to sell COVID-19 shots in the Kingdom, thus providing residents with an opportunity to use its vaccine as an alternative to AstraZeneca and Pfizer's products.[461] Furthermore, as it is known, testing of the Sinovax candidate is still ongoing; therefore, it is possible that this vaccine will be also integrated into the Kingdom's vaccination campaign. In addition to hoarding vaccines for its use within the country, Saudi Arabia also participates in global campaigns aimed at expanding vaccination campaigns in low-income countries. In particular, the government is currently engaged in negotiations with pharmaceutical companies concerning the supply of vaccines to Yemen.[462] This issue is crucial from the perspective of the problem under investigation because it illustrates that even though parallel importing is a valid option for supplying vaccines to low-income countries, countries still prefer discussing this issue directly with vaccine manufacturers in order to prevent possible misunderstandings and potential vaccine supply disruptions in the future.

6.2. Participation of Saudi Arabia in the COVAX Program

The Kingdom of Saudi Arabia is known as one of important partners of Gavi. The organization's official website describes Saudi Arabia as "a major donor and a key partner in international development" and adds that "more than 95 developing countries in Asia, Africa, and other regions of the world have benefited from their aid".[463] The state provides financial assistance through the Saudi Fund for Development and contributes to international and regional development by supporting such institutions as the World Bank, the Islamic Development Bank, the OPEC, and many other organizations.[464] In light of the country's cooperation with Gavi long before the pandemic, it is natural that Saudi Arabia became one of important partners of the COVAX program. The state is

[460] Deema Al-Khudair, "We must end this nightmare: Saudis speak out against vaccine rumors" (online at 20 March 2021) *Arab News* <https://www.arabnews.com/node/1828916/saudi-arabia>.
[461] Business Wire, "Moderna and Tabuk Pharmaceuticals Partner to Commercialize Moderna's COVVID-19 Vaccine in Saudi Arabia" (online at 11 June 2021) *Business Wire* <https://www.businesswire.com/news/home/20210611005274/en/Moderna-and-Tabuk-Pharmaceuticals-Partner-to-Commercialize-Moderna%E2%80%99s-COVID-19-Vaccine-in-Saudi-Arabia>.
[462] Reuters, "Saudi Arabia in Talks with Vaccine Companies to Provide Vaccines to Yemen, Africa" (online at 26 January 2021) *Reuters* <https://www.reuters.com/article/uk-davos-meeting-saudi-finmin-idUSKBN29V0XR>.
[463] Gavi, "Kingdom of Saudi Arabia" (online at 2021) *Gavi* <https://www.gavi.org/investing-gavi/funding/donor-profiles/kingdom-saudi-arabia>.
[464] Ibid.

known as a major support of the program. In June 2020, it pledged $150 million to the organization to support the COVAX project.[465] This figure is relatively high in comparison with the majority of other countries. Only the United States, Germany, the United Kingdom, Swede, Japan, and Canada made larger donations. Moreover, the European Union, which comprises 27 countries, made the total contribution of $477 million, which is only around three times higher than the contribution of the Kingdom.[466] Therefore, Saudi Arabia plays an active role in funding COVAX arrangements.

As a high-income country with a substantial negotiating capacity and extensive resources, the Kingdom could afford entering in direct negotiations with developers of prospective vaccines. Nonetheless, the state still utilized COVAX as an additional source of vaccine supplies. In particular, in January, it received around 500,000 doses of Pfizer vaccines through the COVAX facility, which were used to facilitate the vaccination campaign that had been started in December.[467] The available evidence provides a premise to believe that the utilization of the COVAX facility was a natural part of the state's vaccination strategy that implied exploring all the potential options. In 2020, the country was examining different channels of vaccine supplies, including CureVac, Sputnik V, Sinovax, and other prospective candidates. The COVAX facility was, in this situation, one of many avenues used by the Saudi government.

Over time, it became evident that the COVAX facility would not become a crucial source of supplies for the Kingdom. Therefore, the state's participation in this program should be now primarily explored from the perspective of the country's attempt to increase its regional and international power by facilitating the delivery of vaccines to developing and least-developed nations in the Arab region. In particular, the Kingdom's Crown Prince recently announced a $1 billion grant that is supposed to fund African countries' measures against COVID-19, including the purchasing of vaccines.[468] Such a grant as well as the continuous involvement with the COVAX program are important for the Kingdom's regional ambitions. Woertz and Yellinek referred to Saudi Arabia as a representative of the "middle group" of MENA states in terms of vaccine diplomacy, arguing that it could not use vaccine diplomacy to the same extent as the United Arab Emirates or Turkey.[469] However, an overview of recent trends provides a compelling reason to believe that the situation might dramatically change, allowing the Kingdom to become one of the leaders of the Arab world in terms of leveraging vaccine diplomacy into maximizing power.

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[465] Ibid.
[466] Niall McCarthy, "The Governments Donating the Most Money to COVAX" (online at 5 May 2021) *Statista* <https://www.statista.com/chart/24244/donations-to-covax-by-country/>.
[467] IANS, "Saudi Arabia Receives over Half a Million Doses of Covax" (online at 1 January 2021) *Health World* <https://health.economictimes.indiatimes.com/news/industry/saudi-arabia-receives-over-half-a-million-doses-of-covax/80058797>.
[468] Mariam Nihal, "Saudi Arabia Grants $1Bn to Help African Countries Fight Covid-19" (online at 19 May 2021) *The National News* <https://www.thenationalnews.com/gulf/saudi-arabia/saudi-arabia-grants-1bn-to-help-african-countries-fight-covid-19-1.1225365>.
[469] Eckart Woertz and Roie Yellinek, "Vaccine Diplomacy in the MENA Region" (online at 14 April 2021) *MEI* <https://www.mei.edu/publications/vaccine-diplomacy-mena-region>.

6.3. An Analysis of the Saudi Government's Negotiations with Vaccine Developers: The Role of Political, Economic, and Legal Factors

As explained in this section, the Kingdom engaged in negotiations with many different manufacturers in 2020 in an attempt to secure the maximum number of doses of prospective vaccines for its population. Some of these negotiations, such as those concerning CureVac and Pfizer vaccines, were conducted with pharmaceutical companies. In particular, the government used to negotiate vaccine deals with Pfizer Inc., Moderna Inc., and CureVac N.V. These negotiations were likely to revolve around supply-related and pricing-related issues. In particular, as it is known, the state's negotiations with the Serum Institute of India ended in an agreement at $5 per a vaccine dose, which was higher than the price paid by the European Commission.[470]. At the same time, some other negotiations were fundamentally different due to the incorporation of broader economic and even political factors. In particular, as it is known, the Russian Federation uses its Sputnik vaccine as an instrument of maximizing regional and international power, often linking vaccine-related negotiations to negotiations concerning other issues within the framework of a soft power strategy.[471] Therefore, negotiations concerning the supply of the Russian vaccine to Saudi Arabia were likely to occur on the state-to-state rather than on the country-firm level. Similar assumptions could be also made in regard to the state's negotiations with China concerning the testing of Sinovax vaccines, which, as it is known, are also used by the PCR as an instrument of soft power.

At the same time, whilst negotiations concerning Sinovax and Sputnik vaccines were likely to be framed in line with political negotiations, these two vaccines were not eventually approved for use in the Kingdom. Therefore, the discussion of these negotiations is hardly relevant from the perspective of the problem under investigation. In contrast, the Saudi government's negotiations with Pfizer, Moderna, and AstraZeneca should be analyzed in detail in order to enrich understanding of the factors driving the relationship between Saudi Arabia and vaccine developers. One of the most important observations that should be made in this sphere is that the state primarily employs the instrument of direct negotiations with vaccine manufacturers in an attempt to secure a sufficient number of doses for its population. Such a pattern seems natural considering the status of Saudi Arabia as a high-income country. Its high negotiating power predetermines the Kingdom's advantageous position.

6.4. Treaties Signed by Saudi Arabia Relating to Vaccine Supplies

6.4.1. An Overview of Investment Treaties that Could Affect Regulation of Vaccine-Related IP Rights

[470] Jason Beaubien, "Price Check: Nations Pay Wildly Difference Prices for Vaccines" (online at 19 February 2021) *NPR* <https://www.npr.org/sections/goatsandsoda/2021/02/19/969529969/price-check-nations-pay-wildly-different-prices-for-vaccines?utm_campaign=storyshare&utm_source=twitter.com&utm_medium=social&t=1614345696192>.
[471] Michael Leigh, "Vaccine Diplomacy: Soft Power Lessons from China and Russia?" (online at 27 April 2021) *Bruegel* <https://www.bruegel.org/2021/04/vaccine-diplomacy-soft-power-lessons-from-china-and-russia/>.

An analysis of bilateral investment treaties that were signed by the Kingdom of Saudi Arabia does not indicate any essential barriers to vaccine supply in the country. Furthermore, the available evidence provides a compelling reason to believe that bilateral investment treaties signed by the Kingdom might serve as a powerful incentive encouraging companies to supply vaccines to the state. A recent article by Khachvani assumes that if the international community approves the TRIPS waiver that lifts patent protection and facilitates technology transfer and access to know-how, pharmaceutical companies could rely on investment law for protecting their investments by arguing that any actions associated with such a waiver violate the terms of bilateral investment treaties or treaties with investment provisions.[472] Because of this reason, discussion of bilateral investment treaties and treaties with investment provisions from the perspective of obtaining vaccine supplies is critical for exploring the problem under investigation.

In accordance with the World Health Organization, there are currently 24 countries that are producing vaccines and have functional National Regulatory Authorities.[473] Serbia, Mexico, and Iran produce vaccines that are not WHO prequalified; therefore, it seems highly unlikely that Saudi Arabia would express interest in such products. The remaining 21 countries are engaged in vaccine manufacturing; accordingly, bilateral investment agreements with these countries as well as treaties with investment provisions could be regarded relevant from the perspective of the problem under investigation. However, the majority of these countries produce only slight numbers of doses; therefore, their companies could hardly export vaccines to Saudi Arabia. It does not seems necessary to discuss the cases of these countries in detail given that any scenarios in which companies from these countries could export COVID-19 vaccines to the Kingdom are implausible. After analyzing data on the number of vaccine doses produced by various countries, it was decided to focus on only those countries that have produced at least 150,000 doses by August 2021. The table below summarizes information about these countries and introduces investment agreements signed by Saudi Arabia with these countries that will be discussed in the next sections of the study.

Table 1. *Investment Agreements between Saudi Arabia and Countries Producing COVID-19 Vaccines*

Country	**Number of COVID-19 Doses Produced**	**Investment Agreements with Saudi Arabia**
China	141,624,000	China - Saudi Arabia BIT (1996)
The United States	103,000,000	Saudi Arabia – US TIFA
Germany	70,534,055	Germany - Saudi Arabia BIT (1996)

[472] David Khachvani, "Can Pharmaceutical Companies Counter the Waiver of Their Patents for COVID-19 Vaccines through Investment Treaty Arbitration?" *Kluwer Arbitration Blog* <http://arbitrationblog.kluwerarbitration.com/2021/05/26/can-pharmaceutical-companies-counter-the-waiver-of-their-patents-for-covid-19-vaccines-through-investment-treaty-arbitration/>.

[473] World Health Organization, "List of Vaccine Proudcing Countries with Functional NRAs" (online at WHO <https://www.who.int/initiatives/who-listed-authority-reg-authorities/list-of-vaccine-prod-countries>.

Belgium		BLEU (Belgium-Luxembourg Economic Union) - Saudi Arabia BIT (2001)
India	42,390,000	India - Saudi Arabia BIT (2006) was terminated
The United Kingdom	12,200,000	-
Netherlands	10,496,982	-
Belgium		BLEU (Belgium-Luxembourg Economic Union) - Saudi Arabia BIT (2001)
Russia	10,492,500	-
Switzerland	5,462,338	Saudi Arabia - Switzerland BIT (2006)
South Korea	1,617,000	Korea, Republic of - Saudi Arabia BIT (2002)
Brazil	200,000	-
South Africa	160,000	-

As the table shows, the number of agreements that could be analyzed in this study is relatively low. Furthermore, the BIT with India was unilaterally terminated by the government of India in 2017 in response to the growing number of investor-state claims.[474] The new model BIT adopted by India adopted more restrictive definitions of "investments" and "investors", excluded taxation from the scope of possible claims, eliminated the "fair and equitable treatment" standard, and introduced other measures limiting the country's exposure to possible investor-state disputes.[475] The state started signing new BITs with various countries instead of terminated ones; however, it still has not signed a new agreement with Saudi Arabia to date. Therefore, the supplies of AstraZeneca vaccines from the Serum Institute are currently not regulated by bilateral investment treaties between India and Saudi Arabia.

Saudi Arabia signed a number of treaties with investment provisions that could affect regulation of vaccine-related IP rights. However, most of them, such as the GCC-United States Framework Agreement, GCC-EFTA FTA, and GCC-India Framework Agreement, are currently not

[474] Herbert Smith Freehills, "Mixed Messages to Investors as India Quietly Terminates Bilateral Investment Treaties with 58 Countries" (online at 16 March 2017) *Herbert Smith Freehills* <https://hsfnotes.com/arbitration/2017/03/16/mixed-messages-to-investors-as-india-quietly-terminates-bilateral-investment-treaties-with-58-countries/>.
[475] Herbert Smith Freehills, "Indian International Arbitration E-Bulletin" (online at 16 March 2017) *Herbert Smith Freehills* < https://sites-herbertsmithfreehills.vuturevx.com/33/10790/landing-pages/key-features-of-the-model-bit.asp>.

in force. Most other treaties, at the same time, were signed with Arab countries, which are not among COVID-19 vaccine manufacturers. Therefore, the only treaty with investment provisions that might be relevant to the problem under investigation is the Agreement with the United States Concerning the Development of Trade and Investment Relations.[476] However, its close examination demonstrates that the document's content is not pertinent to regulation of vaccine-related rights. The treaty mentions IP rights in a broad manner, "recognizing the importance of providing adequate and effective protection and enforcement of intellectual property rights".[477] However, it does not include any specific clauses that would affect IPR protection. As explained in the third chapter, this agreement could be rather regarded as a basis for further negotiations between the United States and the Kingdom of Saudi Arabia than a final agreement.

6.4.2. Scope and Definitions

Bilateral investment treaties with South Korea, Switzerland, Belgium-Luxemburg Economic Union, Germany, and China hardly introduce any unusual provisions that could substantially affect vaccine supplies. The scope and definitions of these agreements are similar. All of them utilize the same asset-based definition of investment stating that investment is "any kind of asset, owned or controlled by an investor of a Contracting Party in the territory of the other Contracting Party according to its laws and regulations"[478], which is followed by a non-exhaustive list of the types of investments. From the perspective of the problem under investigation, it is crucial to emphasize that since the agreements do not set out closed lists of covered assets and do not list required characteristics of investment, pharmaceutical companies are unlikely to face difficulties with arguing that their products could be considered as eligible investments under the terms of treaties. Such an issue is crucial given the potential of investment law to serve as an additional layer protecting companies' IP rights in case of the introduction of the TRIPS waiver.

Interestingly, an agreement with Switzerland does not include the "in accordance with host State laws" requirement, whereas all the other four agreements contain such a provision. It was explained in the third chapter of the thesis that the Saudi legislation system is unusual and dynamic since local courts used to refer to uncodified Sharia before 2018 and sometimes referred to traditions rather than laws in making their decisions, such as in case with a request to take an administrative action prior to taking a case to the court.[479] Therefore, investors from Switzerland, including Lonza,

[476] Agreement Between the Government of the Government of the United States of America and the Government of the Kingdom of Saudi Arabia Concerning the Development of Trade and Investment Relations.
[477] Ibid.
[478] Agreement between the Government of the Republic of Korea and the Government of the Kingdom of Saudi Arabia Concerning the Reciprocal Encouragement and Protection of Investments.
[479] Jan Michiel Otto, *Sharia Incorporated: A Comparative Overview of the Legal Systems of Twelve Muslim Countries in Past and Present* (Leiden 2010) 161.

which manufacturers Moderna vaccines[480], are less likely to face unexpected legal complications in Saudi Arabia than companies representing other states due to the absence of the "in accordance with host State's laws" provision in the BIT between Switzerland and Saudi Arabia.

An analysis of the BITs does not reveal any differences between the treaties in terms of defining investors. All of them provide the following definition of investors in respect to Saudi Arabia: "any entity having or having no legal personality and constituted in accordance with the law of the Kingdom of Saudi Arabia and having its head office in its territory such as corporations, cooperatives, enterprises, companies, institutions, offices, establishment, funds, organizations, business associations and other similar entities irrespective of whether or not they are of limited liability".[481] None of them includes permanent residents and excludes dual nationals; moreover, they do not include requirements pertaining to substantial business activities and do not define ownership and control of legal entities. The last two features are critical because, as it is known, they might sometimes act as barriers to investor-state arbitration.[482] In general, none of the provisions in regard to the definition of investors or investments threaten pharmaceutical companies' vaccine-related IP rights. In contrast, they provide them with an opportunity to use protection layers outlined in the agreements to seek protection under investment law in case of IPR breaches or the TRIPS waiver.

The treaties' clauses pertaining to the denial of benefits, a substantive scope of the treaty, and a temporal scope of the treaty are identical except for the fact that the BIT with Switzerland carves out pre-existing disputes. None of the treaties excludes taxation, subsidies, government procurement, and other subject matters from the scope of treaties, which could be considered a positive sign for vaccine developers. Furthermore, the treaties cover both pre- and post-BIT investments and do not include denial of benefits provisions. In comparison with many other BITs, such as new BITs signed by India, the provisions reviewed above could be considered liberal, as they do not introduce any restrictions on investors that could negatively affect the success of their arbitration claims.

6.4.3. Standards of Treatment

All the five treaties under investigation guarantee both national and most-favored-nation treatment to investors. Standards of national treatment provide a relatively high degree of protection; therefore, it is not present in many BITs signed by other countries. The existence of this clause in the text of BITs is a positive factor for investors. Simultaneously, none of them specifies "like circumstances" for comparing investors and local entities, thus adding ambiguity to the justification of possible investor-state claims under the national treatment framework. All the five treaties reviewed

[480] John Miller, "Help Wanted: Lonza Seeks Workers to Lift Moderna Vaccine Output" (online at 29 April 2021) *Reuters* <https://www.reuters.com/business/healthcare-pharmaceuticals/switzerlands-lonza-boost-production-moderna-covid-19-vaccine-2021-04-29/>.
[481] Agreement between the People's Republic of China and the Kingdom of Saudi Arabia on the Reciprocal Promotion and Protection of Investments.
[482] Giovanni Zarra, "The Issue of Incoherence in Investment Arbitration: Is There Need for a Systematic Reform?" (2018) 17 *Chinese Journal of International Law* 137-185.

above have a post-established most-favored-nation treatment provision and use the same exceptions from its scope, including economic integration agreements and taxation treaties. Such a practice is common in BITs[483] and is not indicative of any peculiarities that could affect regulation of vaccine-related IP rights in the country.

The fair and equitable treatment, which is guaranteed in all the BITs, is also described using the same language. Some Saudi BITs, such as the one with Japan, have explicit references to international law in their fair and equitable treatment clauses. Such an issue could provide an additional layer of protection for vaccine developers. However, none of the five BITs analyzed in this section has a link to international law in its fair and equitable treatment provisions; therefore, pharmaceutical companies could not expect preferential treatment based on the FET clause.[484] Simultaneously, it is important to note that vaccine manufacturers from Switzerland still enjoy a higher level of protection because their FET is combined with the national and most-favored-nation treatment clauses.

6.4.4. Relevance of Other Clauses for the Regulation of Vaccine-Related IP Rights

All the five agreements guarantee the full protection and security of investors and prohibit unreasonable, arbitrary, or discriminatory measures. They use the same definitions of expropriation and set the same criteria that should be met in order to expropriate assets, including the Contracting Party's public benefit, a prompt, adequate, and effective compensation, conformity to domestic laws, and a non-discriminatory nature. Interestingly, indirect expropriation is not defined in any treaties reviewed above; furthermore, none of them carves out compulsory licenses from the scope of indirect expropriation. This issue is important because it provides vaccine manufacturers with an opportunity to claim an adequate compensation under investment law in case if the Saudi government issues a compulsory license for their products.

Saudi BITs with South Korea, Switzerland, the Belgium-Luxemburg Economic Union, Germany, and China do not prohibit performance requirements. In doing so, they follow the traditional approach that is also utilized by the overwhelming majority of other BITs except for some U.S., Canadian, and Japanese ones. The absence of such clause provides the country with an opportunity to issue requirements concerning the transfer of knowledge, technology, or production processes.[485] At the same time, the presence of this prohibition could have acted as a strong protection

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[483] Tomy Cole, "The Boundaries of Most Favored Nation Treatment in International Investment Law" (2012) 33 *Michigan Journal of International Law* 537-586.
[484] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.
[485] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *WTI* <https://www.wti.org/media/filer_public/16/eb/16eb7c2b-ded4-4d92-b030-53b4b32eb2f9/protection_of_iprs_through_bits_bboie.pdf>.

layer for vaccine manufacturers preventing the Saudi government from accessing their know-how and exclusive data. By applying this principle, they could elevate contract claims to the level of treaty claims, thus invoking treaty protection mechanisms.

An analysis of other terms of the treaties shows the absence of any major differences between them. All the five documents include subrogation and non-derogation clauses. Whereas the subrogation clause is irrelevant to the problem under investigation, the non-derogation provision has slight relevance, as it ensures that more favorable rules will apply to investors in case of a conflict between provisions of different treaties or laws. None of the treaties includes any transparency clauses; moreover, there are no clauses in regard to the health and environment, labor standards, rights to regulation, corporate social responsibility, corruption, reference to specific investment promotion activities, and a prohibition to lower standards. The documents do not include exhaustive lists of security exceptions and general public policy exceptions. An analysis of the treaties' text does not reveal any unusual clauses that should be discussed in detail in order to enrich understanding of the regulation of vaccine-related IP rights in Saudi Arabia under BITs.

6.4.5. Dispute Settlement

All the BITs offer the same clauses in regard to investment-state dispute settlement except for the relationship between forums. They do not offer mediation or conciliation instruments, cover all the disputes related to investments, and do not utilize constraints to limit the scope of investment-state dispute settlement. Saudi BITs allow investors to put their claims in front of domestic courses as well as use the ICSID framework, whilst the UNCITRAL forum and other forums are not mentioned. The only difference between the five agreements in terms of their description of investment-state dispute settlement mechanisms is related to the relationship between forums. The agreements with South Korea and the Belgium-Luxemburg Economic Union apply the "fork in the road" principle, requiring investors to choose either domestic courts or the ICSID framework. Simultaneously, three other agreements are inconclusive on this matter, apparently suggesting that investors could use both forums.

In general, the available evidence provides a premise to believe that there are no major difference between the Saudi BITs with Switzerland, the Belgium-Luxemburg Economic Union, South Korea, China, and Germany. Pharmaceutical companies from Switzerland could enjoy a higher level of protection due to the absence of the "in accordance with host State's laws" provision in the BIT with Switzerland and the fact that this document links the FET clause to most-favored-nation and national treatment provisions. At the same time, it should be noted that firms from South Korea and Belgium could simultaneously use domestic courts and the ICSID forum for settling investor-state disputes, whilst enterprises from Switzerland, China, and Germany could use only one of these mechanisms. Despite the slight differences outlined above, there is no premise to believe that none of them is fundamental from the perspective of the problem under investigation. All the treaties analyzed above provide similar protection layers to vaccine manufacturers, allowing them to protect their assets

and know-how even in case of the TRIPS waiver. Simultaneously, none of the agreements includes any TRIPS-plus provisions, such as restrictions on compulsory licenses, prohibition of parallel importing, and prohibitions of performance requirements. Thus, IPR protection guaranteed by these BITs does not offer higher layers of protection than those offered by the TRIPS Agreement. There is no evidence to claim that investment law could provide vaccine manufacturers or distributers with an opportunity to protect their rights in front of different forums in a way that is superior to the channels offered by the TRIPS Agreement except for the fact that the sole existence of ISDS mechanisms provides companies with a leverage in negotiations with the Saudi government.

6.5. Difficulties in Implementation of the System of IPR Protection in Saudi Arabia

In order to enrich understanding of the IPR perspective of the vaccine market in Saudi Arabia, it is crucial to point at problems with enforcing laws related to the system of IPR protection in the country. As explained in the third chapter of the thesis, the current IPR system in the country is weak. The country regularly appears in the Priority Watch List of the Office of the United States Trade Representative.[486] A recent report criticizes the state for failing to ensure protection of both unfair commercial use of products and services and of unamortized disclosure of sensitive data that are necessary for obtaining a marketing approval.[487] Such concerns are undoubtedly relevant from the perspective of the problem under investigation because, as stated above, test data contain unique know-how that is mandatory for launching manufacturing of vaccines. Accordingly, any threats to the security of such information could be considered critical.

