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An investigation into the relationship between the public health system and pharmaceutical patents, specifically whether there is a sufficient balance between protecting patent owner's rights and sufficient access to public health, in the context of previous epidemics and Covid-19.

Under the supervision of Dr Paulina Wilson

Assigned word count: 12,000

Actual word count: 11,979

A Dissertation submitted as part of the requirements for Law LL.B Single Honours,

School of Law, Queen's University Belfast

Abstract

The pharmaceutical industry has always been in contention with the access to public health aims and this has led to a deplorable relationship being established. Research indicates that The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994 was a monumental piece of legislation, however criticism and issues eventually arose. This paper investigates why the relationship between intellectual property rights, in particular patents, and the right to affordable and substantial public health is so hostile. In this paper the patents on pharmaceuticals and vaccines are particularly explored, especially in relation to the approaches taken by countries, NGOs, and specific regions. Building on the existing research and case studies this paper asks: can a significant balance be found in evaluating these two important rights? Based on a review of academic literature, case studies, international legislation and recent developments, a balanced argument is presented. In the context of previous epidemics i.e., HIV/AIDS, Malaria and Ebola, to what extent are intellectual property rights enforceable if they hinder the right to sufficient public health access? Research indicates that whilst TRIPS provides a balance of provisions regarding these two sets of rights, the debate continues. The different provisions and solutions provided in TRIPS, i.e., compulsory licensing and voluntary licensing etc, do provide alternative routes and resolutions. On this basis it is recommended that the most balanced approach is using voluntary licensing, where pharmaceutical companies can maintain their intellectual property rights whilst facilitating the access to sustainable public health. Further reform is needed however, to strengthen the effectiveness of this balance and to allow for a more equitable approach.

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Chapter One:

The debate surrounding the relationship between pharmaceutical patent holder's rights and the access to sufficient public health.

1.1 Introduction

The public health system is clearly of fundamental importance considering several governments contribute substantial amounts of money supporting it.[1] It is also apparent patenting and pharmaceuticals occupy an established niche in the healthcare system, due to the vast number of patented pharmaceuticals available.[2] It has been argued that, 'one of the most strongly contested aspects of pharmaceutical policy concerns the role of intellectual property (IP) and regulatory rights in providing economic incentives to firms and in shaping the agenda for basic medical research.'[3] This paper attempts to answer the question of whether a sufficient balance can be found between both sets of rights.

IP law is more relevant than ever due to the unprecedented pandemic and the subsequent race to develop effective vaccines and sufficient treatments for Covid-19. More specifically patents play an extensive role in this and this is supported by the 14 currently approved vaccines (as of April 2021), not to discount the 60 still in development.[4] It also reignites the discussion into the complicated relationship and structure between public health objectives and the pharmaceutical industry's regulatory rights.[5]

1.2 Methodology

This paper was conducted through desk-based research and takes a subjective approach towards the issues surrounding intellectual property, patent law and the access to public health. This paper

[1] Edward Ventose, *Medical Patent Law – The Challenges of Medical Treatment* (1st edn, Edward Elgar Publishing 2011)
[2] Ron Bouchard, *Patently Innovative how Pharmaceutical Firms Use Emerging Patent Law to Extend Monopolies on Blockbuster Drugs* (1st edn, Woodhead Publishing 2012)
[3] ibid.
[4] Jeff Craven, 'COVID-19 Vaccine Tracker' (*Raps.org*, 2021) <https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-vaccine-tracker> accessed 30 March 2021.
[5] ibid.

cultivates the views of many academics and commentators whilst interacting with the different approached taken by NGOs, pharmaceutical companies, and countries. Different pieces of legislation in addition to relevant case studies will be analysed. The purpose of this approach is to dissect the differences between theoretical IP law and the actual practicalities of implementing it in a balance approach. This will allow for a comprehensive analysis of the themes and issues leading to a plausible recommendation for change.