Recent cases in 2016 and 2017 illustrate difficulties related to the protection of health-related intellectual property rights in the Kingdom. As it is known, the government authorized local companies to produce generic versions of innovative pharmaceutical products by providing them with test and other data that were submitted during the marketing approval process; furthermore, a tender was issued to a generic manufacturer in 2018 for the production of a drug that was still covered by patent protection at the time.[488] Whereas the well-known BeoutQ case[489] could be explained by the rivalry with Qatar in addition to difficulties with enforcing IPR laws, the cases outlined above indicate evident threats to pharmaceutical companies operating in the country.

Simultaneously, it is important to emphasize that despite these difficulties, large pharmaceutical companies continued expanding their operations in the Kingdom before the COVID-19 crisis. In particular, Pfizer signed an agreement with Tabuk Pharmaceuticals in 2017 to strengthen

[486] The United States Trade Representative, "2019 Special 301 Report" (online at April 2019) *USTR* <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf>.
[487] Ibid.
[488] Ibid.
[489] The United States Trade Representative, "2019 Special 301 Report" (online at April 2019) *USTR* <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf>.

its manufacturing capabilities in the country by starting at a $50 million plant.[490] Similarly, Moderna also recently reached an agreement with the same company for selling its vaccines in the Kingdom.[491] These examples show that while being cautious about possible IPR breaches in the country, large pharmaceutical companies readily approach the Saudi market due to its substantial size and a large demand on pharmaceutical products.

6.6. Conclusion

The Saudi vaccination campaign is being implemented at an adequate pace, although the country lags behind some other nations in the region, such as Israel and the UAE. The government was negotiating with various vaccine manufacturers in 2020; however, eventually, it focused on Pfizer/BioNTech and AstraZeneca as the main sources of vaccine supplies. The key barriers inhibiting swift vaccination of the population include vaccine hesitancy and supply chain disruptions. Participation in the COVAX program plays an essential role in the Saudi vaccination campaign. The country contributed $150 million to the COVAX Facility, using it both as a source of vaccine supplies and as an instrument of strengthening its influence on the international arena. Over time, the state engaged in negotiations with many different countries and pharmaceutical companies. However, most of these negotiations are hardly relevant nowadays because the state mainly relies on Pfizer and AstraZeneca vaccines now, although the regulatory body has also recently approved Moderna.

Saudi Arabia signed many investment treaties with countries that have significant manufacturing capacity and are engaged in the manufacturing of COVID-19 vaccines. BITs signed with South Korea, Switzerland, the Belgium-Luxembourg Economic Union, Germany, and China include standard clauses without any TRIPS-plus provisions. The "in accordance with a host State's laws" clause might potentially become a source of uncertainty for pharmaceutical companies from all the countries except for Switzerland, but this provision could hardly constitute a substantial problem from the perspective of the research object of this thesis. All the agreements offer national and most-favored-nation treatment to investors. At the same time, it should be noted that the treaty with Japan includes explicit references to international law in the FET clause, thus offering a higher level of protection. The treaties' expropriation clauses are standard and cover the issuing of compulsory licenses are issued. None of the treaties prohibits performance requirements. Certain differences between the agreements exist in relation to ISDS mechanisms, such as the option of using both domestic courts and international forums simultaneously. Nonetheless, it could be concluded that none of the treaties introduces TRIPS-plus rules that could significantly affect regulation of vaccine-

[490] U.S. – Saudi Business Council, "Pfizer Signs Commercial Agreement with Tabuk Pharmaceuticals" (online at 16 February 2017) *U.S. – Saudi Business Council* <https://ussaudi.org/pfizer-signs-commercial-agreement-with-tabuk-pharmaceuticals/>.

[491] Business Wire, "Moderna and Tabuk Pharmaceuticals Partner to Commercialize Moderna's COVVID-19 Vaccine in Saudi Arabia" (online at 11 June 2021) *Business Wire* <https://www.businesswire.com/news/home/20210611005274/en/Moderna-and-Tabuk-Pharmaceuticals-Partner-to-Commercialize-Moderna%E2%80%99s-COVID-19-Vaccine-in-Saudi-Arabia>.

related IPRs. A similar observation could be also made after analyzing the trade agreement with the United States, as this treaty presents a general framework for further negotiations between the states without offering specific provisions that could affect IPRs.

None of the treaties signed by Saudi Arabia limits the government's ability to protect the population's health. The documents analyzed in this chapter do not introduce additional restrictions beyond those offered by the TRIPS Agreement and, thus, do not have a major impact on the balance of parties' interests and rights in the Kingdom in regard to the regulation of vaccine-related IP rights. Possible areas of divergence between the TRIPS Agreement and some BITs reviewed in the section are slight and, thus, are hardly relevant from the perspective of the problem under investigation.

CHAPTER 7. OBTAINING VACCINE SUPPLIES IN AUSTRALIA: RECENT DEVELOPMENTS AND THE IPR PERSPECTIVE

7.0. Introduction

The seventh chapter of the thesis discusses the problem of obtaining vaccine supplies in Australia from the IPR perspective and in light of the COVID-19 pandemic. It starts with outlining the vaccination campaign's milestones in Australia and explaining the reasons behind its relatively slow pace. The second subsection discusses the role of the COVAX program in the Australian vaccination strategy as well as the use of the COVAX Facility in the state's "vaccine diplomacy". Critical examination of investment treaties and free trade agreements signed by Australia with countries that are currently manufacturing COVID-19 vaccines could be found in the third subsection. The scope of the analysis covers the bilateral investment treaty with China and free trade agreements with South Korea, the United States, and China. The chapter emphasizes that the free trade agreement with the United States is the most important document analyzed in this thesis since it includes a variety of essential TRIPS-plus rules that could have a major effect on the ability of Australia to obtain vaccine supplies.

7.1. An Overview of Recent Developments in Obtaining Vaccine Supplies in Australia

Australia has been implementing its vaccination campaign at a moderate pace. By August 31, 2021, only 55.71% of its population received at least one vaccine dose, which is higher than the world's average percentage (42.55%).[492] Whereas the country's progress in this field lags behind the achievements of many developed countries, such as Canada, Israel, Italy, and the United States, which have administered at least one dose to 74.83%, 68.89%, 72.87%, and 62.64% of residents respectively by August 31, the Australian campaign seems slow even in comparison with many developing states, such as Saudi Arabia, Brazil, and Uruguay, which vaccinated 62.86%, 63.37%, and 76.49% of their populations respectively by August 31.[493] By the end of August, only 7.17 million people in Australia were fully vaccinated against COVID-19, which constitutes a little more than 27.80% of the population.[494] In general, it seems justified to assume that the pace of the Australian vaccination campaign remains slower than the pace of vaccination campaigns in most other developed and even some developing states.

Such an outcome seems surprising. Significant wealth of Australia and early negotiations with vaccine suppliers provided experts with a premise to assume that the state would be one of the leading

[492] Our World in Data, "Coronavirus (COVID-19) Vaccinations" (online at 31 August 2021) *Our World in Data* <https://ourworldindata.org/covid-vaccinations>.
[493] Ibid.
[494] Ibid.

nations in the world in terms of vaccination.[495] However, the data suggest that the state failed to meet its own vaccination targets. In particular, Australia managed to administer 4 million doses by 28 May, even though the government had planned to reach this number by the end of March.[496] There is no agreement among experts concerning the reasons behind this situation. Harvey, Koloff, and Wiggins argue that the government failed to implement a consistent strategy from the start, emphasizing that unlike the U.S. and UK governments, the Australian government pre-ordered an insufficient number of vaccine doses from a limited range of suppliers.[497] Kay believes that vaccine hesitancy is the most important cause of slow vaccination, as many Australians are unwilling to get vaccinated because of blood clot concerns.[498] At the same time, the article by Shields implies that supply chain problems and a decision of the European Commission to block the export of 250,000 vaccine doses to Australia negatively affected rollout, becoming a crucial barrier to the vaccination campaign's implementation.[499] It seems justified to assume that all these reasons are relevant from the perspective of the problem under investigation.

Despite the popular belief that Australia was one of the leading nations in the world in terms of its response to the COVID-19 crisis, the Australian government did not engage in negotiations with a significant number of pharmaceutical companies.[500] The US government launched extensive negotiations with multiple pharmaceutical companies in the middle of 2020 and then signed a $2 billion agreement with Pfizer and BioNTech in July; at the same time, the Australian government ordered the first vaccine doses only in September.[501] As Jane Halton, the Commonwealth health department's head, admits, "I was getting a little anxious, that we should strike some deals as well".[502] It is important to emphasize that the original strategy of the Australian government primarily relied on three sources: AstraZeneca, Novavax, and a local vaccine developed by the University of

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[495] Colin Packham, "Australia Expects to Receive Doses of Potential COVID-19 Vaccine Early Next Year" (online at 7 September 2020) *Global News* <https://globalnews.ca/news/7319955/australia-coronavirus-vaccine/>.

[496] Jewel Topsfield and Craig Butt, "Why Has the Vaccine Rollout Been so Slow?" (online at 30 May 2021) *The Sydney Morning Herald* <https://www.smh.com.au/national/why-has-the-vaccine-rollout-been-so-slow-20210529-p57wao.html>.

[497] Adam Harvey, Sashka Koloff and Nick Wiggins, "How Australia's COVID Vaccine Rollout Has Fallen Short and Left Us 'in a Precarious Position'" (online at 23 May 2021) *ABC* <https://www.abc.net.au/news/2021-05-24/australia-covid-vaccine-rollout-what-went-wrong/100151396>.

[498] Byron Kaye, "After Early COVID-19 Response, Australia Stuck in Vaccine Slow Lane" (online at 2 July 2021) *Reuters* <https://www.reuters.com/world/asia-pacific/after-early-covid-19-response-australia-stuck-vaccine-slow-lane-2021-07-01/>.

[499] Bevan Shields, "Europe Blocks 250,000 AstraZeneca Vaccine Doses Bound for Australia" (online at 5 March 2021) *The Sydney Morning Herald* <https://www.smh.com.au/world/europe/europe-blocks-250-000-astrazeneca-doses-bound-for-australia-20210305-p577z3.html>.

[500] Stephen Duckett, "4 Ways Australia's COVID Vaccine Rollout Has Been Bungled" (online at 1 April 2021) *The Conversation* <https://theconversation.com/4-ways-australias-covid-vaccine-rollout-has-been-bungled-158225>.

[501] Ibid.

[502] Adam Harvey, Sashka Koloff and Nick Wiggins, "How Australia's COVID Vaccine Rollout Has Fallen Short and Left Us 'in a Precarious Position'" (online at 23 May 2021) *ABC* <https://www.abc.net.au/news/2021-05-24/australia-covid-vaccine-rollout-what-went-wrong/100151396>.

Queensland.[503] The available evidence provides a compelling reason to believe that the Australian government sought to focus on those vaccines that could have been produced locally. As the Health department's secretary explained, "we are one of the few countries in the world that can make vaccines, and as we have seen now, the only vaccine that we have got plentiful supply is one of the ones that we are making locally".[504] Such a strategy apparently aimed to prevent possible supply chain disruptions.

Unfortunately for Australia, the strategy failed. The administration of AstraZeneca vaccine doses to the population was slow because of supply chain disruptions and blood clot concerns.[505] The Novavax vaccine still has not passed all the necessary clinical trials; therefore, 51 million doses of these vaccine shots are unlikely to arrive to the country in the nearest future.[506] Finally, the development of a local vaccine at the University of Queensland was terminated after several volunteers from Phase 1 had been tested positive for HIV. Even though all these tests turned out to be "false positive", stakeholders terminated testing of the vaccine because the threat of being tested positive for HIV would have definitely discouraged Australians from using the vaccine.[507] As a result, at a certain point of time, the Australian government found itself in a situation when it was forced to look for other sources for obtaining vaccine supplies. Australia purchased 10 million doses of Pfizer vaccines in 2020.[508] Furthermore, the government signed a deal with Moderna for the delivery of 25 million doses, including 10 million doses in the end of 2021 and 15 million doses in 2022.[509] By the end of August, Australia managed to ensure sufficient supplies of vaccines.

Despite the benefits of AstraZeneca vaccines for Australia, especially the option of local production in Melbourne, its supply and administration were accompanied by substantial challenges. First, the state suffered from supply chain disruptions and the European Commission's decision to

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[503] Liam Mannix, "Did Australia Get Its Vaccine Strategy Right?" (online at 16 April 2021) *The Sydney Morning Herald* <https://www.smh.com.au/national/did-australia-get-its-vaccine-strategy-right-20210415-p57jey.html>.
[504] Adam Harvey, Sashka Koloff and Nick Wiggins, "How Australia's COVID Vaccine Rollout Has Fallen Short and Left Us 'in a Precarious Position'" (online at 23 May 2021) *ABC* <https://www.abc.net.au/news/2021-05-24/australia-covid-vaccine-rollout-what-went-wrong/100151396>.
[505] Ibid.
[506] Cassandra Berry, "Novavax Is Absent from Australia's 2021 Vacination Schedule. But It Could be a Useful Booster Later on" (online at 24 June 2021) *The Conversation* <https://theconversation.com/novavax-is-absent-from-australias-2021-vaccination-schedule-but-it-could-be-a-useful-booster-later-on-163014>.
[507] Rob Harris, "Australian COVID Vaccine Terminated due to HIV 'False Positives'" (online at 11 December 2020) *The Sydney Morning Herald* <https://www.smh.com.au/politics/federal/australian-covid-vaccine-terminated-due-to-hiv-false-positives-20201210-p56mju.html>.
[508] Prime Minister of Australia, "Media Release: Australia Secures a Further 50 Million Doses of COVID-19 Vaccine" (online at 5 November 2020) *Prime Minister of Australia* <https://www.pm.gov.au/media/australia-secures-further-50-million-doses-covid-19-vaccine>.
[509] Rod McGuirk, "Australia Signs Deal for 25M Moderna Doses through Next Year" (online at 13 May 2021) *AP News* <https://apnews.com/article/australia-coronavirus-pandemic-coronavirus-vaccine-business-health-a43e8b58564a373b14fa638eb20180d3>.

block the delivery of 250,000 doses to Australia.[510] Second, the pace of domestic production was disappointing, failing to meet the targeted number of 1 million doses per week.[511] Third, reports of blood clotting disorders and the death of two people in Australia negatively affected the public opinion on AstraZeneca. As a result, the Australian Technical Advisory Group on Immunization (ATAGI) announced recommendations to use the Pfizer vaccine for people under 60 years old, while many individuals who were about to receive AstraZeneca doses, including those older than 60 years, refuse from getting vaccinated.[512] However, an outbreak of the Delta forced ATAGI to change its recommendations. Now the body argues that "adults under the age of 60 who do not have immediate access to the Pfizer vaccine should consider the benefits and risks of earlier protection through the AstraZeneca vaccine".[513] Vaccine hesitancy within the Australian society, however, remains an important factor preventing the government from implementing its vaccination campaign swiftly and effectively.

Nowadays, Australia finds itself in a controversial situation from the perspective of vaccination. On one hand, the government ensured the supply and stocking of a sufficient number of vaccine doses for the population. On the other hand, the majority of them are either AstraZeneca shots, which are mostly used for vaccinating people who are older than 60 years old, or Novovax shots. The government indeed stockpiled substantial supplies of AstraZeneca vaccines, but most of them cannot be used in the vaccination campaign due to the reasons outlined above. As a result, Australia takes advantage of these supplies by integrating them into vaccine diplomacy strategies. In particular, the government recently announced that it would send 2.5 million doses to Indonesia as a part of the aid package.[514] The Novavax vaccine, at the same time, still has not been approved in the country. It remains unclear whether Novovax vaccines could be used in the Australian vaccination campaign because in spite of impressive results of test trials, the company experiences significant difficulties with maintaining consistency of the manufacturing process, supplying raw materials, and

[510] Bevan Shields, "Europe Blocks 250,000 AstraZeneca Vaccine Doses Bound for Australia" (online at 5 March 2021) *The Sydney Morning Herald* <https://www.smh.com.au/world/europe/europe-blocks-250-000-astrazeneca-doses-bound-for-australia-20210305-p577z3.html>.
[511] BBC, "What's Gone Wrong with Australia's Vaccine Rollout?" (online at 17 June 2021) *BBC* <https://www.bbc.com/news/world-australia-56825920>.
[512] Adam Harvey, Sashka Koloff and Nick Wiggins, "How Australia's COVID Vaccine Rollout Has Fallen Short and Left Us 'in a Precarious Position'" (online at 23 May 2021) *ABC* <https://www.abc.net.au/news/2021-05-24/australia-covid-vaccine-rollout-what-went-wrong/100151396>.
[513] Australian Government, "About the Vaxzevria (AstraZeneca) COVID-19 Vaccine" (online at 31 August 2021) *Australian Government: Department of Health* <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/learn-about-covid-19-vaccines/about-the-vaxzevria-astrazeneca-covid-19-vaccine#advice-from-atagi-about-the-use-of-the-astrazeneca-vaccine-in-the-context-of-an-outbreak-of-the-covid19-delta-strain>.
[514] Daniel Hurst, "Australia to Send 2.5m AstraZeneca Vaccine Doses to Indonesia as Covid Infections Soar" (online at 7 July 2021) *The Guardian* <https://www.theguardian.com/world/2021/jul/07/australia-to-send-25m-astrazeneca-vaccine-doses-to-indonesia-as-covid-infections-soar>.

ensuring efficiency of supply chains.[515] Therefore, it seems justified to assume that the country experiences certain problems with supplying its vaccination campaign, even though these problems could be hardly compared to the difficulties experienced by most developing and least developed states.

7.2. Participation of Australia in the COVAX Program

The Australian government participates in the COVAX Facility similarly with the way in which other developed countries take part in this project. The country joined the program on 23 September 2020.[516] The country's participation in the COVAX Facility comprises two parts. First, the government has made an upfront payment in the amount of $123.2 million, which is sufficient for purchasing 25 million doses of vaccines.[517] Such a substantial number of doses would be enough for vaccinating around a half of the population. From this perspective, Australia benefits from the COVAX Facility more than most other countries, as the common policy of the project is to provide enough doses for vaccinating 20% of the population. Second, Australia also agreed to pay $80 million to support vaccine accesses for countries with a low level of income.[518] Australia has been an integral part of the COVAX Facility from its start and remains one of the most important actors.

At the same time, it should be noted that whereas Australia has become one of the earliest supporters of the COVAX program, its financial contributions to the project remain limited. By the end of May, 2021, the state only contributed A$3.07 per capita to the program in line with its initial commitment of A$80 million.[519] In contrast, the United States, Canada, the United Kingdom, and Germany contributed A$9, A$7, A$14, and A$18 per capita respectively.[520] There is currently no information about Australia's plans to extend its participation in the COVAX Facility beyond its current commitments; therefore, it is possible that this gap will increase even more.

The available evidence provides a compelling reason to believe that participation in the COVAX Facility is to a large extent a political matter for Australia. As it is known, a high level of tension in the Asia-Pacific region increases the competition between China and the United States, while also creating substantial challenges for Australia, Japan, and the ASEAN bloc, which is

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[515] Kevin Dunleavy, "Novavax's COVID-19 Shot Won't See Much U.S. Use, but a Big Global Market Awaits: Analyst" (online at 22 June 2021) *Fierce Pharma* <https://www.fiercepharma.com/pharma/novavax-covid-19-vaccine-delays-will-impact-u-s-uptake-but-big-global-market-still-awaits>.
[516] Gavi, "Australia" (online at 17 July 2021) Gavi <https://www.gavi.org/investing-gavi/funding/donor-profiles/australia>.
[517] The Australian Government Department of Health, "Australia's Vaccine Agreements" (online at 2021) *The Australian Government: Department of Health* <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/covid-19-vaccine-government-response/australias-vaccine-agreements>.
[518] Ibid.
[519] Dane Moores, "COVAX Summit: Time for Australia to Recommit to Global, Bot just Regional, Vaccine Equity" (online at 31 May 2021) *Devpolicy Blog* <https://devpolicy.org/covax-summit-time-for-australia-to-recommit-to-global-not-just-regional-vaccine-equity-20210531/>.
[520] Ibid.

approached by all the parties in an attempt to expand regional influence.[521] The Australian government views the COVID-19 crisis as a promising opportunity for expanding its influence in the region, which is evident in its Vaccine Access and Health Security Initiative and a vaccine partnership with Quad partners, which provide aid to neighboring countries in the amounts of $532.2 million and $100 million respectively.[522] The fact that Australia uses the COVAX Facility and other vaccine arrangements for political purposes seems obvious. Participants of the recent COVAX Summit hosted by Japan explicitly encouraged the Australia government to recommit its focus to not only regional but also global vaccine equity.[523] In this situation, it seems justified to conclude that the COVAX Facility is an important instrument for the Australian government because it simultaneously helps the country partially satisfy its needs in additional vaccine doses and provides the state with an opportunity to expand its regional presence.

7.3. Treaties Signed by Australia Related to Vaccine Supplies

7.3.1. An Overview of Investment Treaties that Could Affect Regulation of Vaccine-Related IP Rights

It was explained in Chapter 4 that the Australian legislative system provides investors with a sufficient level of protection; furthermore, its maturity ensures effective enforcement of laws and regulations. At the same time, it should be noted that recent trends, such as outcomes of the thalidomide case[524] and the government's success in protecting its tobacco plain packaging policy[525], illustrate the government's ability to use public health concerns to introduce trade-restricting measures. In this situation, it becomes especially important to examine relevant bilateral investment treaties and treaties with investment provisions in order to analyze an extent to which pharmaceutical companies could rely on investment law in protecting vaccine-related intellectual property rights.

It seems justified to use the same structure in this analysis that was used in Chapter 6. The data from the World Health Organization show that countries with the most significant manufacturing capacity on the vaccine market are China, the United States, Germany, Belgium, India, the United

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[521] Weixing Hu and Weizhan Meng, "The US Indo-Pacific Strategy and China's Response" (2020) 20 *China Review* 143-176.
[522] The Australian Government Department of Health, "Australia's Vaccine Agreements" (online at 2021) *The Australian Government: Department of Health* <https://www.health.gov.au/initiatives-and-programs/covid-19-vaccines/covid-19-vaccine-government-response/australias-vaccine-agreements>.
[523] Dane Moores, "COVAX Summit: Time for Australia to Recommit to Global, Bot just Regional, Vaccine Equity" (online at 31 May 2021) *Devpolicy Blog* <https://devpolicy.org/covax-summit-time-for-australia-to-recommit-to-global-not-just-regional-vaccine-equity-20210531/>.
[524] Sarah Farnsworth, "Thalidomide Victims Guaranteed Care for the Rest of Their Lives under Australian-First Court Settlement" (online at 2 December 2013) *ABC* <https://www.abc.net.au/news/2013-12-02/thalidomide-victims-in-australia-get-multi-million-dollar-payout/5128298>.
[525] Reuters, "Resouding Victory: Australia Wins Tobacco Plain Packaging Dispute" (online at 29 June 2018) *The Guardian* <https://www.theguardian.com/business/2018/jun/29/resounding-victory-australia-wins-tobacco-plain-packaging-dispute>.

Kingdom, the Netherlands, Belgium, Russia, Switzerland, South Korea, Brazil, and South Africa.[526] Therefore, the author had to identify and analyze bilateral investment treaties and treaties with investment provisions that had been signed by Australia with all these states.

Table 2. *Investment Treaties signed by Australia with Countries with Significant Vaccine Production Capacity*

Country	**Investment Agreements with Australia**
China	Australia – China BIT (1988); Australia – China FTT (2015)
The United States	Australia – United States FTA (2014)
Germany	-
Belgium	-
India	Australia – India BIT (1999) - Terminated
The United Kingdom	-
Netherlands	-
Belgium	-
Russia	-
Switzerland	-
South Korea	Australia – Korea, Republic of FTA (2014)
Brazil	-
South Africa	-

The table above illustrates that the number of BITs and treaties with investment provisions that are relevant from the perspective of the problem under investigation is slight. Therefore, it was not necessary to use the framework that was utilized in the previous section. A separate analysis of all the four agreements that are still in force seems more rational. Such a decision could be also considered promising because the structures of bilateral investment treaties and free trade agreements are different, making it hard to compare them with each other within the same course of argumentation.

7.3.2. Australia – China BIT (1988)

7.3.2.1. Definitions and Standards of Treatment

The bilateral investment treaty with China is relatively old. Nonetheless, it is still in force; therefore, its provisions are relevant from the perspective of the problem under investigation. This BIT offers a standard definition of investments that could be labeled as asset-based, defining investments as "every kind of asset, owned, controlled or contributed by nationals of one Contracting

[526] World Health Organization, "List of Vaccine Producing Countries with Functional NRAs" (online at 17 July 2021) *WHO* <https://www.who.int/initiatives/who-listed-authority-reg-authorities/list-of-vaccine-prod-countries>.

Party and admitted by the other Contracting Party subject to its law and investment policies applicable from time to time".[527] The definition does not exclude portfolio investment or other specific assets, does not contain an "in accordance with host State's laws" clause, does not provide an exhaustive list of assets that are covered by the agreement, and does not list required characteristics of an investment. The definition of investments provided in the BIT implies that any pharmaceutical product, including a vaccine, is an investment that qualifies for protection under the treaty. It is also important to emphasize that the treaty does not include a clause related to the "substantial business activity" requirement and a definition of ownership of legal entities, which are well-known as popular sources of controversy in investment law.[528] The agreement does not include a denial of benefits provision and does not offer any limitations of the treaty's scope.

Standards of treatment provided by the BIT include most-favored-nation and fair and equitable treatments but do not contain a reference to the national treatment. The absence of national treatment clauses in the BIT is a standard practice for Australia that is consistent with the state's strategy that it implements in signing investment treaties. Since the national treatment clause in investment treaties provides a relatively high level of protection for investors as compared to other clauses and even the TRIPS Agreement, which mentions flexibilities in relation to this provision, Australia rarely includes this provision in its BITs.

The most-favored-nation treatment takes a common form in the BIT with China. The agreement requires Parties to "treat investments and activities associated with investments in its own territory, including compensation under Article VIII and transfers under Article X, on a basis no less favorable than that accorded to investments and activities associated with investments of nationals of any third country".[529] The document offers a post-establishment MFN clause that does not cover taxation treaties and economic integration agreements. Such a provision is very important from the perspective of the problem under investigation because of the substantial number of economic integration agreements that were signed by Australia with other countries. Simultaneously, the clause covers procedural issues, allowing investors to use more "investor-friendly" ISDS mechanisms from other treaties.

The fair and equitable treatment clause is also present in the agreement. The BIT recognizes Parties' obligations to "accord within its territory protection and security to investments and activities associated with investments and, without prejudice to its law, shall not impair by unreasonable or discriminatory measures the management, maintenance, use, enjoyment or disposal of investments".[530] The FET clause does not include an explicit reference to international law and does

[527] Agreement between the Government of Australia and the Government of the People's Republic of China on the Reciprocal Encouragement and Protection of Investments 1988.
[528] Saurabh Jain, *Effectiveness of the Beneficial Ownership Test in Conduit Company Cases* (Doctoral Thesis) (Wellington: Victoria University of Wellington, 2012).
[529] Ibid.
[530] Ibid.

not list specific components of the countries' FET obligation. In general, it seems justified to conclude that the standards of treatment provided by the BIT are limited and provide a relatively weak level of protection. The national treatment is absent in the text of the treaty, and the fair and equitable and most-favored-nation treatment clauses are constrained by the Parties' inability to invoke "investor-friendly" clauses from economic integration agreements.

Other clauses related to the standards of treatment do not contain any unusual provisions. The agreement guarantees the full protection and security of investments in its MFN clause and includes the transfer of funds. It is important to emphasize that the agreement does not stipulate the umbrella case and does not prohibit performance requirements. The absence of clauses constraining performance requirements empowers Parties to issue such requirements in the health care industry, introducing limitations pertaining to knowledge transfer, production processes, or technology.[531] This issue is especially relevant given the attempt of Australia to facilitate local manufacturing of vaccines in partnership with foreign pharmaceutical companies.

7.3.2.2. Expropriation

Like the majority of other BITs, the one signed by Australia with China includes an expropriation clause stating that "A Contracting Party shall not take measures of expropriation or nationalization or other measures having a similar effect relating to any investment unless the measures are in the public interest, non-discriminatory, in accordance with the law of the Contracting Party which has admitted the investment and against reasonable compensation".[532] The criteria described above, including the non-discriminatory nature of a particular measure, the presence of the public interest, compliance with Contacting Parties' laws, and the presence of a reasonable compensation are standard for investment treaties. The clause does not include an explicit definition of indirect expropriation, does not carve out general regulatory measures, and does not exclude compulsory licenses. Therefore, pharmaceutical companies could rely on this BIT in case if their products or some components of these products are expropriated under a compulsory licence.

The calculation of an "adequate" compensation implies defining the value of an investment "immediately before the measures became public knowledge".[533] The agreement offers Parties to use general principles of valuation that consider the amount of capital, replacement value, depreciation, and other pertinent indicators, and indicates that this compensation should include an interest for the period between the expropriation's announcement and the date of payment. Provisions related to

[531] Bertram Boie, "The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?" (online at November 2010) *World Trade Institute* <https://www.wti.org/media/filer_public/c5/47/c5475d4a-f97c-4a8b-a12a-4ae491c6abb3/the_protection_of_iprs_through_bits.pdf>.
[532] Agreement between the Government of Australia and the Government of the People's Republic of China on the Reciprocal Encouragement and Protection of Investments 1988.
[533] Ibid.

compensation that could be found in the BIT between Australia and China do not include any uncommon clauses.

7.3.2.3. Dispute Settlement and Other Clauses

The treaty does not include exceptions from the agreement's scope. In particular, it does not contain a reference to public health as a possible premise to exclude a particular situation from the scope of the BIT. Another important aspect of the agreement is that it requires states to publish laws and regulations "with a view to promoting the understanding of its laws and policies that pertain to or affect investments in its territory of nationals of the other Contracting Party".[534] Such a provision positively affects transparency, allowing investors to examine recent legislative changes and prepare for possible challenges.

Article XII of the treaty offers a detailed description of the ways in which disputes between a Contacting Party and nationals of the other Contracting Party should be settled. In particular, the document offers a framework of investor-state dispute settlement that covers all the disputes that are related to investments. An analysis of the document did not reveal any exceptions from the scope of ISDS. It is important to note that the ISDS mechanism does not require Parties' case-by-case consent, thus simplifying practical utilization of this instrument. The document provides investors with an opportunity to use both the ICSID forum and domestic courts for settling disputes with Contacting Parties. Furthermore, a relationship between these forums is not clarified. As a result, investors could utilize both these options at the same time or in a subsequent order. The absence of a "fork in the road" or "local jurisdictions first" principles in this BIT is a positive sign for investors because it provides them with more flexibility in taking their action against Contacting Parties.

7.3.3. Australia – The United States FTT (2004)

7.3.3.1. The Treaty's Investment Chapter

While all the previous investment treaties are to a certain extent important from the perspective of the problem under investigation, the free trade agreement that was signed between Australia and the United States is arguably the most significant document in terms of its effect on the regulation of vaccine-related intellectual property rights. This agreement contains many provisions that do not harmonize with the TRIPS Agreement and, thus, create essential TRIPS-plus rules. Because of this reason, it seems justified to analyze all the pertinent clauses of this treaty in detail.

The treaty guarantees that national, most-favored-nation, and fair and equitable treatment to investors. The term "minimum standard of treatment", which is at the core of the FET clause, is interpreted in the agreement as "the customary international law minimum standard of treatment of aliens refers to all customary international law principles that protect the economic rights and interests of aliens".[535] The agreement provides relevant clauses in relation to expropriation but specifies that

[534] Ibid.
[535] Free Trade Agreement between Australia and the United States of America 2004.

the expropriation article does not cover compulsory licenses. Similarly with the free trade agreement with South Korea, the one with the United States explicitly prohibits performance requirements in seven different situations, including the one that implies "transferring a particular technology, or other proprietary knowledge to a person in its territory"[536] (Article 11.9(f)); however, it is explained in Article 11.9:3(b) that this clause does not apply "when a party authorizes use of an intellectual property right in accordance with Article 17.9.7 (Patents), or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with, Article 39 of the TRIPS Agreement". [537] The arguments laid out above illustrate that the investment chapter of the free trade agreement hardly contains pertinent clauses from the perspective of the problem under investigation.

7.3.3.2. The IPR Chapter

An analysis of the IPR chapter's text demonstrates that there are five essential TRIPS-plus rules originating from the agreement that are of critical importance for this thesis. In particular, the FTT introduces limitations on compulsory licenses, offers avenues for patent term extensions, puts an additional layer of defense in relation to data exclusivity, integrates regulatory approval into the patent protection framework, and prohibits parallel importing. Limitations on compulsory licensing are one of the most evident TRIPS-plus rule introduced by the free trade agreement. Whereas the treaties with South Korea and China recognized the parties' commitment to the Doha Declaration, the FTT with the United States limits the use of compulsory licenses to only a limited number of situations, specifically "in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency".[538] Such a formulation illustrates the constrained scope of compulsory licensing as per the agreement; simultaneously, it seems justified to assume that it does not introduce essential constraints in regard to compulsory licenses on COVID-19 vaccines. Considering the magnitude of the COVID-19 crisis and its unprecedented implications, investors could barely challenge Parties' decision that this pandemic constitutes a national emergency. Moreover, most ISDS cases related to compulsory licensing do not include such a line of argumentation, as pharmaceutical companies rarely challenge a premise that the lack of certain drugs or vaccines in a particular country constitutes a national emergency.[539] Therefore, the restrictive language that could be found in Article 17.9:7 (b) is hardly crucial for discussing regulation of vaccine-related IP rights.

In addition to setting an exhaustive list of situations in which governments could issue compulsory licenses, the treaty also adds three conditions that should be met during the implementation of this instrument. Whereas the first and the second conditions are standard, the third one contains an essential TRIPS-plus rule because it stipulates that "the Party may not require the

[536] Ibid.
[537] Ibid.
[538] Ibid.
[539] Prabhash Ranjan, "Issuance of Compulsory Patent Licenses and Expropriation in Asian BITs and FTA Investment Chapters: A Study of India, China, Malaysia and Thailand" in Kung-Chung Liu and Julien Chaisse (eds.), *The Future of Asian Trade Deals and IP* (Hart Publishing, 2019), 133-156.

patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorized for use in accordance with this paragraph".[540] A prohibition to require the transfer of know-how, a term that is absent in the text of the TRIPS Agreement, substantially limits applicability of compulsory licenses. Industrial know-how is an essential part of vaccine manufacturing; accordingly, a generic manufacturer could hardly start the production process after gaining access to components of vaccines through bypassing the patent protection.[541] An explicit prohibition to issue auxiliary orders to request access to know-how undermines the ability of countries to start manufacturing their own COVID-19 vaccines. At the same time, this limitation does not apply to those countries that are already engaged in manufacturing processes. In the case of Australia, the government's inability to request the transfer of know-how could hardly undermine the state's manufacturing capacity in regard to AstraZeneca vaccines, as they are already being produced in Melbourne. At the same time, this clause could limit applicability of compulsory licenses for the manufacturing of other COVID-19 vaccines, such as Pfizer or Moderna.

Another important TRIPS-plus rule originating from the FTT is the prohibition of parallel importing. In accordance with Article 17.9:4 of the treaty, "each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means".[542] The clause, therefore, prevents generic manufacturers in Australia from exporting COVID-19 vaccines that are purchased from foreign pharmaceutical companies to third countries. This provision is well-known as one of the most restrictive and significant TRIPS-plus rules because it creates impediments for equitable access to vaccines.[543] It should be also noted that this provision is relevant to Australia given the country's willingness to use the tool of "vaccine diplomacy" in order to extend and strengthen its regional influence.

The next essential group of TRIPS-plus provisions of the treaty is connected with patent terms' extensions. There are two clauses in the treaty that provide avenues for extending patent protection terms beyond the standard period of 20 years, which is guaranteed by the TRIPS Agreement. First, Parties are required to adjust the terms of patents in order to compensate for unreasonable delays in the issuance of patents, which are interpreted as "delays… that shall at least include a delay in the issuance of a patent of more than four years from the date of filing of the application in the Party, or two years after a request for examination of the application has been made,

[540] Free Trade Agreement between Australia and the United States of America 2004.
[541] Eduardo Urias and Syama Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence" (2020) 3 *Journal of International Business Policy* 367-384.
[542] Free Trade Agreement between Australia and the United States of America 2004.
[543] Ronald Labonte and Mira Johri, "COVID-19 Drug and Vaccine Patents are Putting Profit before People" (online at 5 November 2020) *The Conversation* <https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270>.

whichever is later".[544] Article 17.9:8(b) further specifies that "with respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process".[545] Second, the free trade agreement with the United States follows the pattern of the "12-month grace period". Clauses related to patent extensions, especially Article 17.9:8(a) and Article 17.9:8(b), are bright examples of provisions contributing to patents' evergreening. At the same time, their relevancy in the case of COVID-19 vaccines remains limited because the majority of patents related to COVID-19 vaccines have been filed in the last ten years.

A series of TRIPS-plus rules that could be found in Article 17.10 have the effect of slowing down regulatory approval and development of generic pharmaceutical products, thus reducing generic competition. In particular, Article 17.10:1(a) states that "If a Party requires, as a condition of approving the marketing of a new pharmaceutical product, the submission of undisclosed test or other data concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for at least five years from the date of marketing approval by the Party".[546] The data exclusivity clause also prevents generic manufacturers from using marketing approval data from other countries, as "the Party shall not permit third persons… to market the same or a similar product on the basis of evidence of prior marketing approval in another territory, or information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory, for at least five years… from the date of marketing approval by the Party, or the other territory, whichever is late".[547] These restrictions are likely to result in inflated costs of vaccines and cause substantial difficulties for generic manufacturing, slowing down or even eliminating generic competition.[548] Along with other provisions discussed above, Article 17.10 constitutes a layer of TRIPS-plus provisions that substantially complicate local manufacturing of COVID-19 vaccines.

Finally, the last issue raised in the Australia – Untied States FTT that could affect regulation of vaccine-related IP rights is a link between patent protection and market approval. It is common to regulate these two issues separately because they are processed by different authorities and are subject to different regulations.[549] A patent office is supposed to make a decision on whether a particular vaccine meets five requirements included in the patent test (patentability, novelty, inventiveness, utility, and prior use tests), while regulatory authorities focus on assessing efficacy, safety, and quality

[544] Free Trade Agreement between Australia and the United States of America 2004.
[545] Ibid.
[546] Ibid.
[547] Ibid.
[548] Aisling McMahon, "Global Equitable Access to Vaccines, Medicines and Diagnostics for COVID-19: The Role of Patents as Private Governance" (2020) 47 *Journal of Medical Ethics* 142-148.
[549] World Intellectual Property Organization, *Vaccines: Accelerating Innovation and Access: Global Challenges Report* (WIPO Press, 2017).

of a vaccine.[550] In other words, patent infringement is usually not directly connected with decisions of drug regulatory bodies. A link between regulatory approval and a current patent status that is introduced in the free trade agreement limits applicability of TRIPS flexibilities related to compulsory licenses. Mercurio even assumes that this linkage could prevent governments from issuing compulsory licenses at all, as "if the regulatory authority is prohibited from registering generics until the patent expires, the compulsory license will be prevented from coming to fruition".[551] In this situation, the Australia – United States Free Trade Agreement's attempt to link regulatory approval to a product's patent status could undermine Parties' response to the COVID-19 crisis.

Results of the analysis conducted in this chapter illustrate that the free trade agreement between Australia and the United States is the most important investment treaty from the perspective of the problem under investigation. Its TRIPS-plus provisions, including those related to data exclusivity periods, extensions of patent terms, a link between regulatory approval and a patent status, restrictions on compulsory licenses, and prohibitions of parallel importing, could undermine equitable access to vaccines. The effect of this agreement on regulation of vaccine-related IP rights in Australia could translate into three implications. First, these TRIPS-plus rules would inevitably inflate the prices of generic vaccines. As it is known, a low price of generic vaccines is one of its key advantages[552]; however, Australian generic manufacturers could hardly offer cheap COVID-19 vaccines because of the need to invest in their own clinical trials. Second, data exclusivity periods and the need to conduct new clinical trials could delay generic competition. It is possible that the government might prefer investing additional funds into purchasing additional COVID-19 vaccine doses from U.S. pharmaceutical companies instead of waiting until generic manufacturers meet all the requirements that are necessary for applying for regulatory approval. Third, restrictions on compulsory licenses and parallel importing limit the Australian government's ability to export vaccines to members of the ASEAN bloc, thus weakening its "vaccine diplomacy" capacity. All these arguments illustrate significance of the Australia – United States Free Trade Agreement from the perspective of the problem under investigation.

7.3.4. Australia – Korea, Republic of FTA (2014)

7.3.4.1. Definitions and Standards of Treatment

The agreement uses a common asset-based definition of investments. At the same time, the document lists required characteristics of investments, including "the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk"[553] as well as eight possible types of investments, including intellectual property rights. Pharmaceutical products, including

[550] Ibid.
[551] Bryan Mercurio, "Trips-Plus Provisions in Ftas: Recent Trends" in Lorand Bartels and Federico Ortino (eds.), *Regional Trade Agreements and the WTO Legal System* (Oxford University Press, 2006), 215-237.
[552] Qiwei Claire Xue and Lisa Larrimore Ouelette, "Innovation Policy and the Market for Vaccines" (2020) 7 *Journal of Law and the Biosciences* 1-41.
[553] Free Trade Agreement between Australia and the Republic of Korea 2014.

vaccines, meet all the required characteristics of investments; moreover, the fact that IP rights are mentioned as an accepted type of investments simplifies protection of vaccine-related IP rights. Furthermore, the document does not include a controversial "in accordance with host State's laws" provision, which is also a positive sign for investors.

The document contains a denial of benefits clause. In particular, it states that "a Party may deny the benefits of this Chapter to an investor of the other Party that is an enterprise of such other Party and to investments of that investor if the enterprise has no substantive business operations in the territory of the other Party and persons of a non-Party, or of the denying Party, own or control the enterprise".[554] The substantial business activity test, which was originally developed to distinguish between base and straw companies, might be a source of confusion in investment law.[555] Nonetheless, the presence of this controversial provision is unlikely to lead to adverse effects for pharmaceutical companies, as firms manufacturing and distributing vaccines are unlikely to fail the substantial business activity test.

The document describes all the three types of treatment to investors. The national treatment covers pre- and post-establishment investments, while also inserting the "like circumstances test" for comparing the treatment of local and foreign investors. The most-favored nation treatment also covers post- and pre-establishment investments. Interestingly, unlike the BIT with China, the free trade agreement with South Korea excludes procedural issues from the scope of the MFN obligations but does not exclude taxation treaties and economic integration agreements.[556] This issue is critical from the perspective of the problem under investigation because it might be used by investors to invoke a level of protection that is provided in some other free trade agreements, primarily the one with the United States, which offers unprecedented layers of protection.[557] Finally, the fair and equable treatment provision includes a reference to "the customary international law minimum standard of treatment of aliens"[558], which allows investors to rely on international law in taking action against Contracting Parties.

There are two other important features of the FTT with South Korea that should be highlighted in this chapter. First, even though it includes an expropriation clause, this provision is not relevant from the perspective of the problem under investigation because it is specified in the agreement that "this Article shall not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation,

[554] Ibid.
[555] Saurabh Jain, *Effectiveness of the Beneficial Ownership Test in Conduit Company Cases* (Doctoral Thesis) (Wellington: Victoria University of Wellington, 2012), 179.
[556] Free Trade Agreement between Australia and the Republic of Korea 2014.
[557] Free Trade Agreement between Australia and the United States of America 2004.
[558] Free Trade Agreement between Australia and the Republic of Korea 2014.

limitation or creation is consistent with Chapter 13 (Intellectual Property Rights)".[559] Paragraph 5 of the Annex 11-B further clarifies that "except in rare circumstances, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, do not constitute indirect expropriations"[560] and further elucidates that "regulatory actions to protect public health include regulation, supply and reimbursement with respect to… vaccines…".[561] Therefore, expropriation clauses in this agreement are irrelevant from the perspective of the problem under investigation.

Second, the document explicitly prohibits performance requirements. There are seven areas in which performance requirements are explicitly prohibited. One of these provisions might seem crucial from the perspective of the problem under investigation because it prohibits "to transfer a particular technology, a production process, or other proprietary knowledge to a person in its territory".[562] It might seem that this prohibition substantially limits states' ability to take advantage of flexibilities under the TRIPS Agreement because, as explained in this thesis, even though the government might issue a compulsory licence to bypass patent protection related to some vaccine, its production remains challenging due to the lack of necessary data and know-how. However, the treaty clarifies in Article 11.9:4 that the paragraph about performance requirement does not apply to IP-related measures that are conducted in line with the TRIPS Agreement.[563] Therefore, the significance of this clause from the perspective of vaccine-related IP rights is slight.

7.3.4.2. Dispute Settlement and Other Clauses of the Investment Chapter

Dispute settlement mechanisms that are available for investors include investor-state dispute mechanisms as well as alternative options, such as conciliation and mediation. The agreement lists situations in which an investor may use ISDS instruments. This list is general and does not introduce essential constraints from the perspective of the vaccine market. The treaty offers the ICSID Convention and the UNCITRAL Arbitration Rules as possible avenues for taking action against a host State; furthermore, it preserves the parties' right to use any other institution or arbitration rules to which both of them agree.[564] At the same time, surprisingly, the document does not include domestic courts as one of possible options, even though it could be inferred from the text of the document that local courts may be used by parties too in case if both of them agree to utilize this option.

The available evidence does not provide a premise to assume that there are any other essential clauses in the investment chapter of the treaty that could be pertinent for regulating vaccine-related IP rights. The document includes some unusual clauses, such as increased requirements concerning transparency of arbitral proceedings, requirements concerning the collection of relevant information

[559] Ibid.
[560] Ibid.
[561] Ibid.
[562] Ibid.
[563] Ibid.
[564] Ibid.

from current and potential investors, the subrogation clause, and the consolidation of claims, but none of them could become a stumbling block in proceedings concerning vaccine-related IP rights. Simultaneously, it should be noted that the free trade agreement includes a specific chapter on intellectual property rights, which includes several important clauses.

7.3.4.3. Clauses related to IP Rights

The agreement offers a common definition of patents. The need to meet the criteria of novelty, an inventive step, and industrial application, which is described in the treaty, could be also found in the TRIPS Agreement.[565] Clauses pertaining to the exclusion from patentability, exceptions to patent rights, and revocation of patents are also standard and do not have any TRIPS-plus rules. The treaty does not offer additional data exclusivity regulations and does not introduce any limitations on compulsory licenses. In contrast, Article 13.10 of the agreement indicates that "The Parties recognize the importance of the Declaration on the TRIPS Agreement and Public Health" and that "in interpreting and implementing the rights and obligations under Article 13.8, the Parties are entitled to rely upon the Doha Declaration".[566] It could be inferred from this Article that Contacting Parties accept provisions of the Doha Declaration in relation to compulsory licenses.

Despite the fact that the document does not have significant contradictions with the TRIPS Agreement, it has two provisions that could be regarded as TRIPS-plus rules from certain perspectives. First, it should be noted that the document allows patent holders to issue new patents on new uses of products. In particular, the document emphasizes that "each Party confirms that patents shall be available for any new uses or methods of using a known product".[567] In theory, such a provision could be considered a TRIPS-plus rule since references to "new uses of products" are absent in the text of the TRIPS Agreement. At the same time, the literature clarifies that the notion of "new uses" alone could become a solid premise for maintaining evergreening patents, as such a concept is primarily connected with clauses extending the duration of patent protection and regulating the marketing approval process[568], such as Article 18.9:4 of the U.S. Free Trade Agreement with South Korea and Article 17.10:3 of the U.S. Free Trade Agreement with Australia. Nonetheless, the presence of the "new uses" provision is still relevant because it opens the path towards issuing additional patents to prevent generic competition.

Second, the agreement provides a so-called "grace period" to patent applicants. The document states that "Each Party shall disregard information contained in public disclosures used to determine if an invention is novel or has an inventive step if the public disclosure: 1) was made or authorized by, or derived from, the patent applicants; and 2) occurred within 12 months prior to the date of filling in

[565] TRIPS Agreement.
[566] Free Trade Agreement between Australia and the Republic of Korea 2014.
[567] Ibid.
[568] Muhammad Abbas, "Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System" (2019) 15 *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 53-60.

the territory of the Party of the application".[569] This grace period is described in the literature as an example of a TRIPS-plus rule.[570] Simultaneously, like in the case with the acceptance of "new uses", this rule hardly changes dramatically the landscape of IPR protection in relation to vaccine-related IP rights.