1.3 Patents

Patents are created when an invention or discovery is granted exclusive monopoly to the inventor for disclosing the technical information relating to their invention.[6] Once control is granted, the use of the patent is theirs exclusively for a 20-year period, which prevents others from utilising, importing, or selling the claimed invention.[7] These stipulated rules allow the patent system to function, rewarding inventive creations which establishes a space 'conducive to securing the complementary assets, capital, manufacturing, marketing and support' as essential for a functioning marketplace.[8] Organisations namely the World Health Organisation (WHO), an agency of the United Nations (UN) and the World Trade Organisation (WTO) are crucial elements of the framework built around the international patent system. They form international treaties on patent protection on a global scale and strive towards harmonisation, which some countries may not necessarily agree with, due to unequal bargaining power.[9]

1.4 Legislative Frameworks

The WHO and WTO exhibited their involvement in IP law development when The Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (afterwards TRIPS) was first introduced.[10] Their involvement in public health and IP law has further increased since TRIPS. Sell

[6] Abbe Brown and others, *Contemporary Intellectual Property: Law and Policy* (5th edn, Oxford University Press 2019)
[7] ibid.
[8] F Scott Kieff, 'Property Rights and Property Rules for Commercializing Inventions' (2000) 85 MLR 697.
[9] Brown (n 6).
[10] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299. (hereinafter TRIPS Agreement)

outlined that '[since TRIPS, the] WHO increasingly has been drawn into trade issues [including IP issues], and NGOs have had considerable access to the institution.'[11] TRIPS significantly drove the influence of the WHO in the field of public health and IP policy, notably Volansky stated that the 'WHO remains the predominant figure that guides, monitors, teaches, and even regulates Member States on global health', outlining its position in this discussion.[12] Whilst other IP legislation exists and are vital to the international framework, they are beyond the scope of this paper.

Articles 27-34 of TRIPS are key sections relating to the development of patent law.[13] Once enacted TRIPS was set apart from other international legislation due to its comprehensiveness as it subjected all WTO party states to legislate a minimum level of patent protection in addition to creating a judicial body to enforce these rules.[14] It is a progressive piece of legislation however this does not negate the fact that it is open to constructive legal criticism. This argument is convincing as prior to the introduction of TRIPS, developing countries and some developed countries excluded pharmaceuticals from patenting and because of TRIPS, patent holders in these regions now had the capacity to have power over pricing.[15] The implications of IP protection and the relatively high minimum standards set in TRIPS are undoubtedly an uneven disadvantage for developing countries.[16]

Whilst TRIPS did negotiate mandatory protection for pharmaceuticals, leading to crucial incentives for pharmaceutical innovation, developing countries found these patent laws restricted the supply and production of low-cost generic pharmaceuticals developed in local or other developing countries.[17] They argued this would lead to higher prices progressing into a lack of

[11] Susan Sell, 'TRIPS-Plus Free Trade Agreements and Access to Medicines' (2007) 28 LLR 41.
[12] MJ Volansky, 'Achieving Global Health: A Review of the World Health Organization's Response' (2002) 10 TJCIL 223.
[13] TRIPS Agreement (n 10) art 27.1-34.
[14] Andrew Law, *Patents and Public Health: Legalising the Policy Thoughts in the Doha TRIPS Declaration of 14 November 2001* (1st edn, Nomos Publishing 2008).
[15] Richard D Smith, Carlos Correa and Cecilia Oh, 'Trade, TRIPS, And Pharmaceuticals' (2009) 373 The Lancet 684.
[16] ibid.
[17] Monirul Azam, *Intellectual Property and Public Health in the Developing World* (1st edn, Open Book Publishers 2017).

sufficient access for their citizens.[18] The Least Developed Countries (LDCs) of the UN argued that they were already 'struggling to provide their population with prevention, treatment, and care. Patent protection contributes to high costs, placing many critical treatments outside...' their reach.[19] This led to the Council for TRIPS to approve a waiver for pharmaceutical patents until 1 January 2033, or until these countries stop being LDC Members.[20] Therefore, these countries can still produce generic versions of patented pharmaceuticals meaning they can serve the needs of their developing population and remove the hindrance to affordable medicine.[21] TRIPS has been subject to much scrutiny since the beginning of the Covid-19 pandemic, illustrating the need to define a balance between public health and IP policy.

Furthermore, the Doha Declaration 2001 crucially addressed the need to strike a balance between the existing compulsory licensing system and patent protection.[22] Compulsory licensing was identified by many developing countries as a limitation to their public health duties as it was a convoluted process and incorporated several procedural challenges.[23] The Doha Declaration responded to the issues raised and stated that TRIPS should be interpretated in support of public health aims and clarified that countries could avail of any form of the flexibilities that TRIPS provided.[24] Article 31 of the TRIPS Agreement detailed that negotiations should occur with the patent holder before any compulsory licensing or manufacturing of the drug can take place.[25] This proclamation also permitted compulsory licenses to be issued internationally, as to allow for national governments to import the drugs for use in their domestic market.[26] Whilst this provides the patent holder protection, it also may cause significant problems especially with the demand of a pandemic, as this is severely time-consuming process.