7.3.5. Australia – China FTT (2015)

7.3.5.1. The Investment Chapter

The investment chapter of the free trade agreement between Australia and China is similar with the investment chapter of the Australia – Korea FTT. It uses an asset-based definition of investments, lists the same required characteristics of investments, and does not include an "in accordance with host State's laws" clause. Both the treaties include a "denial of benefits" provision, although the Australia – China FTT applies it to investors from States that are under economic sanctions.[571] There are certain differences between the treaties in the field of investors' definitions, but they are hardly relevant for the discussion of vaccine-related IP rights. The document guarantees national treatment to Chinese investors, highlighting that "Australia shall accord to investors of China treatment no less favorable than that it accords, in like circumstances, to its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation and sale or other disposition of investments in its territory".[572] The treaty also guarantees the most-favored-nation treatment to investors, linking a corresponding clause to "like circumstances".[573] At the same time, a fair and equitable treatment clause is absent in its text. Despite the fact that this regularity is uncommon, there is no evidence to believe that it could be a negative sign for investors because a FET provision could be found in the bilateral investment treaty that had been signed by the Parties earlier.

The treaty does not contain an expropriation clause and does not prohibit performance requirements. At the same time, like in the case with the fair and equitable treatment, their absence in the final text of the treaty could be apparently explained by the fact that these issues could be found in the existing bilateral investment treaty between the countries. The reliance on this BIT could be inferred from many clauses of the agreement, such as Article 9.4:4 stating that "… each Party reserves the right to adopt or maintain any measure that accords more favorable treatment to investors of non-parties in accordance with any bilateral or multilateral international agreement in force on, or signed after, the date of entry into force of this Agreement".[574] Therefore, it seems justified to claim that the free trade agreement with China primarily addresses those issues that had not been previously addressed in the corresponding bilateral investment treaty.

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[569] Free Trade Agreement between Australia and the Republic of Korea 2014.
[570] Emmanuel Roucounas, "The Debate Regarding the Grace Period in International Patent Law: A Reminder" (2006) 1 *New Perspectives in Academia* 31-46
[571] Free Trade Agreement Between the Government of Australia and the Government of the People's Republic of China 2015.
[572] Ibid.
[573] Ibid.
[574] Ibid.

One of the most important clauses in the FTT from the perspective of the problem under investigation is limitations of investor-state dispute settlement mechanisms. It is elucidated in Article 9.11 of the treaty that "measures of a Party that are non-discriminatory and for the legitimate public welfare objectives of public health, safety, the environment, public morals or public order shall not be the subject of a claim under this Section".[575] In other words, the document explicitly explains that an investor cannot use ISDS instruments to challenge the government's decision to issue a compulsory license, introduce auxiliary orders related to the disclosure of data, and conduct other measures that could constrain investors' rights in the field of vaccine-related IP rights in an attempt to respond to a public health emergency.

7.3.5.2. The IP Chapter

The IP chapter of the Australia – China FTT resembles the IP chapter of the Australia – South Korea FTT. In particular, it guarantees national treatment to investors and puts forward general principles concerning the protection of undisclosed information. At the same time, it should be noted that this agreement does not include a specific section on patents. Apparently, China and Australia failed to come to a final agreement when drafting a final copy of the agreement and decided to postpone such negotiations. Article 11.8 of the treaty specifies that "The Parties agree to further discuss relevant issues relating to the exhaustion of patent rights"[576], while many other articles state the Parties' commitment to working on further improvement of patent protection. The existing IP chapter of the free trade agreement uses general and vague terms when discussing patents. In particular, Article 11.10 highlights that "Each Party shall provide patent applicants with opportunities to make amendments, corrections and observations in connection with their applications in accordance with each Party's laws, regulations and rules".[577] It seems justified to conclude that the free trade agreement between China and Australia does not contain a shared vision of patent protection and explains that specific clauses related to patents will be further discussed by Parties.

The treaty reaffirms the TRIPS Agreement in the field of flexibilities aimed at responding to a public health emergency. Article 11.1 stipulates that "appropriate measures to protect public health and nutrition may be adopted provided they are consistent with the TRIPS Agreement and this Chapter".[578] Article 11.7, in turn, repeats corresponding clauses from the Australia – South Korea FTT concerning the Parties' recognition of the TRIPS Agreement's principles and their readiness to implement the WTO General Council's decision regarding the Doha Declaration.[579] Such formulations illustrate that the free trade agreement does not introduce any TRIPS-plus rules related to parallel importing and compulsory licensing.

[575] Ibid.
[576] Ibid.
[577] Ibid.
[578] Ibid.
[579] Ibid.

7.4. Conclusion

The vaccination campaign occurs slowly in Australia because of a number of reasons, such as the government's reluctance to engage in early negotiations with pharmaceutical companies, the overreliance on vaccine candidates that have not received regulatory approval yet, vaccine hesitancy, and supply chain disruptions. Pfizer vaccines are currently the basis of the state's vaccination program, while AstraZeneca vaccines are recommended for only those people who are older than 60 years. Australia participants in the COVAX project, but its financial contributions (A$3.07 per capita) are relatively small as compared to the contributions of other high-income countries. The study shows that the COVAX Facility is mainly a political instrument for Australia that is used by the state to increase its regional influence and improve relations with ASEAN countries.

A bilateral investment treaty between Australia and China is relatively old and does not include any TRIPS-plus rules. The free trade agreement with South Korea contains certain clauses that might be interpreted as restrictive provisions, such as the "substantial business activity test" and the prohibition of performance requirements. At the same time, neither the prohibition of performance requirements nor expropriation clauses of the treaty's investment chapter are related to the problem under investigation since the document regulates issues related to public health emergencies and compulsory licenses in the IPR chapter. The chapter on intellectual property rights uses a common definition of patents and hardly introduces TRIPS-plus rules except for the provisions about the "new uses" and the "grace period" to patent applicants.

The free trade agreement with China is similar with the one that was signed with South Korea. At the same time, its investment chapter implicitly states that an investor cannot use ISDS mechanisms to challenge the government's decision to issue compulsory licenses, introduce auxiliary orders related to disclosure of data, and conduct other measures that could constrain investors' rights in relation to vaccine-related IP rights. The IP chapter of the treaty is almost the same with the Australia-China FTT. Simultaneously, the treaty does not include a specific section on patents. Free trade agreements with China and South Korea recognize flexibilities of the TRIPS Agreement and emphasize Parties' rights to use them for the benefit of public health.

The FTT that was signed with the United States introduces a set of TRIPS-plus rules. In particular, it limits the situations in which a Party could issue a compulsory license, offers new avenues for patent term extensions, puts an additional layer of protection in relation to data exclusivity, integrates regulatory approval into patent protection framework, and prohibits parallel importing. Restrictions that are connected with data exclusivity clauses and the integration of regulatory approval into patent protection hurt generic competition, making it hard for Parties to launch the manufacturing of vaccines even if they bypass patent protection with the help of compulsory licenses. The free trade agreement with the United States introduces strict TRIPS-plus

rules that have a significant effect on the ability of Australia to obtain vaccine supplies with the help of TRIPS flexibilities.

The free trade agreement with the United States is the only document that could be viewed as a substantial obstacle to the maintenance of an optimal balance between the rights and interests of stakeholders. The treaty provides pharmaceutical companies from the United States with substantial powers and reduces the state's ability to resolve a possible national health crisis. The balance of power in this document seems to be shifted towards pharmaceutical companies; thus, one may assume that the treaty is not consistent with the principles outlining the utilitarian interpretation of justice as a system of rules that contribute to "the greatest utility".

CHAPTER 8. CRITICAL DISCUSSION OF ALTERNATIVE APPROACHES TOWARDS OBTAINING VACCINE SUPPLIES

8.0. Introduction

An outbreak of the COVID-19 pandemic has become a pressing challenge for the international community. Despite the cancellation of quarantine measures in many countries and optimistic reports about the pace of vaccination in developed states, there is no evidence to claim that the crisis has been successfully overcome. Israel, which has fully vaccinated more than 62.46% of the population by August 31, 2021, was forced to reimpose indoor mask requirements in response to the spread of the Delta variant.[580] In this situation, it seems justified to state that such topics as the TRIPS Waiver, compulsory licenses, parallel importing, and other flexibilities of the TRIPS Agreement in regard to COVID-19 vaccines remain topical. Governments continue exploring different options that could help them obtain a sufficient number of vaccine doses, accelerating their vaccination campaigns and protecting the population against new variants of the Coronavirus.

The current chapter is dedicated to a critical discussion of alternative approaches towards obtaining vaccine supplies that could be taken by those states that are unwilling or unable to negotiate vaccine agreements directly with pharmaceutical companies that would provide enough doses for vaccinating the entire population. This discussion is also relevant to all the countries due to dangers associated with new variants of the Coronavirus and the need to ensure the consistent protection from the COVID-19 pandemic. The first subsection of the chapter critically examines voluntary measures that could help facilitate domestic production of vaccines or provide additional funding for purchasing vaccines from pharmaceutical companies. In particular, the chapter presents the analysis of such measures as public funding patent pools, IPR pledges, and pooled procurement. None of these measures implies violating the existing IPR frameworks. After the detailed analysis of these measures, the chapter presents the discussion of their applicability to the cases of Saudi Arabia and Australia.

The second subsection is devoted to the issue of compulsory licenses, which remain the most well-known mechanism of fueling generic competition in the health care industry. It starts with an overview of recent developments related to the use of compulsory licenses during the COVID-19 pandemic, such as those issued in Israel and Russia, and then critically examines the option of issuing compulsory licenses in Saudi Arabia and Australia to launch domestic production of COVID-19 vaccines. This discussion is shaped in line with the findings of the previous chapters concerning the areas of congruence and divergence between the TRIPS Agreement and investment treaties signed by these countries. The third subsection shifts the focus of the discussion towards parallel importing. This issue is investigated in the context of Saudi Arabia and Australia from two perspectives: the

[580] News Wires, "Israel Tightens Restrictions as Covid-19 Cases Surge" (online at 19 August 2021) *France24* <https://www.france24.com/en/asia-pacific/20210819-israel-tightens-restrictions-as-covid-19-cases-surge>.

option of using parallel importing to obtain additional vaccine supplies and the potential of parallel importing to serve as an instrument of "vaccine diplomacy" strategies pursued by these two countries.

The fourth subsection scrutinizes the existing TRIPS Waiver proposals and discusses potential implications of various scenarios related to the TRIPS Waiver for Saudi Arabia and Australia. At the moment, the situation with the TRIPS Waiver remains uncertain, encouraging scholars and journalists to elaborate on numerous possible outcomes of negotiations on this issue. Considering that many of these scenarios could make a strong impact on the regulation of vaccine-related IP rights, it is necessary to discuss them in detail in the thesis. Finally, the last subsection presents other alternative approaches that have not been covered in the previous subsections. This subsection also considers other alternative approaches affecting the vaccine supply. It is important to emphasize that the thesis relies on the data that were recent at the moment of writing. Therefore, it is possible that the relevance of some claims and arguments might decrease following more recent developments.

8.1. Voluntary Measures

8.1.1. Public Funding of Vaccine Research and Development

The use of public funding to facilitate vaccine development is a popular mechanism that has been widely used during the pandemic. Developed and some developing countries invested substantial amounts of money in research and development activities of pharmaceutical companies. In particular, the United States, Germany, the United Kingdom, the European Union, Canada, Norway, and Singapore reported significant public R&D investments as showed in the table below.[581]

Table 3. *Reported Public Investments in Vaccine Development R&D Activities*

Countries	**Reported R&D Investments**
United States	$2,289 million
Germany	$1,507 million
United Kingdom	$500 million
EU states	$331 million
Canada	$283 million
Norway	$262 million
Singapore	$250 million

Large investments in research and development allowed these countries to sign beneficial agreements with pharmaceutical companies on pre-ordering a significant number of vaccine doses. At the same time, it is important to emphasize that the fact that these states invested such a substantial amount of money in vaccine development does not mean that the countries were solely responsible for

[581] The Knowledge Network on Innovation and Access to Medicines, "COVID-19 Vaccine R&D Investments" (online at 8 July 2021) *Global Health Centre* <https://www.knowledgeportalia.org/covid19-r-d-funding>.

the development of COVID-19 vaccines. In particular, Stanford argues that even though public funding and assistance of the National Institutes of Health made a large contribution to the development of Moderna vaccine, relevant technologies that are at the heart of this product have been a result of privately backed research.[582] Therefore, vaccines that have been developed with the help of public funding could be considered a product of shared efforts of public and private stakeholders.

Despite these claims, many experts are under the opinion that the public funding remains the key driver of innovations on the vaccine market during the COVID-19 crisis. Around £65 million spent on the development of the Oxford/AstraZeneca vaccine was allocated by the UK and overseas governments, while the industry funding accounted for only 2.8% of the money.[583] In 2020, the public sector spent approximately €93 billion on COVID therapeutics and vaccines, a figure that exceeds by far the private sector's investments.[584] The Biomedical Advanced Research and Development Authority alone invested around a billion U.S. dollars in the Moderna vaccine's development.[585] All these arguments illustrate that public funding indeed serves as a powerful mechanism of accelerating vaccine development. However, it is available for only those countries that have simultaneously accumulated significantly wealth, developed necessary expertise and infrastructure for R&D activities, and obtained a significant vaccine manufacturing capacity. Therefore, the option of using public funding to accelerate vaccination campaigns is hardly relevant for the majority of modern states.

8.1.2. Philanthropic Funding of Vaccine Research and Development

The growing level of inequality makes public increase expectations from billionaires and multinational corporations concerning their role in overcoming large-scale crises, such as the COVID-19 pandemic. Citizens of many countries are under the opinion that billionaires try to benefit from the pandemic instead of making donations that could help accelerate the development of vaccines or alleviate negative effects of the Coronavirus on the society.[586] Despite the fact that many billionaires remain reluctant to fund measures against the COVID-19 pandemic, some of them have already made significant donations. In particular, Jack Dorsey donated $1 billion to COVID-related charity, while

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[582] John Stanford, "Thank Private Risk-Taking, Not Public Funding, for Covid-19 Vaccines, Therapies" (online at 5 April 2021) *Stat News* <https://www.statnews.com/2021/04/05/thank-private-risk-taking-not-public-funding-for-covid-19-vaccines-therapies/>.
[583] Michael Safi, "Oxford / AstraZeneca Covid Vaccine Research Was 97% Publicly Funded" (online at 15 April 2021) *The Guardian* <https://www.theguardian.com/science/2021/apr/15/oxfordastrazeneca-covid-vaccine-research-was-97-publicly-funded>.
[584] Health Systems, "€93 Billion Spent By Public Sector on COVID Vaccines and Therapeutics in 11 Months, Research Finds" (online at 12 January 2021) *Health Policy Watch* <https://healthpolicy-watch.news/81038-2/>.
[585] Judy Stone, "The People's Vaccine – Moderna's Coronavirus Vaccine Was Largely Funded by Taxpayer Dollars" (online at 3 December 2020) *Forbes* <https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/?sh=6db109e96303>.
[586] Roxanne Roberts and Will Hobson, "The Pandemic is Testing the Generosity of Billionaires, According to a Washington Post Survey of the 50 Richest Americans" (online at 4 June 2020) *The Washington Post* <https://www.washingtonpost.com/lifestyle/style/the-pandemic-is-testing-the-generosity-of-americas-billionaires-a-washington-post-survey-of-the-50-richest-americans-looks-at-who-has-given-and-who-hasnt/2020/06/01/28149f42-96d2-11ea-9f5e-56d8239bf9ad_story.html>.

Bill Gates allocated approximately $350 million to this purpose.[587] In case if new variants of the Coronavirus create unprecedented threats for the humanity, such donations are likely to increase even more.

Nonetheless, whereas it might seem that donations of Bill Gates, Jack Dorsey, and other philanthropists are significant, they are negligible in comparison with the amount of public funding that is allocated for COVID-related causes. As stated above, R&D investments in the U.S. vaccine industry in response to the pandemic reached $2,289 million; at the same time, the amount of philanthropic funding was only $58 million.[588] In China, philanthropic and public funding in COVID-19 vaccine R&D investments is currently $145 and $8 million respectively.[589] In some countries, philanthropic funding accounts for a substantial part of R&D investments. For instance, in Australia, philanthropic and public funding is $9 and $22 million respectively.[590] Nevertheless, in the majority of states, philanthropists could be hardly considered an important stakeholder from the perspective of the problem under investigation. Philanthropic funding could support the efforts of public and private institutions in developing vaccines, but its role is barely crucial.

8.1.3. Patent Pools

Early reports of the COVID-19 pandemic showed that the international community would need to take unprecedented measures to overcome a large public health crisis. Swift development of COVID-19 vaccines was cited by many experts as a necessary condition for returning "back to normal". Patent pools used to be one of those instruments to facilitate vaccine development that have received a significant amount of attention in the literature in 2019 and 2020. In the most general view, patent pools could be defined as "an agreement between two or more patent owners to license one or more of their patents to one another or to third parties".[591] Contreas, Eisen, Ganz, Lemley, Molloy, Peters and Tietze argue that patent pools are a promising solution because they allow overcoming fragmentation problems and so-called "thickets".[592] IPR pools used to be a relatively popular mechanism during the outbreak of SARS, the H5N1 influenza, and the N1H1 influenza, when they used to serve as private arrangements between a limited number of IPT owners.

Despite limited success related to the use of patent pools on the vaccine market, this instrument has hardly proved its effectiveness during the COVID-19 pandemic. The COVID-19

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[587] Catherine Clifford, "Here's How Many Billionaires Confirmed Giving Money to Covid-19 Pandemic-Related Causes" (online at 30 June 2020) *CNBC* <https://www.cnbc.com/2020/06/30/billionaires-confirmed-to-have-given-money-to-covid-19-fight-wealth-x.html>.
[588] The Knowledge Network on Innovation and Access to Medicines, "COVID-19 Vaccine R&D Investments" (online at 8 July 2021) *Global Health Centre* <https://www.knowledgeportalia.org/covid19-r-d-funding>.
[589] Ibid.
[590] Ibid.
[591] World Intellectual Property Organization (WIPO) "Patent Pools and Antitrust – A Comparative Analysis" (online at March 2014) *WIPO* <https://www.wipo.int/export/sites/www/ip-competition/en/studies/patent_pools_report.pdf>.
[592] Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters and Frank Tietze, "Pledging Intellectual Property for COVID-19" (2020) 38 *Nature Biotechnology* 1146-1149.

Technology Access Pool (C-TAP) is currently the most well-known patent pool that emerged in response to the outbreak of the Coronavirus. It seeks to facilitate sharing of information related to clinical trials' results and gene sequencing research.[593] At the same time, like any other patent pool, C-TAP is voluntary; furthermore, it also promotes the idea of intensifying collaboration between licensors and licensees rather than an equitable access to technologies.[594] Therefore, the ability of C-TAP and other current patent pools to reduce IP barriers to the manufacturing and distribution of COVID-19 vaccines remains questionable.

In theory, patent pools might be a promising strategy for ensuring equitable access to COVID-19 vaccines. Some scholars argue that high-income countries should donate vaccines to developing and least developed states. For instance, Yamey puts forward an assumption that such donations could be beneficial for states or all income levels in line with the principles of the game theory owing to the presence of so-called "positive spillovers".[595] At the same time, de Villemeur, Dequiedt, and Versaevel argue that asking developed countries to show such good will would be unreasonable.[596] Instead of doing so, the scholars recommend expanding patent technology access pools because this instrument, which is already widely used for combating other diseases, provides pharmaceutical companies with extra revenues, thus creating a certain incentive for abandoning some of their IP rights.[597] Despite the calls of many scientists and journalists for the expansion of patent pools, the role of this instrument in vaccine development during the COVID-19 crisis remains limited. At the same time, there is a compelling reason to believe that the situation might change in the near future because patent pools are viewed in the literature as a "third way" that would simultaneously preserve the existing IPR frameworks and improve poor nations' access to vaccines.[598] In other words, expansion of COVID-19 patent pools could be an outcome of compromise decision making during negotiations on the TRIPS Waiver.

8.1.4. Patent Pledges

IPR pledges are another option to ensure an equitable access to vaccines within the existing IPR framework. During the period between 9 March 2020 and 7 May 2020, voluntary pledges on

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[593] World Health Organization, "WHO Director-General's Opening Remarks at the Media Briefing on COVID-19 – 11 March 2020" (online at 11 March 2020) *WHO* <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

[594] Ana Santos Rutschman, "How 'Vaccine Nationalism' Could Block Vulnerable Populations' Access to COVID-19 Vaccines" (online at 17 June 2020) *The Conversation* <https://theconversation.com/how-vaccine-nationalism-could-block-vulnerable-populations-access-to-covid-19-vaccines-140689#:~:text=The%20problems%20posed%20by%20nationalism,to%20vital%20public%20health%20good>

[595] Gavin Yamey, "Rich Countries Should Donate Their Vaccines" (2021) 590 *Natur*e 529.

[596] Etienne Billette De Villemeur, Vianney Dequiedt, Vianney and Bruno Versaevel, "Pool Patents to Get COVID Vaccines and Drugs to All" (19 March 2021) 592 *Nature* 529.

[597] Ibid.

[598] Etienne Billette de Villemeur, Bruno Versaevel and Vianney Dequiedt, "Intellectual Property and Covid-19: How Can We Accelerate Vaccination Globally?" (online at 25 April 2021) *The Conversation* <https://theconversation.com/intellectual-property-and-covid-19-how-can-we-accelerate-vaccination-globally-159467>.

COVID-related ingredients and technologies were made by AbbVie, SMITHs Group, Medtronic, Fortress and Labrador Diagnostics, University of California Berkeley Innovative Genomics Institute, Oxford University, and Allen Institute for AI; furthermore, some organizations have also declared coordinated pledges, including Open COVID Pledge, Harvard-MIT-Stanford, Open COVID-19 Declaration, and Welcome Trust Publishers' Pledge.[599] The main goal of such pledges is to make IP rights freely available, although their conditions might vary.[600] Pledges may take the form of standard, compatible, or alternative licenses. This instrument has already showed its potential to facilitate technology transfer in vaccine-related areas; nonetheless, its effectiveness is constrained by a low number of organizations that have made pledges.[601] Thus, pledges alone cannot be considered a powerful mechanism of facilitating the manufacturing and distribution of COVID-19 vaccines.

At the moment, patent pledges have not reached an extent that would allow stakeholders to consider them as an essential issue affecting vaccine development. Most of pledges related to the COVID-19 pandemic are not connected with vaccines. In particular, the Welcome Trust Publishers' Group pledge addresses copyrights, Fortress offers royalty-free licenses to organizations carrying out Coronavirus testing, the Smiths Group's pledge is dedicated to ventilator designs, and AbbVie decided to refuse from enforcing patents related to its drug Kaletra in response to the threat of compulsory licenses[602]. Only a small number of pledges eliminate certain IPR barriers to vaccine manufacturing; however, as stated above, their number and scope remain low. Therefore, there is no evidence to believe that IPR pledges are currently an effective mechanism of accelerating vaccine manufacturing.

8.1.5. Pooled Procurement

Pooled procurement is an umbrella term referring to various pooling activities that could be carried out in line with different organizational arrangements. The study by Kaufman, Keller, Yadav, and Chalkidou reveals that a variety of pooled procurement arrangements could take the forms of informed buying, coordinated informed buying, group contracting, central contracting and purchasing, and group purchasing and distribution.[603] The difference between these approaches is connected with a degree of coordination between countries. In particular, the mechanism of informed buying is characterized by the lowest degree of coordination, as states share information about suppliers and prices but purchase supplies separately, whilst the instrument of group purchasing and distribution

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[599] Jorge Contreras, Michael Eisen, Ariel Ganz, Mark Lemley, Jenny Molloy, Diane Peters and Frank Tietze, "Pledging Intellectual Property for COVID-19" 38 *Nature Biotechnology* 1146-1149.
[600] Jorge Contreras and Meredith Jacob, *Patent Pledges: Global Perspectives on Patent Law's Private Ordering Frontier* (Edgar Elgar Publishing, 2017), 28.
[601] Ibid.
[602] Jorge Contreras, "Intellectual Property Pledges for COVID-19: A Scorecard" (online at 26 April 2021) *Info Justice* <http://infojustice.org/archives/43114>.
[603] Julia Kaufman, Janeen Madan Keller, Prashant Yadav and Kalipso Chalkidou, "Covid-19 Surfaces New Directions for Old Challenges: Three Lasting Ways to Improve Global Health Procurement" (online at 29 July 2020) *Center for Global Development* <https://www.cgdev.org/blog/covid-19-surfaces-new-directions-old-challenges-three-lasting-ways-improve-global-health>.

entails making group purchasing and conducting fully integrated supply chain operations.[604] Pooled procurement might address a number of problems faced by countries, such as information asymmetry, constrained purchasing capacity, and low resilience of supply chains.