[18] ibid.
[19] ibid.
[20] Decision of the Council for TRIPS (6 November 2015) IP/C/73 <http://docsonline.wto.org>
[21] *Global Intellectual Property Rights—Knowledge, Access and Development*, ed. by Peter Drahos and Ruth Mayne (Palgrave Macmillan, 2002), pp. 201–13.
[22] World Trade Organization, Ministerial Declaration (14 November 2001) WT/MIN(01)/DEC/1.
[23] Dina Halajian, 'Inadequacy of TRIPS & the Compulsory License: Why Broad Compulsory Licensing is Not a Viable Solution to the Access Medicine Problem' (2013) 38 BJIL 1190.
[24] ibid.
[25] Declaration on the TRIPS Agreement and Public Health (14 November 2001) WT/MIN(01)/DEC/W/2.
[26] Munir Suboh and Felicity Hammond, 'The Role of Patents In COVID-19' [2020] *The Patent Lawyer*.

1.5 Compulsory Licensing

Compulsory licensing is when the government overrides the patent holder's rights and allows a third party to produce a patented product.[27] This was one of the flexibilities included in TRIPS for public benefit. In the mid-2000s Thailand tried to negotiate with Merck, AbbVie, and Abbott Laboratories to reduce the prices of efavirenz, lopinavir to treat their HIV/AIDS patients at the height of the epidemic, however the offers were expensive leading Thailand to issue a compulsory license in 2006.[28] This allowed the government to import generic versions of the antiretroviral drugs at a remarkably lower price from India and treat patients rapidly.[29] Similarly, in 2007 Brazil issued a compulsory license for efavirenz, as they faced similar problems with Merck. Merck offered efavirenz at the price of US$760 PPPY (per patient per year) but with compulsory licensing Brazil imported efavirenz at US$170 PPPY.[30] Evidently, enacting the flexibilities of compulsory licensing allowed Thailand and Brazil to treat the challenges and was a practical way to access affordable antiretroviral drugs.

1.6 Voluntary Licensing

The alternative to compulsory licensing is voluntary licensing and this is when IP holders voluntarily grant licenses to their patents, which allows for generic companies to produce that product.[31] There are also market outlines and quality requirements set in place by the patent holder allowing them to still protect their invention and attain some control.[32] This could be beyond useful because when companies produce a single drug or vaccines, there could potentially be dozens or even hundreds of patent applications. Specifically, some of the bestselling pharmaceuticals have over 131 patent applications.[33] Medicines and vaccines involve several patents as they cover not

[27] 'WTO, 'Compulsory Licensing of Pharmaceuticals And TRIPS' (*Wto.org*, 2021) <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 1 April 2021.
[28] Nathan Ford and others, 'Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand' (2007) 21 AIDS 21.
[29] ibid.
[30] ibid.
[31] Randall Kuhn and Reed Beall, 'The time for pharmaceutical compulsory licensing has expired' (2012) 18 Nature Medicine 1168.
[32] ibid.
[33] 'Data on America's Bestselling Drugs – I-MAK' (*I-mak.org*, 2021) <https://www.i-mak.org/2019-bestselling> accessed 10 March 2021.

only the active ingredients, which is the primary patent, but they also extend to the different features of the drug or vaccines, i.e., formulations, dosages, and the conditions that the drug or vaccine can treat.[34]

1.7 The role of vaccines

Vaccines are pivotal in developing the public health system, as they provide populations the chance to curb the spread of infectious diseases with the possibility of eradicating them.[35] The Covid-19 humanitarian crisis has exposed the faults within the patent law mechanism, so much so that the WHO is calling it 'a catastrophic moral failing.'[36] India and South Africa have proposed a plan asking the WTO to 'allow all countries to choose to neither grant nor enforce patents and other (IP) related to COVID-19 drugs, vaccines, diagnostics, and other technologies for the duration of the pandemic, until global herd immunity is achieved.'[37] South Africa are allegedly paying more for the Pfizer/BioNTech vaccine doses than the EU, possibly because the EU publicly invested in the early stages of development or their advance purchase agreement.[38] This seems to undermine the humanitarian crisis that is currently ongoing simply for privatisation of profits.[39] The question posed is, would the sharing of technology not be for the betterment of the masses, rather than maintaining the status quo of preserving the global scarcity to uphold the market?[40] Looking at the pharmaceutical industry's history, pushing the legal boundaries of IPRs has always been the norm, but perhaps Covid-19 poses a chance for change.[41]