The mechanism of COVAX Facility was already discussed in detail in Chapter 6 and Chapter 7. At the same time, it should be noted that COVAX is not the only pooled procurement initiative that has been launched to combat the COVID-19 pandemic. The Strategic Fund established by the Pan-American Health Organization (PAHO) already showed its effectiveness in facilitating anti-Coronavirus measures, even though its emphasis is not placed on vaccines.[605] A recent conference on the outcomes of the initiative showed that the Fund could produce such benefits as lowered prices on medicines, improved quality controls, enhanced delivery lead times, increased resilience of supply chains, and safeguarded essential services.[606] The Global Fund includes a variety of products related to COVID-19 diagnostics, such as Nuclear Acid Extraction kit, Covas SARS-CoV-2 tests, and many other items.[607] The Africa Medical Supplies Platform is also a well-known pooled procurement initiative that accumulates orders for medical equipment and diagnostics in such categories as masks, surgical masks, hand sanitizers, ventilators, surgical gloves, face shields, thermometers, oxygen concentrators, isolation gowns, and diagnostic test kits.[608] Such initiatives as the PAHO's Strategic Fund and the Africa Medical Supplies Platform already serve as strong mechanisms of improving countries' preparedness for the pandemic.

At the same time, the majority of pool procurement initiatives do not include orders on COVID-19 vaccines, which is a critical driver of states' ability to control the pandemic's spread. Due to the fact that developed states are negotiating vaccine deals separately, pharmaceutical companies are in a position to charge increased prices for their products owing to the monopolistic position on the market. A recent study showed that Moderna and Pfizer/BioNTech charged governments approximately $41 billion above the vaccines' production cost, as the vaccines' average purchasing cost exceeds its production cost by around 24 times.[609] In particular, the United Kingdom has paid £1.8 billion more than Moderna and Pfizer vaccines' production cost, the price of Moderna vaccines for South Africa turned out to be 15 times higher than the production cost, and Israel agreed to pay a

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[604] Ibid.
[605] Javier Guzman, Julia Kaufman and Morgan Pincombe, "Better Together: Exploring the Role of Pooled Procurement in Improving Access to Medicines amid COVID-19" (online at 2 August 2021) *Center for Global Development* <https://www.cgdev.org/blog/better-together-exploring-role-pooled-procurement-improving-access-medicines-amid-covid-19>.
[606] Ibid.
[607] The Global Fund, "Pooled Procurement Mechanism Reference Pricing COVID-19 Diagnostics" (online at 30 July 2021) *The Global Fund* <https://www.theglobalfund.org/media/10233/covid19_diagnosticsreferenceprices_table_en.pdf>.
[608] Africa Medical Supplies Platform, *AMSP* (online at 2021) https://amsp.africa/.
[609] Oxfam International, "Vaccine Monopolies Make Cost of Vaccinating the World against COVID at least 5 Times More Expensive than It Could Be" (online at 29 July 2021) *Oxfam International* <https://www.oxfam.org/en/press-releases/vaccine-monopolies-make-cost-vaccinating-world-against-covid-least-5-times-more>.

price that was 24 times higher than the production cost for Pfizer vaccines.[610] The available evidence provides a compelling reason to believe that the pharmaceutical companies' margin could be reduced with the help of pooled procurement. However, most developed states started pursuing vaccine hoarding strategies since the pandemic's start, negotiating deals that secure more vaccines than necessary for covering the population, thus increasing demand on the market and preventing low-income countries from negotiating more favorable deals with pharmaceutical companies.[611] Therefore, the international community has missed a chance to use the mechanism of pooled procurement to contribute to the equitable access to vaccines. Such a position could be hardly considered just because it undermines the international community's ability to overcome the pandemic.

Despite the prevalence of vaccine hoarding trends, limited success of COVAX shows that pooled procurement has a potential to accelerate vaccination campaigns. By August 31, 2021, the COVAX Facility delivered approximately 251 million vaccines to 141 countries, while securing, optioning, or receiving as donations almost 5.1 billion doses.[612] The scope of the program has been expanding, contributing to the implementation of vaccination campaigns in many states, including those which failed to negotiate separate vaccine supply deals with pharmaceutical companies. For instance, on August 31, the COVAX Facility managed to deliver 1,614,740 vaccine doses that had been donated by Japan to Nepal, while also preparing a new shipment to Zimbabwe.[613] At the same time, as explained in Chapter 5, COVAX cannot serve as the only source of vaccine supplies for a vaccination campaign because its primary goal is to secure vaccine shots that could cover at least 20% of a country's population. Expansion of a country's cooperation with the COVAX Facility could be an effective instrument of facilitating vaccination campaigns, but the COVAX program remains relatively slow as compared to most other methods of obtaining vaccine supplies.

Despite the program's limitations, it seems justified to note that the benefits of COVAX are accessible not only for developing and least developed but also for developed states. In particular, a partnership with the COVAX Facility could be an effective instrument of hedging risks. During the pandemic's outbreak, many countries started investing significant amounts of money into R&D activities on the vaccine market and engaged in negotiations with pharmaceutical companies to pre-order vaccine candidates. However, many of these candidates have still not been approved, while some pharmaceutical companies ceased their vaccine development activities. By 28 December 2020, governments ordered approximately 410 million doses of CureVac vaccines, even though the

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[610] Ibid.
[611] Belinda Smith, "Wealthy Countries Are Buying far More COVID-19 Vaccines than They Need – and That's Bad News for the End of the Pandemic" (online at 27 March 2021) *ABC News* <https://www.abc.net.au/news/science/2021-03-28/covid-19-vaccines-covax-pandemic-wealthy-countries/100023022>.
[612] Unicef, "COVID-19 Vaccine Market Dashboard" (online at 31 August 2021) *Unicef* <https://www.unicef.org/supply/covid-19-vaccine-market-dashboard>.
[613] Ibid.

company had not finished all the necessary clinical trials by that time.[614] Recent results of the clinical trials show that the vaccine has the efficacy of only 47%, making it highly unlikely to compete with such vaccines as those produced by Pfizer, AstraZeneca, and Johnson & Johnson.[615] Accordingly, those countries that pre-ordered a substantial number of CureVac vaccines and expected to rely on this product in their vaccination campaigns were forced to switch to new vaccines. Participation in the COVAX Facility could help such states hedge their risks, securing a number of reliable COVID-19 vaccine shots from other developer that would be sufficient for vaccinating the most vulnerable population groups.

8.1.6. Voluntary Measures within the Context of Australia and Saudi Arabia

Neither Australia nor Saudi Arabia are among the world's leaders in terms of vaccination. By August 31, 2021, these two countries managed to fully vaccinate only 27.80% and 42.20% of their populations respectively.[616] Furthermore, as explained in Chapter 6 and Chapter 7, vaccination campaigns in these two countries face substantial barriers owing to the growing vaccine hesitancy and supply chain disruptions. In this situation, it seems necessary to discuss the potential of approaches reviewed in this chapter to improve the access of these two countries to COVID-19 vaccines both to accelerate the existing vaccination campaigns and to ensure the availability of new vaccines that might be developed in response to new variants of the Coronavirus.

The available evidence provides a compelling reason to believe that public funding could serve as an effective instrument of accelerating R&D activities. By the beginning of August, Saudi Arabia and Australia allocated $150 million and $22 million of public funding respectively to COVID-19 vaccine R&D investments.[617] It is important to emphasize that Saudi Arabia allocated $150 million through CEPI, which illustrates that this action could be rather considered a diplomatic and political act than an instrument of obtaining vaccine supplies. The Kingdom's initiatives in using public funding to facilitate domestic production have been limited. It is known that the King Abdulaziz University and SaudiVax were engaged in the development of a COVID-19 vaccine candidate.[618] However, there is currently no information about the success of this initiative.

Interestingly, it could be inferred from indirect sources that health care researchers experience substantial problems with receiving funds and financial resources in order to carry out their research

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[614] Outlook Web Bureau, "Everything about 9 Covid Vaccines and 8 Billion Doses Pre-Ordered so Far" (online at 28 December 2020) *Outlook India* <https://www.outlookindia.com/website/story/world-news-everything-about-9-covid-vaccines-and-8-billion-doses-pre-ordered-so-far/368622>.
[615] Carl Zimmer, "CureVac's Covid-19 Vaccine Disappoints in Clinical Trial" (online at 16 June 2021) *The New York Times* <https://www.nytimes.com/2021/06/16/health/covid-vaccine-curevac.html>.
[616] Our World in Data, "Coronavirus (COVID-19) Vaccinations" (online at 31 August 2021) *Our World in Data* <https://ourworldindata.org/covid-vaccinations>.
[617] The Knowledge Network on Innovation and Access to Medicines, "COVID-19 Vaccine R&D Investments" (online at 8 July 2021) *Global Health Centre* <https://www.knowledgeportalia.org/covid19-r-d-funding>.
[618] Emily Judd, "Coronavirus: Scientists in Saudi Arabia to Develop COVID-19 Vaccine" (online at 9 June 2020) *Al Arabiya English* <https://english.alarabiya.net/coronavirus/2020/06/09/Coronavirus-Saudi-Arabian-universities-collaborating-on-COVID-19-vaccine>.

projects.[619] Despite the fact that the Kingdom's research and development capabilities in the health care industry have been rapidly growing[620], it seems that the government does not allocate a sufficient amount of public funding to support clinical trials. Certain progress in this field could be observed in 2018, when the newly created Saudi Network for Clinical Trials started launching initiatives to support clinical research.[621] However, by the beginning of the COVID-19 pandemic, the medical research industry of Saudi Arabia was not ready yet to compete with the medical research sectors of developed states. Increasing the amount of public funding allocated to R&D activities, such as the ones carried out by SaudiVax and the King Abdulaziz University, could help the state facilitate vaccine development. In case if new variants of the Coronavirus require the development of new vaccines, this strategy could help Saudi Arabia prepare for the next wave of the pandemic.

At the same time, philanthropic funding could hardly make a significant effect on the country's ability to produce COVID-19 vaccines. Philanthropy has been expanding in the Gulf region; however, most NGOs and charitable organizations cooperate closely with governments and hardly act as independent bodies that are able to launch large-scale projects.[622] Therefore, it does not seem rational to discuss the potential of philanthropic funding to act as a strong driver of vaccine development in Saudi Arabia.

Unlike Saudi Arabia, Australia has a mature medical industry; accordingly, its research and development capabilities are stronger. During the period between 2010 and 2015, the life sciences sector had been contributing around $4 billion gross value on an annual basis to the economy.[623] However, the industry's confidence in the Australian R&D capabilities in the health sector has recently decreased.[624] Considering that Australia used to be one of the world's leading countries in terms of health care innovations and medical breakthroughs[625], stakeholders expected that this state would become one of the first countries to develop a COVID-19 vaccine. Reliance on domestic production of vaccines used to be a key pillar of the country's Coronavirus response strategy.[626] Despite the failure of the University of Queensland's vaccine candidate, the country still expects that

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[619] Sultan Al Dalbhi, Abdulaziz Alodhayani, Yasser Alghamdi, Salma Alrasheed, Alyah Alshehri and Noura Alotaibi, "Difficulties in Conducting Clinical Research among Healthcare Practitioners in Saudi Arabia: A Cross-Sectional Survey" 8 *Journal of Family Medicine and Primary Care* 1877-1883.
[620] Ikram Ul Haq, Shafiq Ur Rehman, Hanan Al-Kadri and Rai Khalid Faroooq, "Research Productivity in the Health Sciences in Saudi Arabia: 2008-2017" 40 *Annals of Saudi Medicine* 147-154.
[621] Nature Research Custom Media, "Putting Saudi Arabia on the Clinical Trial Map" (online at 2021) *Nature* <https://www.nature.com/articles/d42473-019-00408-w>.
[622] Elizabeth Dickinson, "5 Things to Know about Gulf Philantrophy" (online at 15 May 2017) *Devex* <https://www.devex.com/news/5-things-to-know-about-gulf-philanthropy-90262>.
[623] Medical Technology Association of Australia, "Industry Key to Boosting Health and Medical Research" (online at 9 May 2019) *MTAA* <https://www.mtaa.org.au/news/industry-key-boosting-health-and-medical-research>.
[624] Ibid.
[625] Australian Government Department of Health, "Medical Research" (online at 4 August 2021) *Australian Government Department of Health* <https://www.health.gov.au/health-topics/medical-research>.
[626] Adam Harvey, Sashka Koloff and Nick Wiggins, "How Australia's COVID Vaccine Rollout Has Fallen Short and Left Us 'in a Precarious Position'" (online at 23 May 2021) *ABC* <https://www.abc.net.au/news/2021-05-24/australia-covid-vaccine-rollout-what-went-wrong/100151396>

local vaccines will become a valid option for facilitating its vaccination campaign in the near future.[627]

Media report promising news about the development of Australian vaccines. The first mRNA vaccine was recently produced in Melbourne by the Monash Institute of Pharmaceutical Sciences and is set for clinical trials.[628] Two other Australian-based developers recently re-focused their candidates, including COVAX-19, which is known as the most promising vaccine candidate from Australia, to target new variants.[629] However, the heads of these organizations complain about the lack of public funding, which slows down the vaccine development process and forces them to look for other alternatives.[630] The fact that philanthropic funding accounts for almost 30% of the overall COVID-19 vaccine R&D investments in Australia[631] illustrates that the government indeed chose not to fund the development of local vaccines after the disappointing outcomes of clinical trials of the University of Queensland's vaccine candidate.

Considering that Australia has significant R&D capabilities and a substantial manufacturing capacity, the use of public and philanthropic funding to accelerate the development of local vaccines seems to be a promising option for the country. Such a strategy could help Australia prepare for possible waves of new Coronavirus variants, as many developers focus their efforts on responding to new mutations of the virus. As Vaxine's official explains, "given we are slightly behind the frontrunners, we had to look strategically as if there was something we could be doing that the frontrunners haven't done… obviously, it will put the other companies back further if they have to start again".[632] By using the instruments of philanthropic and especially public funding, Australia could prepare itself for responding to a large public health crisis that may occur in case if the existing vaccines show limited effectiveness in preventing the spread of new Coronavirus mutations.

Neither patent pools nor patent pledges could be regarded as effective tools for stimulating research and development of COVID-19 vaccines in Saudi Arabia and Australia. As stated above, none of these instruments currently has a scope that justifies presenting it as a driver of equitable access to vaccines. If these mechanisms become more popular owing to countries' ongoing negotiations concerning the TRIPS waiver, they might be utilized by Saudi Arabia and Australia to

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[627] Joseph Dunstan and Neelima Choahan, "Australia's First Locally Made COVID-19 mRNA Vaccine Candidate Is Set for Clinical Trials" (online at 20 June 2021) *ABC News* <https://www.abc.net.au/news/2021-06-20/mrna-covid-19-vaccine-trials-in-australia-variant-booster/100229294>.
[628] Ibid.
[629] Nick Sas, "More than 200 COVID-19 Vaccines Are Still in Development, with Some Now Focusing on Mutant Strains and Older People" (online at 23 January 2021) *ABC News* <https://www.abc.net.au/news/2021-01-24/covid19-the-other-vaccines-in-development/13069922>.
[630] Ibid.
[631] The Knowledge Network on Innovation and Access to Medicines, "COVID-19 Vaccine R&D Investments" (online at 8 July 2021) *Global Health Centre* <https://www.knowledgeportalia.org/covid19-r-d-funding>.
[632] Nick Sas, "More than 200 COVID-19 Vaccines Are Still in Development, with Some Now Focusing on Mutant Strains and Older People" (online at 23 January 2021) *ABC News* <https://www.abc.net.au/news/2021-01-24/covid19-the-other-vaccines-in-development/13069922>.

stimulate R&D activities on the vaccine market. However, at the moment, such discussion seems untimely.

Pooled procurement is also hardly a credible solution for these two countries given that they have already launched their vaccination campaigns. As explained above, the COVAX Facility is currently the only effective pooled procurement instrument that helps nations access COVID-19 vaccines. Its main goal is to provide low-income countries with a sufficient number of vaccine shots for administering two doses to at least 20% of the population. Australia and Saudi Arabia have already fully vaccinated 27.80% and 42.20% of their populations respectively by 31 August[633] primarily with the help of vaccine agreements that had been negotiated directly with vaccine suppliers. Therefore, the role of such instruments as COVAX in facilitating the countries' vaccination campaigns cannot be crucial.

One of the few possible benefits of the COVAX Facility for Saudi Arabia and Australia is risk hedging, as a partnership with Gavi provided these countries with an opportunity to secure a certain number of vaccine doses in case of some undesirable scenarios, such as vaccine shortages or a failure of prospective vaccine candidates to pass clinical trials. This scenario, in particular, is relevant for Australia, which heavily relied on Novavax, AstraZeneca, and the University of Queensland's vaccines. At a certain point, it became evident that these vaccines could not play a major role in the country's vaccination campaigns. Accordingly, the COVAX Facility could be regarded as an alternative source of COVID-19 vaccines for the state. The country secured 25.5 million vaccine doses from the COVAX Facility in April.[634] Therefore, pooled procurement is currently one of mechanisms utilized by the Australian government to obtain a sufficient number of vaccine doses.

The importance of this instrument for Saudi Arabia seems less evident because of two reasons. First, the country has been much more successful than Australia in implementing its vaccination campaign. Second, it continues relying on AstraZeneca vaccines, whereas Australia used to administering this vaccine only to people who are older than 60 years in July, 2021, even though this recommended was recently changed.[635] In this situation, it seems justified to argue that the use of the COVAX Facility as a source of vaccine supplies is a more relevant option for Australia than it is for Saudi Arabia. At the same time, none of these countries could rely on pooled procurement as the main source of vaccine supplies because of the program's slow pace.

8.2. Compulsory Licenses

[633] Our World in Data, "Coronavirus (COVID-19) Vaccinations" (online at 2 August 2021) *Our World in Data* <https://ourworldindata.org/covid-vaccinations>.
[634] Daniel Hurst, "Scott Morrison Pledges 20m More Pfizer Vaccine Doses for Australia's Trouble-Plagued Rollout" (online at 9 April 2021) *The Guardian* <https://www.theguardian.com/australia-news/2021/apr/09/scott-morrison-pledges-20m-more-pfizer-vaccine-doses-for-australias-trouble-plagued-rollout>.
[635] Jordan Hayne and Widia Jalal, "Older Australians Stuck in Vaccine Limbo due to GPs' Advice Not to Receive AstraZeneca, Ineligibility for Pfizer" (online at 7 July 2021) *ABC News* <https://www.abc.net.au/news/2021-07-08/gp-vaccine-covid-rollout-pfizer-astrazeneca/100270284>.

8.2.1. The Use of Compulsory Licensing during the COVID-19 Pandemic

The existence of barriers rooted in investment law that prevent or limit the use of compulsory licenses under the TRIPS Agreement is aligned with Article 31 of the Vienna Convention on the Law of Treaties. In particular, Article 31(1) states that "a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose".[636] The available evidence provides a compelling reason to believe that investment treaties signed between Parties constitute a part of the context since " the context… shall comprise… any agreement relating to the treaty… [or] any instrument which was made between all the parties in connection with the conclusion of the treaty".[637] Accordingly, the Parties' right to introduce limitations on the use of compulsory licenses directly derives from corresponding provisions of the Vienna Convention on the Law of Treaties and could not be regarded as a discriminatory measure. Despite limitations grounded in investment law, compulsory licenses are still widely viewed as an instrumental method to address public health crises.

The idea of using a compulsory license during the COVID-19 pandemic to develop a drug against the virus or an effective vaccine seems natural. The TRIPS Agreement provides countries with the option of "the use of the subject matter of a patent without the authorization of the right holder… in the case of a national emergency or other circumstances of extreme urgency".[638] An outbreak of one of the most dangerous viruses in the Contemporary period of the human history undoubtedly constitutes a national emergency; therefore, the grounds for issuing a compulsory license could be hardly challenged. This statement applies not only to the TRIPS Agreement but also to all the investment treaties seeking to limit the number of situations in which a Party could issue a compulsory license, such as free trade agreements signed by the United States with Australia, Morocco, Jordan, and many other countries. Even the most restrictive agreements recognize Parties' right to issue compulsory license in case of national emergencies; therefore, none of them could be used by investors to challenge compulsory licenses that are issued during the COVID-19 on the grounds that the pandemic does not justify the use of compulsory licensing.

Despite the existence of compulsory licenses as a well-known flexibility provided by the TRIPS Agreement, the popularity of this tool has been low before the pandemic. During the period between 2012 and 2019, for example, it has been used only 13 times in the world, and Ecuador accounted for 6 out of these 13 cases.[639] Relative unpopularity of this instrument could be explained by several reasons, including enduring bureaucratic processes that accompanied the issuing of compulsory licenses, the risk of lawsuits, reputation losses, and even the threat of sanctions from

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[636] Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331.
[637] Ibid.
[638] TRIPS Agreement, Article 31(b).
[639] South Centre, "Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic" (online at 2 March 2021) *South Centre* <https://www.southcentre.int/wp-content/uploads/2021/03/Compulsory-licenses-table-Covid-19-2-March.pdf>.

developed states, such as in the case with the compulsory license on Kaletra, which was issued in Brazil.[640,641,642] Furthermore, as explained in the third chapter of the thesis, a compulsory license is often ineffective because it helps bypass only the layer of patent protection, failing to provide generic manufacturers with an access to know-how. Despite these shortcomings, the issuing of compulsory licenses still used to be the most well-known avenue towards ensuring equitable access to vaccines before the pandemic, which explains the high interest towards this instrument in many countries.

In the beginning of the pandemic, the disease's effect on the health care sector remained unclear. Therefore, a number of governments chose to proceed with swift actions to introduce new laws simplifying the use of compulsory licensing. In April 2021, The Brazilian Senate approved a bill that regulates the use of compulsory licenses in health emergencies and introduces a number of provisions that overcome traditional limitations of compulsory licenses.[643] In particular, this document allowed the state to issue a license on a set of technologies simultaneously and request technical information from patent holders that is mandatory for reproducing the technology.[644] Similar provisions could be found in the COVID-19 Emergency Response Act introduced by the Canadian government. In accordance with the Act, "The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application".[645] This clause enabled the government to use the instrument of compulsory licenses to respond to the COVID-19 pandemic.

On March 17, 2020, the Chilean Chamber of Deputies approved a resolution concerning the use of compulsory licenses during the pandemic. The resolution states that "the coronavirus epidemic… constitutes sufficient justification for the granting of the non-voluntary licenses contemplated in article 51º No. 2 of Industrial Property Law No. 19.039 to facilitate access to vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of people infected by the coronavirus virus in Chile, for public health reasons and/or national emergency".[646] A similar resolution was adopted in Ecuador.

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[640] Jennifer Bjornberg, "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation" (2006) 27 *Northwestern Journal of International Law & Business* 199-226.
[641] Eduardo Urias and Shyama Ramani, "Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence" (2020) 1 *Journal of International Business Policy* 1-18.
[642] Stacey Lee, "Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?" (2013) 44 44 *Georgetown Journal of International Law* 1-12.
[643] Senado Federal Gabinette do Senador NELSINHO TRAD, PARECER Nº 79, DE 2021.
[644] Robert Castro De Figueiredo, "Brazilian Senate Approves Bill on the Compulsory Licensing of COVID-19 Vaccines' Patents" (online at 12 May 2021) *Kluwer Patent Blog* <http://patentblog.kluweriplaw.com/2021/05/12/brazilian-senate-approves-bill-on-the-compulsory-licensing-of-covid-19-vaccines-patents/>.
[645] COVID-19 Emergency Response Act (S.C. 2020, c. 5), Section 19.3.
[646] Luis Gil Abinader, "Chilean Chamber of Deputies Approves Resolution for Compulsory Licenses for Patents Relating to the Coronavirus Virus" (online at 17 March 2020) *Knowledge Ecology International* <https://www.keionline.org/32385>.

The document encourages the Republic's President and the Minister of Public Health to "use the administrative and technical mechanisms to grant compulsory licenses, access to experimental data, and access to technologies for the affordable supply of vaccines, drugs, diagnostics, and devices that treat and prevent Covid-19".[647] The measures taken by Ecuador and Chile showed the countries' preparedness for utilizing compulsory licenses to fuel domestic production of vaccines in case if the crisis could not have been overcome in other ways.

The Hungarian government introduced a similar document on 17 May, 2020. In accordance with the Government Decree 212/2020, "with a view to satisfying the needs arising within Hungary in connection with the health crisis… the Hungarian Intellectual Property Office… shall issue a public health compulsory license… for the exploitation of a) a medical product or an active substance under patent..., or a medical device or an investigational medicinal product under patent protection, or b) a procedure, equipment or tool under patent protection that is required for the production of a healthcare product".[648] The quotation above shows that the government decree hardly introduced any new rights of the Hungarian government and rather sought to reaffirm the government's right to use the existing flexibilities of the TRIPS Agreement.

In March 2020, the Federal Government of Germany introduced the Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance[649] that was supposed to expand the government's power when responding to the pandemic. In particular, the document changed Subsection 5 of Section 5 of the Infection Protection Act, stating that "an invention relating to one of the products mentioned in No. 4 [narcotics, medical devices, laboratory diagnostics, aids, personal protective equipment and products for disinfection…] shall be used in the interest of public welfare or in the interest of the security of the Federal Republic of Germany; the Federal Ministry of Health may instruct a subordinate authority to make such an order;…"[650] Indonesia also introduced a regulation reaffirming the government's right to use compulsory licenses. According to the Presidential Regulation No. 77, the government may either implement patents itself or assign a third party to do it in case of a "very urgent need in the public interest" in relation to "pharmaceutical and/or biotechnology products which are expensive and/or required to overcome diseases that can cause sudden death in large numbers, significant disabilities, and constitute a global public health emergency".[651] Both the documents reviewed above are similar with those that were discussed in the

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[647] Avelina Ponce, "Ecuador: Patents, Compulsory Licenses and the Covid-19" (online at 2020) *International Bar Association* < https://www.ibanet.org/article/7C9B53CA-3240-4D6E-9E5C-61BCDE61B0CE>.
[648] Government Decree No. 212/2020 on Public Health Compulsory Licenses for Exploitation within Hungary
[649] World Intellectual Property Organization, "Germany: Act on the Protection of the Population in the Event of an Epidemic Situation of National Importance" (online at 27 March 2020) *WIPO* <https://www.wipo.int/news/en/wipolex/2020/article_0008.html>.
[650] Ibid.
[651] Mitha Fuji Adiati and Wulan Mogesmiranti, "Government Introduces Regulation Dealing with Compulsory Licenses" (online at 7 September 2020) *Managing IP* <https://www.managingip.com/article/b1n8qnbc1zqnh0/government-introduces-regulation-dealing-with-compulsory-licences>.

previous paragraphs, as they primarily aimed to reaffirm the existing rights of national governments to utilize compulsory licenses in case of emergencies.

Unlike Germany, Hungary, Chile, and Brazil, Russia adopted a more aggressive regulation in response to the pandemic. Before the pandemic's spread, the Russian Government had amended Article 1360 of the Civil Code, emphasizing "… the right… to provide… a protection of life and health of the citizens to allow the use of an invention, utility model, or industrial design without the consent of the patent holder…".[652] Apparently, this change had been made in order to ensure the country's resilience against sanctions. However, on March 3, 2020, the Government introduced another bill in relation to compulsory licenses that offered a provision that could not be found in resolutions and regulations discussed in the previous paragraphs. In particular, this bill stated that "the Government… has the right, in the cases and on the conditions provided for by an international treaty of the Russian Federation, to make a decision on the use of an invention for the production in the territory of the Russian Federation of a drug for the purpose of exporting it without the consent of the patent holder…".[653] It seems justified to assume that this provision was primarily added to the legislation in order to empower the country to increase its influence on the international arena by exporting vaccines and drugs against the Coronavirus to other countries.

Despite these changes in the legislations of many countries, the instrument of compulsory licenses has not been widely used to date to encourage generic production of vaccines or drugs against COVID-19. The data from the South Centre show that only Russia, Hungary, and Israel issued compulsory licenses on the grounds of national security in relation to the COVID-19 pandemic.[654] These countries issued licenses for Remdesivir, Remdesivir, and Lopinavir/ritonavir respectively.[655] Such a small scope of the instrument's use could be explained by several reasons. First, there is currently no drug against the Coronavirus that could allow countries to overcome the pandemic in a swift manner, as all the attempts to develop such medicines have failed to date. Second, the manufacturing of vaccines, as stated above, is a complex process that requires substantial resources and an access to know-how; accordingly, a shift to generic manufacturing is a risky strategy for a country given possible problems that might be encountered due to the open confrontation with pharmaceutical companies that produce vaccines, such as Pfizer or Moderna, and the threat of sanctions from developed states that lobby their interests. Third, the pandemic did not turn out to be as dangerous for the population in terms of lethality as expected. Accordingly, many governments chose not to take radical measures that would violate the existing IPR frameworks as well as those that

[652] Neemesh Chheda, "Russia Compulsory License" (online at 12 July 2021) *Kluwer Patent Blog* <http://patentblog.kluweriplaw.com/2021/07/12/russia-compulsory-license/>.
[653] Ibid.
[654] South Centre, "Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic" (online at 2 March 2021) *South Centre* <https://www.southcentre.int/wp-content/uploads/2021/03/Compulsory-licenses-table-Covid-19-2-March.pdf>.
[655] Ibid.

could deteriorate the countries' image on the international arena and worsen their relations with other states. Considering the factors outlined above, the issuing of compulsory licenses could be no longer considered as a measure conducive to the achievement of "the greatest utility".

8.2.2. The Use of Compulsory Licenses in Saudi Arabia and Australia to Obtain Additional Vaccine Supplies

Similarly with such countries as Israel, Russia, and Ecuador, Australia changed its legislation during the COVID-19 crisis to simplify the issuing of compulsory licenses. In particular, amendments in the Patents Act indicate that "The court may order a compulsory license to be granted if certain conditions are met, including that demand in Australia for the invention is not being met on reasonable terms, authorization to exploit the invention is essential to meet that demand and it is in the public interest to grant the license… if the person seeking the compulsory license is the patentee of another invention and is seeking the license to exploit that other invention, the court must also be satisfied that the other invention involves an important technical advance of considerable economic significance on the original invention".[656] Furthermore, changes in relation to the Crown exploitation of inventions state that the government may issue a compulsory license on the grounds of an emergency if "the relevant Minister considers the exploitation is required because of an emergency".[657] The introduction of the "public interest" test that should be applied by courts in the compulsory licensing cases and the announcement of Ministers' right to determine particular situations as "emergencies" simplifies the issuing of compulsory licenses.

At the moment, there is no clarity in regard to a relationship between Crown use provisions and a compulsory license. Matheson and Kirkins assume that compulsory license and crown use provisions might be triggered together.[658] At the same time, crown use provisions might be harder to implement due to the fact that it would be easier for investors to contest them.[659] For example, whereas the provisions of free trade agreements with the South Korea and China concerning indirect expropriation do not apply to compulsory licenses, they would apply to any cases in relation to crown use provisions. Therefore, it seems justified to assume that even if Australia triggers the crown use provision in relation to the use of patented vaccines, it would still issue a compulsory license for the same product to safeguard itself from court actions.

The legislation of Saudi Arabia also does not include any essential barrier to the use of this instrument in case of health care emergencies. Implementing Regulations introduced by the Saudi Authority for Intellectual Property state that a license could be issued "to meet a state of emergency or

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[656] Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020, No. 9, 2020.
[657] Ibid.
[658] Sarah Matheson and Artemis Kirkinis, "Compulsory License and Crown Use Provisions in the COVID-19 Pandemic – the Australian Perspective", 16 *Journal of Intellectual Property Law & Practice* 484-497.
[659] Ibid.

other very compelling circumstances"[660] It is crucial to emphasize that the Kingdom has never issued compulsory licenses in its history. At the same time, it seems that the purposes of this instrument could be effectively achieved in Saudi Arabia even without triggering the enduring procedure of compulsory licensing. As stated above, Saudi pharmaceutical companies received a marketing approval in 2016 and 2017 to produce generic versions of innovative pharmaceutical products with the help of test and other data that were provided by innovators to receive a marketing approval; moreover, a national tender was reportedly given to a generic manufacturer in 2018 to produce a product that was covered by patent protection.[661] In other words, the Kingdom has the history of bypassing patent law to approve generic manufacturing even without issuing compulsory licenses.

An analysis of investment treaties signed by Saudi Arabia does not show any significant TRIPS-plus rules that could prevent the issuing of compulsory licenses. Saudi BITs state the same conditions for indirect expropriation. All of them are aligned with the TRIPS Agreement. These documents require that expropriation "should be conducted in public interest or/and to pursue an important public purpose".[662] It seems justified to assume that the COVID-19 pandemic meets these criteria, thus allowing the Saudi government to issue compulsory licenses on COVID-19 vaccines or their components. None of bilateral investment treaties and free trade agreements signed by the Kingdom includes any barriers to compulsory licensing.

Bilateral investment treaties signed by Australia also do not introduce TRIPS-plus rules in relation to compulsory licenses. The "public purpose" test is aligned with the "public interest test" that was recently introduced in Amendments to the Patents Act. Like in the case with Saudi BITs, none of Australian BITs prohibits or limits the use of compulsory licenses. Free trade agreements with countries that currently manufacture COVID-19 vaccines confirm the Australian government's right to use flexibilities of the TRIPS Agreement, including compulsory licenses. For example, the FTT with South Korea emphasizes that "the Parties recognize the importance of the Declaration on the TRIPS Agreement and Public Health" and that "in interpreting and implementing the rights and obligations under Article 13.8, the Parties are entitled to rely upon the Doha Declaration".[663] The same provision could be also found in the FTT with China.

Certain constraints in relation to the use of this mechanism could be found in the Free Trade Agreement with the United States. The document limits the scope of compulsory licensing to "cases of public non-commercial use, or of national emergency, or other circumstances of extreme

[660] SABA Intellectual Property, "Implementing Regulations for Compulsory Licensing Issued in Saudi Arabia" (online at 6 July 2020) *SABA* <https://www.sabaip.com/news/implementing-regulations-for-compulsory-licensing-issued-in-saudi-arabia/>.
[661] The United States Trade Representative, "2019 Special 301 Report" (online at April 2019) *USTR* <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf>.
[662] Agreement between the Republic of Singapore and the Kingdom of Saudi Arabia concerning the Promotion and Reciprocal Protection of Investments 2006
[663] Free Trade Agreement between Australia and the Republic of Korea 2014.

urgency".[664] Furthermore, it states that "the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorized for use in accordance with this paragraph".[665] The first TRIPS-plus rule is hardly relevant to the case of the COVID-19 crisis because courts and arbitral bodies are unlikely to rule that the pandemic that has already led to the death of 4.4 million people worldwide[666] does not constitute "a national emergency" or a "circumstance of extreme urgency". Simultaneously, the second TRIPS-plus rule could be regarded as an essential barrier to the issuing of compulsory licenses. As explained in the fifth chapter of the thesis, test data and know-how constitute crucial pillars of the manufacturing process. Generic manufacturers are unlikely to produce effective vaccines without access to such data. Accordingly, an explicit prohibition to issue auxiliary orders requiring companies to provide such data undermines the government's ability to take advantage of compulsory licenses to produce generic versions of COVID-19 vaccines.

Results of the study show that the free trade agreement between Australia and the United States is currently the only investment treaty that introduces essential barriers to the use of compulsory licensing and violates the principles of justice as per the utilitarian interpretation of this concept. All the other investment treaties do not set any TRIPS-plus rules in this area. Because of this reason, it seems justified to conclude that Saudi Arabia can effectively use compulsory licenses to produce generic versions of vaccines and use auxiliary orders to gain an access to undisclosed data. Australia may also utilize this instrument to launch the production of all the generic vaccines except for those products whose patents belong to U.S. companies. In particular, Australia might experience difficulties with using compulsory licenses to launch the domestic production of such vaccines as Pfizer/BioNTech, Moderna, and Johnson & Johnson. The country does not produce any of these vaccines; accordingly, it does not have access to know-how. Neither know-how nor test data could be accessed through auxiliary orders due to restrictive provisions of the free trade agreement with the United States.

In light of the challenges examined in this thesis, it is important to emphasize that the issuing of compulsory licenses on all the vaccines would be a complicated and risky process both in Saudi Arabia and in Australia. The loss of reputation, problems in relations with certain other countries, and possible difficulties with negotiating new agreements with vaccine manufacturers are essential risks that prevent both these countries from using this instrument. Furthermore, an inability to access know-how and undisclosed data remain evident barriers to generic manufacturing. The available evidence provides a compelling reason to believe that generic manufacturing of AstraZeneca in Australia is currently the only scenario in which a compulsory license could help one of the countries examined in

[664] Free Trade Agreement between Australia and the United States of America 2004.
[665] Ibid.
[666] Worldometer, "Coronavirus Death Toll" (online at 20 August 2021) *Worldometer* <https://www.worldometers.info/coronavirus/coronavirus-death-toll/>.

this thesis to obtain additional vaccine supplies in a quick manner. This vaccine is already being produced in Melbourne; therefore, generic manufacturers could hardly face problems with using relevant know-how. Simultaneously, the absence of restrictive investment treaties with the United Kingdom allows the Australian government to request marketing approval data through auxiliary orders. The issuing of compulsory licenses on all the other vaccines does not seem rational both in Saudi Arabia and in Australia due to the reasons outlined above. The instrument's ineffectiveness is especially evident in the case of vaccines made by U.S. companies since the Australian government is prohibited from providing undisclosed information or technical know-how in relation to the vaccine by the Australia-U.S. FTT.

In general, it seems justified to state that the existing legal frameworks do not provide Saudi Arabia and Australia with an opportunity to use compulsory licenses to ensure the swift generic manufacturing of COVID-19 vaccines. In theory, the Australian government could issue such a license to facilitate the domestic production of AstraZeneca, but such a measure is hardly necessary for the country given the fact that this vaccine used to be recommended exclusively to people who are older than 60 years. Despite the fact that ATAGI recently changed its recommendation, encouraging people below 60 years old who do not have an immediate access to Pfizer vaccines to consider using AstraZeneca vaccines, the number of young people choosing this option is unlikely to be high given vaccine hesitancy and reported cases of blood cloths. Therefore, the demand on these vaccines could hardly increase rapidly in the near future. Furthermore, the state has already accumulated significant reserves of AstraZeneca and is now forced to send them to other countries in line with the "vaccine diplomacy strategy" owing to the low demand on these vaccines among Australians. Therefore, results of the research do not reveal any realistic scenarios in which Saudi Arabia or Australia would issue compulsory licenses on COVID-19 vaccines in the near future. A decision to issue a compulsory license in such settings would not be rational from the pragmatic perspective.

8.3. Parallel Importing

8.3.1. Parallel Importation in the Saudi and Australian Legislation

Parallel importing is one of the most important flexibilities of the TRIPS Agreement that allow countries respond to a health care crisis. At the same time, there is no consistency in national legislations in terms of parallel importation; therefore, this issue should be approached separately in the case of each particular country. Neither Saudi Arabia nor Australia have legislative barriers to parallel importation. The Saudi legislation is silent on this matter, as the term "parallel import" could not be found in any local laws. In theory, a company may register trademarks at the Customs and provide the names of all the authorized importers in order to prevent parallel importation by unauthorized resellers, but this path is too complex to be deemed realistic in the case of COVID-19

vaccines.[667] Therefore, the instrument of parallel importing could be effectively utilized by the Kingdom to obtain additional vaccine supplies.

The Australian legislation also does not prevent parallel importation. Furthermore, recent amendments to the Trade Marks Act simplified the use of parallel import. The section was supposed to "reduce the evidentiary burden on [parallel importers]".[668] By making importers demonstrate the presence of reasonable inquiries to get the trade mark owner's consent without additional requirements, the amendment prevents them from facing the accusations of infringement of the trade mark. Donaldson argues that "undoubtedly, new Section 122A will have an effect in limiting actions that a registered trade mark proprietor may take in relation to parallel imports of goods".[669] In general, neither Australia nor Saudi Arabia prohibits parallel importation or sets essential barriers to its implementation. Furthermore, unlike New Zealand, which banned all the unapproved vaccines, including parallel imports of Pfizer/BioNTech[670], these countries' regulatory authorities did not ban the trade in unapproved vaccines in relation to parallel imports. Therefore, in theory, Saudi Arabia and Australia could rely on parallel importation as one of the instruments of obtaining additional vaccine supplies.

8.3.2. The Possibility of Using Parallel Importation in Saudi Arabia and Australia

None of the bilateral investment treaties examined in the thesis prohibits parallel importation. This term is not even mentioned in their texts. The Free Trade Agreement between Australia and the United States is the only investment treaty examined in this thesis that introduces restrictions on parallel importation. Article 17 of this document, in particular, states that "each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means".[671] Therefore, the Australian government could not utilize the mechanism of parallel importation in relation to Johnson & Johnson, Moderna, Pfizer/BioNTech, and other COVID-19 vaccines that were patented by U.S. pharmaceutical companies. Simultaneously, it could still utilize this instrument in relation to all the other vaccines.

Results of the study do not provide sufficient evidence for speculating on the possibility of using parallel importation instruments to export vaccines to other countries. Considering that parallel

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[667] Talal Abu-Ghazaleh Legal, "Parallel Import in the Middle East" (online at 25 October 2020) *TAG-Legal* <http://www.tag-legal.com/UploadFiles/Publications/Parallel%20Import%20-%20brief%20TAG-Legal.pdf>.
[668] Allens, "Changes to Australia's IP Laws Take Effect" (online at August 2018) Data Allens < https://data.allens.com.au/pubs/pdf/ip/reportipaug18.pdf>.
[669] Sandy Donaldson, "Parallel Universes Converge: Trade Mark Act Amendments" (online at 7 November 2018) *DW Fox Tucker* <https://www.dwfoxtucker.com.au/2018/11/parallel-universes-converge-trade-mark-act-amendments/>.
[670] Nick Paul Taylor, "Asia-Pacific Roundup: New Zealand Bans Unapproved COVID Vaccines" (online at 4 May 2021) *Regulatory Focus* <https://www.raps.org/news-and-articles/news-articles/2021/5/asia-pacific-roundup-new-zealand-bans-unapproved-c>.
[671] Free Trade Agreement between Australia and the United States of America 2004.

importation is primarily an instrument that is utilized by developing countries to reduce the price on pharmaceutical products, the utilization of this mechanism could have been a promising option for developing and least developed countries, including those that are current recipients of vaccines under the vaccine diplomacy strategies of Saudi Arabia and Australia. However, it is necessary to examine the legislation of each particular country in order to determine whether this state could receive vaccines from Australia and Saudi Arabia under parallel importation.

8.4. TRIPS Waiver Proposals

8.4.1. Ongoing Discussion of the TRIPS Waiver

Intense discussions related to the TRIPS Waiver are one of the most intriguing aspects of the problem under investigation. On 2 October 2020, a proposal for a waiver was submitted to the Council for TRIPS Communication with a request that "the obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19".[672] The introduction of such waiver is aligned with the Marrakesh Agreement Establishing the World Trade Organization citing that a waiver from certain WTO obligations could be issued under exceptional circumstances.[673] This measure seems to be based on the liberal interpretation of the concept of justice that calls for the equitable access to vaccines.

Despite numerous proposals put forward by various countries and groups of states, a consensus on this matter has not been reached to date. The new revised proposal was co-sponsored and supported by 63 and 100 countries respectively, yet the United Kingdom, Japan, Australia, Switzerland, the European Union, and some other developed countries continue opposing decision making in this sphere.[674] Some experts state that by asking for more time to monitor the situation and examine possible outcomes of the waiver, these countries use "delaying tactics", thus allowing large pharmaceutical companies to engage in direct negotiations with the maximum number of countries.[675] Moreover, certain countries try to support moderate initiatives, such as COVID-19 patent pools or trade and health initiatives seeking to liberalize trade in essential medicine goods and remove trade barriers.[676] Both these tactics prevent productive decision making in regard to the TRIPS Waiver.

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[672] World Trade Organizations, "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment, and Treatment of COVID-19" (online at 25 May 2021) *WTO* <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True>.
[673] Marrakesh Agreement Establishing the World Trade Organization.
[674] Kerry Cullinan, "Time to End 'Delaying Tactics' on TRIPS Waiver, Say India and South Africa Ahead of Critical WTO Meeting" (online at 4 April 2021) *Health Policy Watch* <https://healthpolicy-watch.news/time-to-end-delaying-tactics-on-trips-waiver-say-india-and-south-africa/>.
[675] Ibid.
[676] European Commission, "Ottawa Group Proposes a Global Trade and Health Initiative" (online at 23 November 2020) *EC* <https://trade.ec.europa.eu/doclib/press/index.cfm?id=2215&title=Ottawa-Group-proposes-a-global-Trade-and-Health-Initiative>.

The most recent meeting of the WTO's General Council with August, 31 as a cutoff date took place on 27-28 July 2021. Despite the fact that all the participants of the meeting agreed that the goal of overcoming the COVID-19 pandemic was a crucial priority for the international community, they did not reach a consensus in regard to the TRIPS Waiver. In particular, Ambassador Dagfinn Sørli noted that "while delegations remain committed to the common goals of providing timely and secure access to high quality, safe, efficacious, and affordable vaccines and medicines for all, disagreement persists on the fundamental question of whether the proposed waiver is the appropriate and most effective way to address the shortage and inequitable distribution of and access to vaccines and other COVID related products… likewise, in the discussions on the EU initiative, disagreement persists on the fundamental question of whether this proposal is the appropriate and most effective way to address the shortage and inequitable distribution of access to vaccines and some of the COVID related products".[677] This citation shows that the international community has apparently reached an impasse in negotiations on the TRIPS Waiver.

At the moment, it seems justified to assume that the TRIPS Waiver's introduction is a highly unlikely scenario. Despite the support of the United States, the majority of developed countries are still opposed to the Waiver. Co-sponsors of the proposal do not possess leverages that could be used to overcome this opposition. The case of Australia exemplifies this pattern. The Australian government has been repeatedly pressed by journalists, scholars, opinion leaders, and non-government organizations to support the Waiver, but the government has not changed its position, insisting on the need to spend more time on examining all the possible scenarios and supporting the idea of waiving certain TRIPS provisions only at the general level.[678] During the period between May and August 2021, co-sponsors of the Waiver did not manage to find new supporters of the proposal; therefore, there is currently no premise to assume that the situation will change in the near future. The only possible scenario that should be considered in this situation is the rapid spread of the Coronavirus's Delta variant leading to the increased danger to the population. A substantial increase in the number of COVID-19 infections and deaths in the world could stimulate the international community to reconsider the stance on the TRIPS Waiver. In such a situation, the introduction of the TRIPS Waiver would become a rational decision from the utilitarian perspective

8.4.2. Potential Benefits of the TRIPS Waiver

Even if the TRIPS Waiver is introduced, there is currently no clarity in regard to its implications. The U.S. Trade Representative noted that "The Administration believes strongly in intellectual property protections, but in service of ending this pandemic, supports the waiver of those

[677] World Trade Organization General Council, "Chair Urges Members to Focus on Priorities, Outcomes for MC12" (online at 28 July 2021) *World Trade Organization* <https://www.wto.org/english/news_e/news21_e/gc_28jul21_e.htm>.
[678] Denham Sadler, "Australia Urged to Back Vaccine IP Waiver" (online at 28 July 2021) *Innovation Aus* <https://www.innovationaus.com/australia-urged-to-back-vaccine-ip-waiver/>.

protections for COVID-19 vaccines".[679] It could be inferred from this citation that the USA provides only limited support for the Waiver, focusing only on those provisions that are connected with vaccines. Such an approach may be ineffective given the need to respond to the COVID-19 pandemic with the help of different instruments, including diagnostics, treatment, and vaccination.

Furthermore, the Waiver itself hardly introduces any novel clauses that could not be found among the existing flexibilities of the TRIPS Agreement. In particular, compulsory licenses are already available for countries with sufficient manufacturing capacity. From this perspective, it might seem that the introduction of the Waiver would be redundant. However, a close analysis of the proposal and the specifics of compulsory licensing leads to a conclusion that such a point of view is not justified. Whereas the Waiver indeed does not introduce new avenues towards bypassing the existing IPR framework, it simplifies the use of the existing flexibilities.

First, the Waiver allows bypassing bureaucratic barriers that are currently among the most important barriers to vaccine equity. Specialists criticize the 2005 Amendment of the TRIPS Agreement for being overly costly and complicated, which might be the reason why an exporting compulsory license has been issued only once to date.[680] This single case illustrates difficulties related to the procedure that is required for using this flexibility. After applying to use the newly established legislation for issuing export-oriented compulsory licenses, Apotex received an approval from the regulatory body on June 2006 and identified Rwanda as the company's customer on July 2007[681]. After formally contacting the patent holder as required by the TRIPS Agreement, Apotex applied for a compulsory license on September 2007, received its on May 2008, and manufactured the first batch on September 2008.[682] Around three years passed during the period between Apotex's application for a compulsory license and the first batch's manufacturing. The TRIPS Waiver could have significantly accelerated this process, as the company would not need to engage in all the bureaucratic procedures. Therefore, even though the TRIPS Waiver in its proposed format would not offer revolutionary instruments for bypassing IPR frameworks, it could facilitate domestic production by removing administrative and bureaucratic barriers that accompany compulsory licensing, especially those that prevent the issuing of export-oriented compulsory licenses.