[34]'Pharmaceutical Patent Myths' (*I-mak.org*, 2021) <https://www.i-mak.org/wp-content/uploads/2020/12/Patent-Myths-2020-12-17.pdf> accessed 30 March 2021.
[35] Qiwei Xue and Lisa Ouellette, 'Innovation Policy and The Market for Vaccines' (2020) 7 JLB 1.
[36] 'WHO Director-General's Opening Remarks At 148Th Session of The Executive Board' (*Who.int*, 2021) <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board> accessed 5 April 2021.
[37] 'Governments Must Support Proposal to Waive Coronavirus COVID-19 Patents' (*MSF International*, 2020) <https://www.msf.org/governments-must-support-proposal-waive-coronavirus-covid-19-patents> accessed 15 January 2021.
[38] Owen Dyer, 'Covid-19: Countries are learning what others paid for vaccines' (2021) 372 BMJ <https://www.bmj.com/content/372/bmj.n281> accessed 28 April 2021.
[39] ibid.
[40] ibid.
[41] Olivier J Wouters and others, 'Challenges in Ensuring Global Access To COVID-19 Vaccines: Production, Affordability, Allocation, And Deployment' (2021) 397 The Lancet 1023.

1.8 Summary

IP and patent jurisprudence have been brought into the forefront of global conversation especially because of the Covid-19 pandemic. Chapter 2 will dive into the arguments in favour of both supporting patent protection or public health access by examining how pharmaceuticals patents and vaccines were dealt with in previous epidemics i.e., HIV/AIDS, Malaria and Ebola. With the numerous amounts of patent applications in progress for vaccines and pharmaceuticals, can there be a balance struck between patent protection, public health access and the humanitarian facet?

Chapter Two:

Past epidemics and health crises: challenges, approaches and lessons learnt

2.1 Introduction

This chapter delves deeper in the investigation of the ongoing debate into how far patent protection extends and to what degree it is acceptable if it hinders access to public health. Firstly, this investigation was significantly amplified by the HIV/AIDS epidemic. The analysis is focused on the compulsory licensing of pharmaceuticals and this approach is taken as there was no vaccine developed and the only course of action was treatment. Secondly, the Malaria epidemic and the different strategies that NGOs have taken to avoid the complications of IP are examined. This analytic approach is taken as the outbreak was widespread and different countries took various strategies, but the focus is NGOs. Lastly, the Ebola crisis will be considered as there were sizable problems that were exposed in relation to dealing with global health crises. This chapter will review the common themes and issues arising in addition to the different approaches taken by individual countries, NGOs, and regions.

2.2 Case study one: HIV/AIDS

Over 95% of HIV-infected people live in the developing world and 95% of the deaths from AIDS are also in the developing world.[42] In comparison, there is a significant reduction of mortality in the developed world due to access to the highly active antiretroviral pharmaceuticals.[43] The increase in access to these antiretroviral pharmaceuticals used in treatment has allowed more than 5 million HIV-infected people to acquire treatment.[44] The Doha Declaration affirms that patent rules are to be implemented and interpreted in a manner that allows for access to pharmaceuticals and public health protection.[45] The HIV/AIDS crisis outlined the heightened awareness of the role that patents

[42] 'Patent Situation Of HIV/AIDS-Related Drugs In 80 Countries' (*Who.int*, 2020) <https://www.who.int/3by5/en/patentshivdrugs.pdf> accessed 1 April 2021.
[43] ibid.
[44] Ellen Hoen, 'Driving a decade of change: HIV/AIDS, patents and access to medicines for all' (2011) 14 JIAS 15.
[45] ibid.

play in high HIV drug prices, leading to health activists contesting that TRIPS and patents have a key role in denying people access to HIV/AIDS drugs.[46] The rights and protections set out for patent holders are clear and pharmaceutical companies fiercely defend their position, claiming that these rights allow a return on R&D investments and continue to provide incentive to new creators.[47]

2.3 Different approaches taken by countries:

This section is critically analysed on a country basis, specifically Brazil, South Africa, and India, due to the large-scale legislative provisions that were introduced and their significance to the discussion.

2.3.1 *Brazil*

Brazil was one the first countries to implement the generic production of HIV/AIDS drugs and medicines through its programmes and indicated to the world that it was possible to provide safe antiretrovirals (ARVs) with limiting factors.[48] This was seen as a controversial policy and in direct conflict with patent rights and protections and many went as far as stating that this would hinder the incentive to research and develop a solution for the crisis.[49] The distribution programme was freely provided to Brazilian citizens, allowing those HIV-infected persons to have free access to life saving treatment. Whilst Brazil's programmes relied on producing low-cost generic versions of ARVs, which had no outstanding patents in Brazil, they came under pressure from wealthier countries that tried to coerce them into implementing tighter patent protections.[50] This resulted in Brazil enacting national pharmaceutical patents laws in 1996, which was nine years before it was required under TRIPS obligations.[51] The implementation of this legislation began increasing the price of patented drugs, which led to a significant strain on their budget and national HIV/AIDS

[46] Hoen (n 44).
[47] ibid.
[48] Hoen (n 44).
[49] ibid.
[50] Renata Reis and others, 'Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in The Global South' (*Abiaids.org.br*, 2009) <http://www.abiaids.org.br/_img/media/Intellectual_Property_internet.pdf> accessed 21 March 2021.
[51] ibid.

programmes. It was recorded that three of the seventeen patented medicines took up over 75% of the HIV/AIDS drug budget leading to a serious strain on the government.[52]

Before the legislation was introduced in Brazil, the use and production of generic versions of patented drugs was a resounding success, UNAIDS found that five generic AIDS drugs and the country's universal policy of access to ARVs benefited all AIDS and HIV-infected people.[53] UNAIDS found that the death rate was nearly halved, which was a massive accomplishment for Brazil.[54] The number of opportunistic infections was reduced by 60-80%, demonstrating that setting aside patents and producing generic ARVs created a significant impact on the challenges of the epidemic.[55]

2.3.2 *South Africa*

During the HIV/AIDS crisis, South Africa already had patents in force hence why the government made the decision to pass the Medicines and Related Substances Control Act, Act No. 90 of 1997.[56] This Act allowed for parallel imports, leading to local South African companies to produce the necessary drugs under compulsory licensing, under Section 22c.[57] Evidently, the South African government interpreted the TRIPS provisions as permitting the implementation of legislation that addressed public health concerns, allowing them to take necessary steps in securing a national strategy plan. However, in 1999 the US and South African governments came to an agreement on the interpretation of TRIPS and established that TRIPS was created to ensure there would be a significant amount of IP protection, but it was also made to account for governments needing to address their countries' social and public health needs.[58] This is demonstrated in Articles 31 and 6 of TRIPS, where Article 31 allows a country to grant the use of a patent without the authorisation

[52] Ford (n 28).
[53] 'Patent Situation' (n 42).
[54] ibid.
[55] ibid.
[56] Medicines and Related Substances Control Act, 92 of 1997.
[57] ibid sec 22(c).
[58] William Fisher and Cyrill Rigamonti, 'The South Africa AIDS Controversy: A Case Study in Patent Law and Policy'' (*Boris.unibe.ch*, 2005) <https://boris.unibe.ch/69881/1/South%20Africa.pdf> accessed 13 April 2021.

of the patent holder and Article 6 relates to how countries decide to deal with exhaustion in a way suited to their domestic policy aims.[59]

Subsequently, the South African government's decision to introduce the Medicines and Related Substances Control Act 1997 and allow for parallel imports and compulsory licensing, was a significantly progressive decision and an effective interpretation of their obligations under TRIPS. In deciding this, the government was scrutinised intensely by the western world, specifically the US.[60] The US argued that the South African legislative measures initiated an attack on the rights of the relevant HIV/AIDS medicines' patent holders as well as the pharmaceutical industry. Whilst these concerns were warranted and did outline the significant criticisms of the application of IP standards, they were ultimately addressed thoroughly in the Doha Declaration. The Doha Declaration did assert the rights of countries to implement the crucial public health policies and measures that might be required during an epidemic such as the HIV/AIDS epidemic. The ARVs necessary for HIV/AIDS treatment would not have been accessible had the patent rights been used to overrule the essential public health aims.[61] The implication of this is clear, IPRs are important however these can be set aside if they hinder the access to sufficient public health and affordable medicines.