Second, the Waiver could encourage developing and least developed states to use compulsory licenses without the fear of retaliation from developed countries and large pharmaceutical companies. At the moment, the reluctance of many countries to issue compulsory licenses could be explained not by legislative barriers but rather by concerns that the wide use of compulsory licenses

[679] Katherine Tai, "Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver" (online at 5 May 2021) *Office of the United States Trade Representative* <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>.
[680] Kaitlin Mara, "Efficacy of TRIPS Public Health Amendment in Question at WTO" (online at 1 March 2010) *Intellectual Property Watch* <https://www.ip-watch.org/2010/03/01/efficacy-of-trips-public-health-amendment-in-question-at-wto/>.
[681] Ibid.
[682] Ibid.

could face sanctions of developed states and the refusal of pharmaceutical companies to engage in new vaccine agreements with them. The threat of sanctions to Brazil for issuing a compulsory license on Kaletra is one of the most well-known examples of how developed states, primarily the United States, could use their economic and political influence to prevent developing and least developed countries from enjoying flexibilities provided by the TRIPS Agreement.[683] The TRIPS Waiver's introduction could help eliminate this threat because the U.S. support of the measure would imply that the country would not impose sanctions on countries that start producing vaccines domestically.

8.4.3. Limitations of the TRIPS Waiver

Despite these two potential benefits of the TRIPS Waiver, its introduction would not be able to resolve the existing barriers to vaccine equity because of several reasons. First, the waiver does not clarify how generic manufacturers could access know-how. A country could provide test data to generic manufacturers, but there are currently no instruments except for auxiliary orders that would empower states to make pharmaceutical companies share know-how. Furthermore, if a state issues such an order requiring companies to provide generic manufacturers with know-how, it remains unclear how it could monitor this process. Even if states eventually reach a consensus concerning the TRIPS Waiver, this measure could not facilitate the sharing of know-how and, thus, would bare the same shortcomings as compulsory licensing. Specialists argue that the international community and states should develop some additional instruments to stimulate the sharing of know-how in the health care sector with the help of tax exemptions, cheap credit lines, or some other incentives.[684] If these additional instruments are not present, the TRIPS Waiver is unlikely to induce a desirable effect in terms of facilitating domestic production of COVID-19 vaccines.

Second, many developing and least developed states do not have necessary manufacturing capacity to produce COVID-19 vaccines. Accordingly, they either would not be able to enjoy benefits of the TRIPS Waiver or would need to engage in direct negotiations with generic manufacturers from other countries in order to obtain vaccine supplies. Such process might be as challenging as the process of negotiating with the existing vaccine manufacturers. Because of this reason, it seems justified to assume that the TRIPS Waiver's benefits would be primarily accessible to those countries that have sufficient manufacturing capacity, such as South Africa and India, while others would still struggle with overcoming substantial barriers to access COVID-19 vaccines.

Third, even though the TRIPS Waiver could protect countries from lawsuits based on the TRIPS Agreement, states would remain exposed to the threat of lawsuits that are filed through different means on the grounds of relevant provisions in the investment law. In particular, de Figuiredo emphasizes that in spite of the Waiver's developments, "patent proprietors will still be

[683] Jennifer Bjornberg, "Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation" (2006) 27 *Northwestern Journal of International Law & Business* 199-226.
[684] Hans Morten Haugen, "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) Prevent COVID-19 Vaccines as a Global Public Good?" (2021) 24 *The Journal of World Intellectual Property* 195-220.

entitled to enforce their rights through different means, including through international treaties for the promotion and protection of foreign investments".[685] The majority of investment treaties do not introduce TRIPS-plus provisions, but they repeat many clauses of the TRIPS Agreement and, thus, provide investors with the same level of protection. The TRIPS Waiver, therefore, could not lead to any significant changes in the area of manufacturing COVID-19 vaccines if it is not accompanied by other measures at the international level that would waive IPR-related clauses of investment treaties that are connected with COVID-19 vaccines. The existing literature does not offer a substantial amount of information on the ways in which the TRIPS Waiver could be supplemented by a necessary investment law waiver, but it seems justified to assume that debates concerning this new waiver could be even more intense than those surrounding the TRIPS Waiver.

8.4.4. The Relevancy of Different TRIPS Waiver Scenarios for Saudi Arabia and Australia

There is no evidence to claim that the TRIPS Waiver could substantially affect an access of the Australian and Saudi populations to COVID-19 vaccines. While this measure could become a promising solutions for such countries as India or South Africa, neither Australia nor the Kingdom of Saudi Arabia could benefit from its implementation to an extent that would significantly affect the pace of vaccination. As explained above, both the countries have already achieved certain progress in their vaccination campaigns, even though Australia lags behind most other developed countries. Furthermore, after facing certain problems with vaccine supplies, these states managed to ensure a sufficient number of doses. The lack of vaccine supplies is currently not the key obstacle to vaccination campaigns in these two countries. In particular, AstraZeneca vaccines are widely available both in Australia and in Saudi Arabia, whereas the supplies of Pfizer vaccines in the countries have been swiftly growing. However, the growing vaccine hesitancy trends in the states prevent the governments from demonstrating such an impressive pace of vaccination campaigns as the one in Israel, the United States, or the United Arab Emirates.

The TRIPS Waiver could hardly help Saudi Arabia and Australia overcome the problem of vaccine hesitancy. Furthermore, like in the case with compulsory licenses, this Waiver could not boost the domestic production of COVID-19 vaccines unless the international community finds a way to stimulate the sharing of know-how. Without this additional measure, Australian generic manufacturers could not launch the domestic production of any other COVID-19 vaccines than AstraZeneca since this vaccine is already being produced in Melbourne. However, as stated above, the option of producing AstraZeneca domestically is already available for the Australian government through the conventional use of compulsory license. The domestic production of other vaccines, at the same time, does not seem plausible until the international community and the Australian government

[685] Roberto Castro de Figueiredo, "TRIPS COVID-19 Waiver, Patent Breaking and Investment Arbitration" (online at 27 July 2021) *Kluwer Patent Blog* <http://patentblog.kluweriplaw.com/2021/07/27/trips-covid-19-waiver-patent-breaking-and-investment-treaty-arbitration/>.

find a way to encourage Pfizer/BioNTech, Moderna, Johnson & Johnson, and other vaccine manufacturers to share their know-how.

If such instruments are not introduced, Australia will not be able to request know-how from U.S. pharmaceutical companies via auxiliary orders or some other mechanisms due to an explicit prohibition of such measures in the free trade agreement with the United States. In light of the arguments laid out above, it seems justified to conclude that the TRIPS Waiver in its proposed form will not affect an access of the Australian population to vaccines. This instrument could be utilized to launch the domestic production of AstraZeneca vaccines given that Australian companies could already access necessary know-how due to the ongoing production of this product in Melbourne; however, generic manufacturing of these vaccines could be launched through compulsory licenses as well. At the same time, the Waiver would hardly help the Australian government launch the domestic production of most other vaccines, including those that currently constitute the basis of the government's vaccination campaign.

It is also important to emphasize that the significant wealth possessed by the country empowers it to purchase secondhand vaccines from other countries. In particular, in August, the state purchased around 1,000,000 Pfizer vaccine shots from Poland in an attempt to facilitate its vaccination campaign.[686] Negotiation of direct deals with other countries to purchase secondhand vaccines simultaneously illustrates a challenging situation with the COVID-19 pandemic in Australia. On August 6, Sydney reported 279 locally acquired COVID-19 cases, which was the highest number in the history; furthermore, disturbing numbers were reported in many states of the country leading to the introduction of strict lockdowns covering around 60% of the Australian population.[687]and points at the country's ability to obtain additional vaccine supplies without the need to bypass the existing IPR frameworks and even use flexibilities of the TRIPS Agreement.

It might seem that similar conclusions could be also made in regard to Saudi Arabia. The country has the necessary manufacturing capacity to launch the generic production of COVID-19 vaccines, but there are currently no instruments to access pharmaceutical companies' know-how, which significantly reduces the likelihood of producing high-quality products domestically. However, a closer analysis shows that the cases of these two countries are different from each other. Saudi Arabia has investment treaties with China, Germany, Belgium, South Korea, and Switzerland in effect, while Australia signed BITs with South Korea and China and free trade agreements with China and the United States. The fact that Saudi Arabia and the United States of America have not signed a free trade agreement yet implies that U.S. pharmaceutical companies would not be able to seek

[686] Paulina Duran, "Australia Purchases Pfizer Vaccines from Poland as COVID-19 Infections Spike" (online at 15 August 2021) *Reuters* <https://www.reuters.com/world/asia-pacific/australia-purchases-pfizer-vaccines-poland-covid-19-infections-spike-2021-08-14/>.
[687] Renju Jose, "Delta Spreads in Sydney as Australia Widens COVId-19 Restrictions" (online at 6 August 2021) *Reuters* < https://www.reuters.com/world/asia-pacific/australias-victoria-reports-six-local-covid-19-cases-first-day-lockdown-2021-08-05/>.

protection under investment law if their IP rights were violated. In other words, such firms as Pfizer or Johnson & Johnson could rely either on international IPR law or on local legislation in protecting their IP rights in the Kingdom. The first avenue would be unavailable in the case of the TRIPS Waiver, whereas the second option seems inherently problematic due to inconsistency and unpredictability of the Saudi legislative system. The arguments put forward above illustrate that the TRIPS Waiver that is not accompanied by additional measures waiving IPR provisions in investment law exposes Australia to possible lawsuits from U.S. pharmaceutical companies, whereas this risk is not present in the case of Saudi Arabia due to the absence of relevant investment agreements with the USA.

Results of the research illustrate that the TRIPS Waiver might simplify domestic production of COVID-19 vaccines in Saudi Arabia and Australia, but the ways in which this influence could occur remains vague. The Waiver could reduce bureaucratic and administrative barriers that should be passed by generic manufacturers before starting production, but the lack of an access to know-how is likely to prevent Australia and Saudi Arabia from launching domestic production of high-quality vaccines following the Waiver. Furthermore, it seems justified to assume that none of these countries requires this measure because both of them have already secured a sufficient number of vaccine doses and possess wealth to purchase additional shots in case of need.

In light of the arguments put forward above, it seems justified to conclude that introduction of the TRIPS Waiver in its current form could be useful for Saudi Arabia and Australia only in three situations. First, the Waiver could help the governments launch domestic production of vaccines in response to the new waves of the Coronavirus and the spread of new variants that turn out to be more dangerous. If a threat to the population magnifies, the TRIPS Waiver might serve as an effective instrument of quickly producing additional vaccine doses provided that the governments find a way to encourage the sharing of know-how.

Second, this measure may be useful for bypassing patent protection of particular components that are necessary for producing a COVID-vaccine. As it is known, both Saudi Arabia and Australia are currently engaged in the process of developing their own vaccines. The Monash Institute of Pharmaceutical Sciences has recently set the first Australian mRNA vaccine for clinical trials[688], whereas two other Australian companies re-focused their vaccine candidates to target new variants of the Coronavirus.[689] Ongoing efforts to produce local vaccines could be also observed in Saudi Arabia. In light of the countries' attempts to develop local vaccines, the TRIPS Waiver could serve as an effective instrument for getting an access to some specific components of vaccines. If a local

[688] Joseph Dunstan and Neelima Choahan, "Australia's First Locally Made COVID-19 mRNA Vaccine Candidate Is Set for Clinical Trials" (online at 20 June 2021) *ABC News* <https://www.abc.net.au/news/2021-06-20/mrna-covid-19-vaccine-trials-in-australia-variant-booster/100229294>.
[689] Nick Sas, "More than 200 COVID-19 Vaccines Are Still in Development, with Some Now Focusing on Mutant Strains and Older People" (online at 23 January 2021) *ABC News* <https://www.abc.net.au/news/2021-01-24/covid19-the-other-vaccines-in-development/13069922>.

company is currently in the process of developing a vaccine but cannot use some specific antigens, stabilizers, or adjuvants, the Waiver could indeed serve as a useful tool facilitating an access to such components.

Third, benefits of the TRIPS Waiver could be exploited in a "vaccine diplomacy" strategy. As it is known, both Saudi Arabia and Australia try to use the COVID-19 crisis to extend their regional influence. The Kingdom regularly ships vaccines to Yemen in an attempt to increase its positions in this country in the rivalry against Iran[690], whereas Australia has sent substantial amounts of AstraZeneca vaccine shots to ASEAN countries in line with the competition between China and the Quads in the Asia-Pacific region.[691] The TRIPS Waiver could serve as an effective mechanism of leveraging significant manufacturing capacity of the countries into producing vaccine doses that could be further exported to developing countries. As stated above, Australia has an opportunity to produce AstraZeneca vaccines locally with the help of a compulsory license but does not use this option due to the unpopularity of this vaccine in the country, enduring bureaucratic procedures that should be passed to start generic production, and possible reputation losses. The TRIPS Waiver might help solve the second and the third problem, allowing Australia to produce AstraZeneca vaccines locally and then ship them to such countries as Indonesia, Sri Lanka, Thailand, and Cambodia in line with the "vaccine diplomacy" strategy.

8.5. Summary

An outbreak of the COVID-19 pandemic created unprecedented challenges for the international community in terms of overcoming the existing IPR frameworks towards vaccine equity. Despite the growing realization of the fact that the existing approaches towards facilitating vaccination campaigns are ineffective, there is no agreement among scholars and policymakers concerning the best ways to provide the maximum number of people with an access to high-quality vaccines. Voluntary measures, such as public and philanthropic funding of vaccine research and development, patent pools, patent pledges, and pooled procurement, are important drivers of vaccination, but their effectiveness remains limited. Public funding contributed to the vaccine research and development in certain developed states, while pooled procurement in the form of COVAX provided developing and least developed states with a sufficient number of vaccine shots to vaccinate the most vulnerable population groups. At the same time, patent pledges and patent pools have been ineffective.

The research showed that both Australia and Saudi Arabia could use public and philanthropic funding to accelerate R&D activities on the vaccine market and facilitate development and testing of

[690] Reuters, "Saudi Arabia in Talks with Vaccine Companies to Provide Vaccines to Yemen, Africa" (online at 26 January 2021) *Reuters* <https://www.reuters.com/article/uk-davos-meeting-saudi-finmin-idUSKBN29V0XR>.

[691] Daniel Hurst, "Australia to Send 2.5m AstraZeneca Vaccine Doses to Indonesia as Covid Infections Soar" (online at 7 July 2021) *The Guardian* <https://www.theguardian.com/world/2021/jul/07/australia-to-send-25m-astrazeneca-vaccine-doses-to-indonesia-as-covid-infections-soar>.

the existing vaccine candidates. Neither patent pledges nor patent pools currently serve as credible instruments of ensuring vaccine equity; therefore, their relevancy for the cases of Australia and the Kingdom of Saudi Arabia is questionable. Finally, the COVAX Facility could be hardly an effective tool for these two states given that its implementation is slow and focuses on only a small percentage of the population. Both the countries have already secured a sufficient number of vaccine doses to vaccinate their population.

Both compulsory licenses and parallel importation are important flexibilities of the TRIPS Agreement that could be utilized by states to obtain additional vaccine supplies via importation or domestic production. However, difficulties with accessing know-how, the fear of retaliation from developed states and pharmaceutical companies, and enduring bureaucratic barriers render these instruments ineffective during the COVID-19 crisis. In theory, Saudi Arabia can use both these flexibilities, as they are not prohibited by investment treaties. Simultaneously, Australia could not utilize the instrument of parallel importation in regard to vaccines patented by U.S. pharmaceutical companies due to restrictive clauses of the free trade agreement with the United States.

The available evidence provides a compelling reason to believe that the TRIPS Waiver discussed by the international community could hardly induce revolutionary changes in terms of vaccine equity. They could result in certain benefits by eliminating bureaucratic barriers and relieving developing and least developed countries from the fear of developed states' retaliation in the case of compulsory licenses. Simultaneously, the Waiver in its proposed form would suffer from such limitations as a failure to regulate an access to know-how, insufficient manufacturing capacity of many developing and least developed countries, and the possibility of lawsuits on the grounds of investment law. At the moment, there is no reason to believe that Saudi Arabia or Australia could benefit from the TRIPS Waiver. Simultaneously, this measure might help launch domestic production in the case of the new variant's spread, bypass patent protection of particular components that are necessary for producing a COVID vaccine, and produce certain vaccines, such as AstraZeneca, locally in line with the vaccination diplomacy strategy.

CHAPTER 9. CONCLUSION AND RECOMMENDATIONS

9.1. An Overview of the Study's Findings

The spread of the COVID-19 pandemic created pressing challenges for the international community in terms of finding a way to balance public interests and private rights, simultaneously using the existing IPR frameworks to stimulate innovation in the health care sector and ensuring that the populations of developing and least developed countries could access high-quality COVID-19 vaccines. There is still no agreement among scholars concerning the best ways to maintain this balance, which is evident in intense discussions of the TRIPS Waiver. Therefore, it is becoming increasingly topical to explore the ability of different countries to facilitate their vaccination campaigns with the help of flexibilities that are allowed by the TRIPS Agreement, such as compulsory licenses and parallel importation methods. Despite the seeming effectiveness of these flexibilities, some countries cannot fully utilize them during the COVID-19 pandemic because of restrictions introduced by investment law and implicit limitations preventing the transfer of technology and know-how.

The current thesis sought to determine to what extent bilateral investment treaties and treaties with investment provisions signed by Saudi Arabia and Australia balance the interests of relevant stakeholders in relation to the development, manufacturing, and distribution of COVID-19 vaccines in light of the TRIPS Agreement. The research had to investigate the nature and distinctive features of BITs and treaties with investment provisions regulating health-related IP rights in light of the COVID-19 crisis, explore the application of the TRIPS Agreement, BITs, and treaties with investment provisions to the regulation of health-related intellectual property rights in light of the COVID-19 pandemic, examine the areas of congruence and divergence between the TRIPS Agreement and investment treaties in regard to the regulation of health-relation IP rights, the clarification of priorities in case of overlapping, and the existing dispute resolution mechanisms in light of the COVID-19 crisis, and identify the key implications of the ongoing COVID-19 crisis for the regulation of health-related IP rights related to the development, manufacturing, and distribution of COVID-19 vaccines, especially through investment treaties and the TRIPS Agreement. All these research objectives were completed within the context of Australia and the Kingdom of Saudi Arabia.

The existing literature offers a substantial number of valuable insights into the interaction between the TRIPS Agreement and investment treaties in the field of regulating health-related IP rights. At the same time, there have been no studies to date that would systematically analyze the ability of investment treaties to balance the rights and interests of stakeholders in Australia and Saudi Arabia in light of the TRIPS Agreement and within the context of the COVID-19 crisis. Therefore, this dissertation targeted an evident research gap. It should be also noted that the research adopted a pragmatic stance in analyzing texts of legal documents and utilized the utilitarian principles of justice to evaluate different legal arrangements, which could be considered as a novel approach.

It was found that most investment treaties signed by Australia and Saudi Arabia are standard and do not include any unusual features in regard to the regulation of health-related IP rights. They offer a set of common clauses pertaining to standards of treatment, expropriation provisions, and investor-state dispute settlement mechanisms. Certain differences between them, such as those pertaining to the availability of specific ISDS forums and the presence of the "umbrella clause", are not crucial from the perspective of the problem under investigation. All the documents reviewed in this study except for the free trade agreement between Australia and the United States do not include significant TRIPS-plus provisions. This agreement, at the same time, introduced several important TRIPS-plus clauses, such as limitations on the scope of compulsory licensees, prevention of requirements concerning the transfer of know-how, prohibition of parallel importation, and a link between marketing approval and patent protection. These clauses are not consistent with the principles of justice as per the utilitarian interpretation of this concept. The research revealed significant implications of the COVID-19 crisis for the regulation of health-related IP rights related to the development, manufacturing, and distribution of COVID-19 vaccines, including those pertaining to the issuing of compulsory licensing in light of the existing bureaucratic barriers and the pressure of developed countries.

The second chapter following the introduction focused on the investigation of the TRIPS Agreement and investment treaties from the perspective of the regulation of health-related IP rights. It was found that the TRIPS Agreement plays a crucial role in the regulation of health-related IP rights by setting strict regulations and restrictions that negatively affect access to affordable drugs and vaccines. One may argue that developing and least developed countries are at a disadvantage owing to the TRIPS Agreement because they are prevented from addressing health care crises by IPR frameworks introduced by the document. Simultaneously, the TRIPS Agreement offered certain flexibilities for these states that could help them alleviate health care crises, including transitional periods, a five-year term for recognizing patents, the "exhaustion of rights" clause, and compulsory licenses. The document also does not prevent the use of parallel importation, which could be utilized by countries to obtain a sufficient amount of medicines and vaccines from other states.

BITs and treaties with investment provisions also have an essential impact on the regulation of health-related IP rights. The "umbrella clause", standards of treatment, expropriation clauses, ISDS mechanisms, and the "in accordance with a host State's laws" provision directly affect the regulation of health-related IP rights. Moreover, some treaties introduce TRIPS-plus rules, such as limitations of the compulsory licenses' scope, prohibition of parallel importation, patent term extensions, prohibition of performance requirements, and data exclusivity clauses. Some of these rules contribute to unequitable access to drugs and vaccines.

The third chapter discussed in detail the system of IPR protection in Saudi Arabia and Saudi investment treaties in light of the regulation of health-related IP rights. It was found that the system of IPR protection in the state is relatively weak. The country could be found in the Priority Watch List of

the Office of the U.S. Trade Representative owing to weak patent protection for innovative pharmaceutical products, a failure to prevent the unauthorized disclosure of test data, and online piracy.[692] The government recently introduced new regulations to strengthen IPR protection, but their enforcement remains weak. It was also emphasized in the chapter that Saudi courts often make inconsistent decisions. In particular, they sometimes deny parties' lawsuits for violation of IP rights based on the grounds that these parties did not take an administrative action prior to taking a case to the court, even though such a requirement is not present in the legislation.

Investment treaties signed by the Kingdom of Saudi Arabia do not set significant TRIPS-plus rules. They guarantee post-establishment national, most-favored-nation, and fair and equitable treatment for investors, thus providing a relatively high level of protection. None of these treaties sets limitations on compulsory licenses, prohibits performance requirements, or prevents parties from using parallel importation methods. The use of compulsory licenses is regulated by expropriation clauses that offer standard rules in regard to the scope of expropriation and the calculation of compensation. There are certain differences between different treaties in regard to the availability of ISDS forums, a relationship between these forums, the use of the "in accordance with a host State's laws" and "umbrella" clauses, and standards of treatment. Nonetheless, none of them creates substantial implications for the regulation of health-related IP rights from the perspective of the problem under investigation.

The fourth chapter focuses on the system of IPR protection in Australia and the distinctive features of Australian investment treaties. It was found that Australia has a mature system of IPR protection with consistent IPR frameworks and an effective system of law enforcement. Experts criticize certain recent developments in the Australian legislation, specifically IP law amendments[693], but this criticism is not indicative of the country's deteriorated business climate for investments in the health care sector. At the same time, it should be noted that the contemporary system of IPR protection prioritizes public health concerns over private interests. The plain packaging case and the case against Philip Morris illustrated the Australian government's willingness to spend substantial amounts of money on protecting its right to restrict trade for public health purposes.[694] The study did not find major areas of divergence between the TRIPS Agreement and most investment treaties signed by Australia. The overwhelming majority of clauses that could be found in these treaties are standard and do not set any TRIPS-plus rules. The free trade agreement with the United States, however, is an

[692] The United States Trade Representative, "2019 Special 301 Report" (online at April 2019) *USTR* <https://ustr.gov/sites/default/files/2019_Special_301_Report.pdf>.
[693] Medicines Australia, "Medicines Australia Angry over IP Law Amends" (online at 26 July 2019) *The Pharma Letter* <https://www.thepharmaletter.com/article/medicines-australia-angry-over-ip-law-amends>.
[694] Patricia Ranald, "When Even Winning Is Losing. The Surprising Cost of Defeating Philip Morris over Plain Packaging," (online at 26 March 2019) *The Conversation* <https://theconversation.com/when-even-winning-is-losing-the-surprising-cost-of-defeating-philip-morris-over-plain-packaging-114279>.

important exception from this case, as this document introduces many TRIPS-plus provisions. A detailed discussion of these clauses could be found in the seventh chapter of the thesis.