The several antiretrovirals, including azido thymidine, which were used in the ARVs and HIV/AIDS treatments, were vital in battling the HIV/AIDS crisis and before the introduction of the South African legislation, the patent protection held would have priced these drugs out of reach from the general population in the country, leaving the country exposed to a greater health crisis.[62] These incentives provided to the patent holders offered a good resolution, as royalty payments were made to the patent holders of azido thymidine as well as the other patented antiretroviral drug.[63] In

[59] TRIPS Agreement (n 10) art 6, 31.
[60] Olasupo Owoeye, 'Intellectual Property and Equitable Access to COVID-19 Vaccines and Therapeutics' (2020) 42 EIPR 584.
[61] ibid.
[62] Cheluchi Onyemelukwe and others, 'Patents, Access to COVID-19 Vaccines and Medicines, and Traditional Medicine: A Dilemma for African Countries' (2020) 42 EIPR 569.
[63] ibid.

this, South Africa was able to avoid the lawsuit against them and exhibited that there was a sufficient balance in relation to the interpretation of TRIPS.[64]

In 2003, the Joint UN Programme on HIV/AIDS and the WHO declared the lack of access to medicines and HIV/AIDS treatments a global health emergency and stated that there would be a campaign titled "3 by 5" to get over three million people on ARVs by 2005.[65] Due to the rising political momentum and the growing public outrage because of the inaction of the international community, the Global Fund and the US's Emergency Plan for AIDS Relief made it possible for countries to purchase HIV/AIDS drugs in large quantities. This led to pharmaceutical companies being compelled to respond to the patent challenges by agreeing to grant voluntary licences for their patents. After the South African discussions, Thailand was granted permission from the US to issue compulsory licenses for HIV/AIDS drugs under patents.[66] In South Africa, Boehringer-Ingelheim and GlaxoSmithKline extended their voluntary licenses as part of the agreement made in the AIDS Law Project.[67] This occurred because the Treatment Action Campaign and other organisations had filed a complaint with the South African Competition Commission, which they were successful with.[68]

2.3.3 *India*

India did not have provisions in The Patents Act 1970 for pharmaceuticals patents until they had to be implemented under TRIPS in 2005.[69] Therefore, Indian pharmaceutical companies were able to produce several low-cost generic versions of HIV drugs and even went as far as creating 'fixed dose

[64] ibid.
[65] Amir Attaran and Lee Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?' (2001) 286 JAMA 1886.
[66] ibid.
[67] Niels Obel and others, 'Impact of Non-HIV and HIV Risk Factors on Survival in HIV-Infected Patients on HAART: A Population-Based Nationwide Cohort Study' (2011) 6 PLOS ONE <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0022698> accessed 31 March 2021
[68] Tenu Avafia, Jonathan Berger and Trudi Hartzenberg, 'The Ability of Select Sub-Saharan African Countries to Utilise Trips Flexibilities and Competition Law to Ensure A Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries' (*Unctad.org*, 2006) <https://unctad.org/system/files/official-document/ictsd-tralec2006d3_en.pdf> accessed 5 April 2021.
[69] Jennie Connor, Natasha Rafter and Anthony Rodgers, 'Do Fixed-Dose Combination Pills or Unit-of-Dose Packaging Improve Adherence? A Systematic Review' (2004) 82 BWHO 935.

combinations', by combing two or more medicines into one single pill.[70] This innovation was facilitated by the lack of patented medicines and these different combinations were shown to simplify chain management and reduce the risk of resistance to the medication.[71] Whilst these companies in India were not the first to produce this type of combination, they were the first to produce the first line regimen that the WHO recommended that included, stavudine, lamivudine and nevirapine.[72] These were vital in securing essential care to their HIV-infected patients at a relatively low cost and additionally resulted in many other developing countries successfully following suit.[73]

Moreover, in 2001 Cipla, one of India's generic pharmaceutical producers, was found to offer a combination of the ARVs for $350 PPPY, essentially offering care for less than a dollar per day.[74] Another company offered a $2 generic form of the Pfizer fluconazole patent, which is an AIDS related meningitis drug and originally cost $17.[75] The significant price reduction offered by Cipla at the time resulted in extensive media outrage that flagged the message outlining that pharmaceutical companies were abusing the system and taking advantage of the devastating public health crisis.[76] Ultimately, this drew the attention of other organisations and governments causing other generic producers to reduce the prices of the pharmaceuticals, leading to India being recognised as the 'pharmacy of the developing world'.[77] By 2008, 95% of the global donor funded ARVs was comprised full of generics, mostly from India, and the generic ARVs purchased from PEPFAR grew from 15% to 89% within three years.[78] PEPFAR was estimated to have made over