The fifth chapter shifts the focus of the discussion to vaccines. It illustrates the unique nature of these pharmaceutical products, highlighting their unattractiveness for investors due to saving calculation, monetization, and distribution difficulties as well as high investments required for research and development and popular vaccine hesitancy patterns. The chapter showed that a typical vaccine comprises an active ingredient and its elements, antigens, adjuvants, stabilizers, preservatives, and antibiotics. All these components as well as the production method and product formulation and administration techniques are usually protected by patents. Whereas compulsory licenses could be used to bypass these layers of patent protection, generic manufacturers would not receive access to know-how through compulsory licenses, which might slow down the process of generic production or even prevent generic competition.

Vaccines pass the preclinical, safety evaluation, effectiveness evaluation, regulatory approval and licensure, and continuous monitoring phases. This process usually lasts around 15 years, as companies need a substantial amount of time to meet regulatory requirements of all the states in which they seek to import vaccines and monitor vaccines' effectiveness in various settings.[695] Unprecedented threats induced by the COVID-19 pandemic helped countries accelerate this process, swiftly developing effective vaccine candidates. However, the ability of developing and least developed countries to access high-quality COVID-19 vaccines remains constrained to date. The COVAX Facility is currently the only effective method allowing them to access vaccine doses that would be sufficient for vaccinating the most vulnerable groups. The use of most other options, such as patent pools, voluntary pledges, and compulsory licenses, is hardly a plausible scenario. States are forced to engage in direct negotiations with vaccine manufacturers, which increases a gap between high-income and low-income countries and undermines equitable access to vaccines.

The sixth chapter of the thesis was dedicated to recent developments in obtaining vaccine supplies in Saudi Arabia within the IPR context and possible avenues towards accelerating the country's vaccination campaign. It was demonstrated that the state has been maintaining an acceptable pace of vaccination. By August 31, the state administered 105.07 doses per 100 people, which is a substantially higher number than the world's average figure.[696] In 2020, the Kingdom was negotiating with various vaccine supplies, including CureVac, Russian companies, AstraZeneca, Pfizer/BioNTech, and others. At the moment, AstraZeneca and Pfizer vaccines constitute the basis of the state's vaccination campaign, although Moderna products have also been recently authorized. The country's vaccination campaign has been occurring swiftly, although its speed was recently decreased

[695] European Medicines Agency, "The Evaluation of Medicines, Step-by-Step" (online at 18 August 2020) *EMA* <https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/evaluation-medicines-step-step>.
[696] Our World in Data, "Coronavirus (COVID-19) Vaccinations" (online at 31 August 2021) *Our World in Data* <https://ourworldindata.org/covid-vaccinations>.

owing to vaccine hesitancy and supply disruptions. The state is one of major donors of the COVAX Facility with the overall pledge of $150 million.[697] Direct agreements with pharmaceutical companies and the COVAX Facility are the only sources of vaccine doses for the country, although the role of the COVAX Facility remains slight.

Investment treaties signed by the Kingdom do not set any barriers to vaccine supply. An analysis of the country's BITs with Germany, the Belgium-Luxembourg Economic Union, Switzerland, and South Korea as well as the Saudi Arabia – US TIFA demonstrates the absence of TRIPS-plus rules in these documents that could restrict the use of flexibilities offered by the TRIPS Agreement to obtain additional vaccine supplies. All of them include standard clauses. Certain differences between the treaties exist in the sphere of using the "in accordance with a host State's laws" clause and specific ISDS mechanisms, but these difficulties are hardly crucial from the perspective of the problem under investigation. The trade & investment framework agreement with the United States, at the same time, does not include any specific provisions that would affect investors' health-related IPRs. Therefore, it is not relevant to the current discussion.

The seventh chapter discusses the same issues and trends that were explored in the previous section but focuses on the context of Australia. Unlike Saudi Arabia, Australia experiences evident problems with vaccinating its population, as only 47.27% of residents received at least one vaccine dose by August 31.[698] Despite substantial wealth of the state and early negotiations with various pharmaceutical companies, the government failed to secure a sufficient number of vaccine doses. The initial strategy seeking to launch domestic production of vaccines failed following disappointing clinical trials of the University of Queensland's vaccine candidate.[699] At the same time, partnerships with Novavax and AstraZeneca did not lead to desirable outcomes because whereas the former still has not started producing vaccines, products of the latter are now recommended only to people who are older than 60 years old because of blood cloth cases.[700] Nowadays, Australia continues implementing its vaccination campaign primarily based on Pfizer vaccines, whereas AstraZeneca vaccines are used only for vaccinating the elderly and supplying vaccination campaigns of other companies in line with the "vaccine diplomacy" approach.

All the BITs and treaties with investment provisions signed by Australia except for the free trade agreement with the United States do not set any TRIPS-plus rules prohibiting the use of TRIPS

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[697] Gavi, "Kingdom of Saudi Arabia" (online at 2021) *Gavi* <https://www.gavi.org/investing-gavi/funding/donor-profiles/kingdom-saudi-arabia>.
[698] Our World in Data, "Coronavirus (COVID-19) Vaccinations" (online at 31 August 2021) *Our World in Data* <https://ourworldindata.org/covid-vaccinations>.
[699] Rob Harris, "Australian COVID Vaccine Terminated due to HIV 'False Positives'" (online at 11 December 2020) *The Sydney Morning Herald* <https://www.smh.com.au/politics/federal/australian-covid-vaccine-terminated-due-to-hiv-false-positives-20201210-p56mju.html>.
[700] Adam Harvey, Sashka Koloff and Nick Wiggins, "How Australia's COVID Vaccine Rollout Has Fallen Short and Left Us 'in a Precarious Position'" (online at 23 May 2021) *ABC* <https://www.abc.net.au/news/2021-05-24/australia-covid-vaccine-rollout-what-went-wrong/100151396>.

flexibilities to obtain additional vaccine supplies. The BIT with China offers common standards of treatment, regulates the use of compulsory licenses through the expropriation clause, and does not prohibit performance requirements. Its dispute settlement clauses are standard are empower investors to use ISDS mechanisms to protect their health-related IP rights. The free trade agreements with China and South Korea have similar clauses in respect to the standards of treatment, the definition of investments, and the use dispute settlement mechanisms. The agreements' expropriation clauses do not cover compulsory licenses; furthermore, a prohibition of performance requirements does not apply to measures that are aligned with the TRIPS Agreement. Both documents emphasize that parties recognize flexibilities outlined in the Doha Declaration. At the same time, the agreement with South Korea has two TRIPS-plus provisions that might affect the regulation of vaccine-related IP rights. First, the document includes the "new uses" clauses; second, it offers the "grace period" to patent applicants.[701] None of these clauses, however, could make a substantial influence on the regulation of health-related IP rights within the context of COVID-19 vaccines.

The free trade agreement with the United States was found to introduce several TRIPs-plus rules. First, it limits the use of compulsory licenses to only three cases. Second, it prevents parties from requiring the transfer of know-how. Third, the document prohibits parallel importation. Fourth, the agreement presents two avenues for extending patent protection terms beyond the standard period of 20 years. Fifth, Article 17.10 of the agreement could slow down regulatory approval and development of generic pharmaceutical products through restrictive data exclusivity clauses.[702] Finally, it should be also noted that a link between marketing approval and patent protection, which is outlined in the document, could prevent governments from issuing compulsory licenses or at least significantly increase the amount of time that would pass from the moment of issuing a compulsory license to the moment of the actual start of generic production.[703] Most of these clauses except for restrictions that are set on the scope of compulsory licenses have a direct effect on the regulation of health-related IPRs within the context of COVID-19 vaccines. Therefore, this agreement was found to be the most important document from the perspective of the problem under investigation, substantially limiting the Australian government's ability to obtain additional supplies of vaccines patented by U.S. companies through flexibilities offered by the TRIPS Agreement.

Finally, the eighth chapter of the thesis offered a critical discussion of alternative approaches towards obtaining vaccine supplies in the context of Australia and Saudi Arabia. The chapter started with analyzing voluntary measures that could be used to facilitate vaccination campaigns, such as public and philanthropic funding of domestic production, development of local vaccines owing to patent pools and patent pledges, and pooled procurement. It was found that public funding of local

[701] Free Trade Agreement between Australia and the Republic of Korea 2014.
[702] Free Trade Agreement between Australia and the United States of America 2004.
[703] Bryan Mercurio, "Trips-Plus Provisions in Ftas: Recent Trends" in Lorand Bartels and Federico Ortino (eds.), *Regional Trade Agreements and the WTO Legal System* (Oxford University Press, 2006), 215-237.

research and development activities could be high-priority tasks for both countries. Some local companies, especially those located in Australia, have already achieved certain progress in developing new vaccine candidates. An increase in public and possibly philanthropic funding could accelerate this process. This recommendation is especially topical given that many of these candidates target new variants of the Coronavirus and, thus, could be more effective against the Delta variant than Pfizer, AstraZeneca, and Moderna.[704] Neither patent pools nor patent pledges are currently viable options for fueling domestic production due to the fact that these instruments are not utilized by major pharmaceutical companies. Finally, pooled procurement, especially the COVAX Facility, serves as an important method to hedge risks and ensure that Australia and Saudi Arabia receive a certain number of vaccine doses even if vaccine supplies under direct vaccine agreements get disrupted. At the same time, a slow pace of the COVAX program and a low number of doses delivered to each country make this mechanism useful primarily for low-income states. Its value for Saudi Arabia and Australia, at the same time, remains limited.

The chapter shows that many countries changed their legislation in 2020 to simplify the issuing of compulsory licenses; nonetheless, none of the states has issued a compulsory license to date in regard to COVID-19 vaccines or vaccine components. The fear of retaliation from developed states, primarily the United States, the risk of disrupting relations with pharmaceutical companies and failing to engage in vaccine supply agreements in the future, enduring bureaucratic and administrative barriers to the use of this instrument, and its slow pace contribute to the perceived ineffectiveness of compulsory licenses within the context of COVID-19 vaccines. Furthermore, even if a government succeeds in issuing a compulsory license, generic production could fail due to the absence of necessary know-how. States might try issuing auxiliary orders to obtain this know-how, but this process seems even more problematic than the conventional use of compulsory licenses. In this situation, it seems justified to conclude that neither Australia nor Saudi Arabia could issues compulsory licenses to facilitate their vaccination campaigns.

In theory, Australia could issue compulsory licenses to launch the generic production of AstraZeneca vaccines because these vaccines are already being produced in Melbourne. However, such a possibility does not seem attractive for the country. First, AstraZeneca vaccines are not recommended to people who are younger than 60 years old unless they do not have an immediate access to Pfizer vaccines. Reported cases of blood cloths in relation to AstraZeneca products translate into vaccine hesitancy; as a result these vaccines could not be used to vaccinate the entire Australian population. Second, the government already secured a sufficient number of AstraZeneca vaccine

[704] Nick Sas, "More than 200 COVID-19 Vaccines Are Still in Development, with Some Now Focusing on Mutant Strains and Older People" (online at 23 January 2021) *ABC News* <https://www.abc.net.au/news/2021-01-24/covid19-the-other-vaccines-in-development/13069922>.

doses. It even supplies them to other countries in the region, such as Indonesia.[705] Results of the study showed that the use of compulsory licenses to trigger the generic production of AstraZeneca vaccines could be useful only for supplying the vaccination campaigns of other states in line with "vaccine diplomacy" strategies. However, even this scenario seems highly unlikely due to the shortcomings of compulsory licenses that were outlined in the previous paragraph.

The Australian and Saudi legislations allow parallel importation. Therefore, both Australia and Saudi Arabia could use this instrument to obtain additional vaccine doses. The Australian government, however, cannot utilize parallel importing methods to supply vaccines that are patented by U.S. companies due to the prohibition of parallel importation in the free trade agreement that was signed by Australia with the United States. None of other investment treaties restricts the use of parallel importation.

The chapter showed that debates over the TRIPS Waiver are ongoing. There is still no agreement among diplomats and scholars concerning the best ways to approach this issue. Parties have reached an impasse in their negotiations, as disagreements persist on the fundamental question of whether the proposed waiver is the most appropriate and effective way to address the shortage and inequitable distribution of vaccines and other COVID-related products. The study found that the TRIPS Waiver's introduction is a highly unlikely scenario. In spite of the United States' support of the Waiver, the resistance of many developed countries, including European states and Australia, prevents productive outcomes of negotiations.

The TRIPS Waiver in its proposed form could bring only limited benefits for countries. It does not address many important issues related to the COVID-19 pandemic, such as the transfer of know-how and patent protection of products that are used for diagnostics and treatment purposes. The Waiver's benefits, in this situation, are primarily connected with the elimination of administrative and bureaucratic barriers to the use of compulsory licenses and the implicit support of compulsory licenses by developed states. Developing and least developed countries are more likely to try launching generic production of COVID-19 vaccines due to the absence of the fear of retaliation from the United States and large pharmaceutical companies following the Waiver's introduction.

At the same time, the proposed Waiver would still fail to solve many important problems, such as difficulties with the sharing of know-how, limited manufacturing capacity of many developing and least developed countries, and the threat of lawsuits on the grounds of investment treaties. The study showed that the proposed TRIPS Waiver would not affect the access of Australian and Saudi populations to COVID-19 vaccines. Neither Australia nor the Kingdom could benefit from its implementation to an extent that would significantly affect the pace of vaccination. The states have already achieved certain progress in their vaccination campaigns; furthermore, the Waiver would not

[705] Daniel Hurst, "Australia to Send 2.5m AstraZeneca Vaccine Doses to Indonesia as Covid Infections Soar" (online at 7 July 2021) *The Guardian* <https://www.theguardian.com/world/2021/jul/07/australia-to-send-25m-astrazeneca-vaccine-doses-to-indonesia-as-covid-infections-soar>.

overcome the problem of vaccine hesitancy, which is currently the key factor slowing down the countries' vaccination. The Waiver could be useful for Australia and the Kingdom of Saudi Arabia by helping governments launch domestic production in response to new waves and variants of the Coronavirus, bypass patent protection of particular vaccine components, and supply vaccination campaigns of other countries in line with "vaccine diplomacy" strategies. However, the Waiver could hardly induce significant changes in countries' vaccination campaigns since it would not eliminate the key barriers to their implementation and the main obstacles to domestic production of COVID-19 vaccines.

In general, the current study showed that most bilateral investment treaties and treaties with investment provisions signed by Australia and the Kingdom of Saudi Arabia appropriately balance the rights and interests of IP right holders, investors, and the public on the issue of COVID-19 vaccine development, manufacturing, and distribution in light of the TRIPS Agreement. It was found that the free trade agreement between Australia and the United States is currently the only document reviewed in the study that is inconsistent with the principles of justice as per the utilitarian interpretation of this term. Significant TRIPS-plus provisions introduced by this document weaken the government's position in negotiations with pharmaceutical companies and reduce its ability to prevent a health crisis in Australia. All the other investment treaties are fully compliant with the principles of justice, as they maintain an optimal balance between the rights and interests of different stakeholders.

9.1.1 Limitations

The study has several limitations that should be considered by scholars who would like to apply the findings of this thesis in further research. First, the study is dedicated to a problem that is subject to frequent alterations in an environment with strict time constraints. The situation has been changing rapidly, making many previous insights and discussions irrelevant. For instance, in the beginning of 2020, the TRIPS Waiver was hardly regarded as a realistic document. However, the support of this initiative by the new U.S. administration has turned its introduction into a possible scenario. One may assume that some external events that take place in the next several months could render certain aspects of the study outdated.

Second, a significant number of arguments raised in this study rely on assumptions and reports of third parties. Unfortunately, access to valuable information that was necessary for completing this research is restricted; therefore, the author was forced to collect data from numerous external sources, including those that were not peer-reviewed. In this situation, it is possible that results of the research were affected by biases of journalists, experts, and scholars whose papers were reviewed in the research. It should be noted, however, that necessary measures were taken to minimize the possible influence of these biases on the study's findings.

Third, the current thesis focuses exclusively on the context of the COVID-19 pandemic. The spread of the Coronavirus created unprecedented challenges for the international community, dramatically changing the context in which common IPR-related research problems could be

examined. The available evidence provides a compelling reason to believe that most findings of this study could not be applied to the discussion of health-related IPRs in regard to any other context, such as polio vaccines, because most arguments that are raised by scholars when discussing the COVID-19 pandemic are irrelevant in other settings. Therefore, inferences of the thesis should be discussed exclusively within the context of COVID-19 vaccines.

9.2. Implications of the Study

The study has important implications for different parties. The study's implications for policymakers in Saudi Arabia and Australia could be useful for planning and modifying vaccination campaigns. In particular, findings of the research might be valuable when negotiating new vaccine agreements with pharmaceutical companies and considering the use of parallel importation and compulsory licenses to obtain additional vaccine supplies. The study also provides valuable insights into the role of bilateral investment treaties and treaties with investment provisions in regulating health-related IP rights within the context of the COVID-19 pandemic. In particular, the research might be useful for Saudi politicians when negotiating a free trade agreement with the United States in the future because it shows that restrictive clauses of free trade agreements that are often requested by the United States complicate the use of flexibilities offered by the TRIPS Agreement.

The research also has implications for pharmaceutical companies. The goal of balancing public interests and private rights prevents vaccine developers from insisting on the need to preserve the existing IPR frameworks unchanged and to encourage the "vaccine hoarding" behavior of states. In other words, pharmaceutical companies are expected to agree to some concessions, such as voluntary pledges, the sharing of know-how, or refusal from patent protection of some technologies or components. The current study provides valuable information about possible scenarios in which states could bypass the existing patent protection or strengthen flexibilities offered by the TRIPS Agreement to obtain additional vaccine supplies. These scenarios should be necessarily considered by pharmaceutical companies in order to find optimal mechanisms for protecting their IP rights.

Implications of the thesis for scientists should be also highlighted. An outbreak of the COVID-19 pandemic has led to the growing interest in research topics associated with vaccine-related intellectual property rights. At the same time, many issues raised by scholars in this field are novel and, thus, require detailed examination in light of the existing conceptual frameworks and recent data. The current thesis made a significant contribution to the academic literature by presenting a detailed discussion of the areas of congruence and divergence between investment treaties and the TRIPS Agreement in regard to the regulation of health-related IPRs during the COVID-19 pandemic. Even though the focus of the research is primarily put on the cases of Saudi Arabia and Australia, its findings might be also valuable for discussing the regulation of vaccine-related intellectual property rights in other countries. In particular, implications of the research may be useful for analyzing alternative scenarios for obtaining additional vaccine supplies for those low-income countries that

currently suffer from the lack of vaccine shots and do not possess enough resources for securing more supplies through any other channel besides the COVAX Facility.

9.3. Recommendations for Authorities

Development of practical recommendations for authorities of Saudi Arabia and Australia that could help facilitate vaccination campaigns and obtain additional vaccine doses was not the main objective of the thesis. Nonetheless, findings of the research provide a sufficient amount of evidence for speculating on the ways to enhance and accelerate vaccination campaigns in both these countries. First, the study shows that authorities could increase public funding and stimulate philanthropic funding of local research and development activities. Many Australian companies have achieved significant progress in developing COVID-19 vaccines. A vaccine candidate of the Monash Institute of Pharmaceutical Sciences has been already set for clinical trials, whereas two other candidates focus on targeting new variants. Certain progress in this sphere could be also observed in the Kingdom of Saudi Arabia, as the government relies on research and development activities of SaudiVax and the King Abdulaziz University as a potential sources of new vaccines. Considering that the existing vaccines are only partially effective against the Delta variant, the idea of increasing public investment to develop local vaccines that could specifically target new mutations of the Coronavirus seems promising. Therefore, authorities are recommended to increase public funding in research and development activities of local companies.

Second, local authorities could continue exploring the possibility of utilizing compulsory licenses to start generic production of COVID-19 vaccines. There are currently no legislative barriers to the issuing of compulsory licenses to start generic production of some vaccines. Saudi and Australian governments are recommended to examine the possibility of issuing auxiliary orders to require the transfer of know-how and utilizing other alternative methods to receive necessary know-how from pharmaceutical companies. There is currently no need to issue compulsory licenses in the countries, but such a possibility might become more topical in the near future following the spread of more dangerous variants of COVID-19. Therefore, authorities must examine this scenario and prepare necessary plans depending on different outcomes of negotiations concerning the TRIPS Waiver and other external factors.

Third, authorities should also prepare a series of local regulations that could be issued to support different outcomes of these negotiations. If the TRIPS Waiver is introduced, this decision will not eliminate patent protection under investment law. Therefore, governments should have clear plans for bypassing the protection of IPRs under investment treaties in the case of the TRIPS Waiver's introduction. Unfortunately, it does not seem possible to put forward other recommendations for Australian and Saudi authorities due to a high level of uncertainty surrounding the problem under investigation. It remains unclear whether the international community will reach a final decision on the TRIPS Waiver; furthermore, implications of different Waiver-related scenarios are currently vague. One may hardly predict the actions of pharmaceutical companies in this situation as well as the

response of national governments. Therefore, it is difficult to formulate specific recommendations for Saudi and Australian governments except for those related to the need to increase public funding in research and development activities of local companies and to examine all the possible scenarios in response to the spread of new variants of the Coronavirus and the TRIPS Waiver's introduction.

9.4. Recommendations for Further Research

The study provides many promising areas for further research that could be interesting from the theoretical and practical perspectives in light of the COVID-19 pandemic. First, the research shows that the transfer of know-how from vaccine developers to generic manufacturers is the most problematic issue preventing generic production. Therefore, scholars should explore all the possible mechanisms through which governments, the international community, or other relevant stakeholders could require the transfer of know-how. The available evidence provides a compelling reason to believe that the absence of know-how sharing practices rather than patent protection is now the key barrier to generic production of COVID-19 vaccines; therefore, scholars should investigate possible mechanisms of stimulating or requiring the sharing of know-how.

Second, scientists might consider analyzing the potential of pooled procurement initiatives to contribute to vaccine equity. The current thesis considered only the COVAX Facility when examining pooled procurement; however, it seems justified to argue that countries could also launch other initiatives based on this mechanism in order to negotiate favorable agreements with vaccine manufacturers. By using pooled procurement models, they could increase their bargaining power and, thus, negotiate more favorable prices on vaccine shots, while, at the same time, preventing pharmaceutical companies from setting different prices on vaccine shots in varied agreements and contributing to a gap between high-income and low-income countries in terms of vaccine equity.

Third, scientists are recommended to examine in detail different scenarios in relation to the TRIPS Waiver. It was found in the study that the TRIPS Waiver might become an important factor facilitating vaccine equity. Whereas its relevancy for the cases of Australia and Saudi Arabia is limited, its introduction could play a revolutionary role in boosting vaccination in such countries as India or South Africa. An analysis of various scenarios related to the TRIPS Waiver could help identify possible implications of different variations of a final Waiver for different countries. Scholars could consider analyzing all the possible cases and exploring their implications for the use of compulsory licenses in the cases of specific states.

Fourth, an increased amount of attention should be paid to the role of investment treaties in protecting intellectual property rights of pharmaceutical companies after the introduction of the TRIPS Waiver. As explained in the research, many vaccine developers could continue using patent protection mechanisms to prevent generic manufacturing even if patent protection under the TRIPS Agreement is waived. It currently remains unclear how the Waiver would address this problem. Scientists, therefore, could investigate the potential role of investment treaties in preventing generic manufacturing of COVID-19 vaccines following the TRIPS Waiver's introduction. They could also

analyze possible measures that could be taken by governments to facilitate generic manufacturing in spite of barriers connected with investment law.

Fifth, the academic literature could benefit from deeper understanding of the role of parallel importation in boosting vaccination campaigns of developed, developing, and least developed countries. Parallel importation is one of the most well-known flexibilities of the TRIPS Agreement; however, it was not analyzed in detail in the current thesis, as its focus was mainly put on compulsory licenses. Therefore, it might be a promising idea to discuss the applicability of parallel importation to the cases of various countries both for obtaining additional vaccine supplies and for importing vaccine doses to other countries in line with "vaccine diplomacy" strategies.

Finally, the sixth recommendation that could be put forward based on the findings of this thesis is to analyze the relevancy of patent term extensions for the problem under investigation. At the moment, patent term extensions are one of TRIPS-plus rules that seem irrelevant for the regulation of health-related IPRs during the COVID-19 pandemic. Most components and technologies used for manufacturing vaccines have only been recently patented; therefore, the extension of their patent terms is hardly a pertinent matter. However, it seems justified to assume that the COVID-19 pandemic will not end in the near future owing to the spread of new variants. Therefore, it is possible that vaccine equity within the context of the Coronavirus will remain a topical problem even when patent terms of some vaccines extend. Therefore, the TRIPS-plus rule of patent term extensions might become relevant. A critical examination of the role of this TRIPS-plus rule in preventing generic competition on the vaccine market, thus, seems to be a promising research area.

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