[70] Thomas Moulding, Asim Dutt and Lee Recichman, 'Fixed-Dose Combinations of Antituberculosis Medications to Prevent Drug Resistance' (1995) 14 AIM 951.
[71] ibid.
[72] ibid.
[73] Donald McNeil, 'Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa' *New York Times* (2001).
[74] 'AIDS Triple Therapy for Less Than $1 A Day' (*Doctors Without Borders*, 2001) <https://www.doctorswithoutborders.org/what-we-do/news-stories/news/aids-triple-therapy-less-1-day> accessed 25 March 2021.
[75] ibid.
[76] McNeil (n 73).
[77] ibid.
[78] Brenda Waning, Ellen Diedrichsen and Suerie Moon, 'A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries' (2010) 13 JIAS 35.

$323 million savings over the four years, demonstrating how successful the use and access of generic pharmaceuticals was for not only patients but also companies.[79]

2.4 Considerations

Whilst compulsory licensing works well in some countries, many do not believe it would solve the health crisis. It was argued that if pharmaceutical companies were given a sufficient licensing fee, there would be a partial solution to the debate concerning the balance of interests involved in a health crisis.[80] HIV/AIDS drugs need a sophisticated manufacturer to develop the drugs and this type of technology is inaccessible to many in developing countries. Meaning that even if compulsory licensing is available, it may not globally solve all the problems associated with pharmaceutical affordability related to HIV/AIDS, considering that many developing countries do not have the infrastructure to handle this.[81] Further emphasising that TRIPS and the IPRs of pharmaceutical companies are not intrinsically the only hinderance to the availability of HIV/AIDS treatments.[82]

An issue arising around compulsory licensing is the time scale in which the licenses are granted in addition to the negative consequences stemming from enacting a compulsory license. Whilst the case of South Africa was successful, in countries like Malaysia it was a more complex matter. Malaysia utilised the introduction of the Doha Declaration and after failed negotiation with patent holders Bristol-Myers Squibb and GlaxoSmithKline, they issued a compulsory license for the Malaysian governments use of the HIV/AIDS ARVs and imported the ARVs from India, which, as previously mentioned, exploited their local production sites to supply their neighbouring regions.[83] Moreover, the license was only granted after a three-year period of negotiations, due to the complicated nature of their domestic regulations, where three different government entities were required to be involved in the negotiations. It is easily suggested that compulsory licensing is the

[79] Charles Holmes and others, 'Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs' (2010) 304 JAMA 313.
[80] 'Patent Situation' (n 42).
[81] ibid.
[82] 'Patent Situation' (n 42).
[83] ibid.

optimal solution to balancing patent holder's rights and providing accessible public health care, however the reality is the process is much more complicated and lengthier. International frameworks such as TRIPS can only go as far as domestic legislation allows, creating a significant problem, notwithstanding the waiver that TRIPS permits lasting until 2033.

Another criticism of compulsory licensing is that in practice it raises several questions regarding the payments, as under Article 31(c) patent holders are permitted to receive 'adequate remuneration' based on the economic value of the country.[84] This is generally decided on a case-by-case basis however, the remuneration obligation also affects situations where the drug is not patent protected in the importing country, leading to the critical view of compulsory licenses.[85] Collins-Chase contends that in cases as such, the country importing the drugs under TRIPS would be in a worse position than if they domestically produced the drugs.[86] Furthermore, the article hinders exportation to countries lacking sufficient infrastructure and in need of vital drugs as subsection (f) prevents drugs produced under a compulsory license to be exported if the export is the sole purpose of the license.[87] Clearly, compulsory licensing is not an all-encompassing solution and has restrictions and negative consequences that are detrimental, mostly to developing countries, outlining the downfalls of some TRIPS sections. It is comprehensible why several HIV/AIDS medicines and treatments are mainly produced in generic supplier countries such as India and Brazil.[88]

The drugs under patent for the treatment of HIV/AIDS create obstacles for procurement and outline the critical debate surrounding the balancing of rights and public health access. Seemingly, a vaccine would be easier to support the fight against HIV/AIDS and deliver to developing countries, but the lack of investment and interest indicates the underwhelming tailoring to the needs

[84] Jenny Wakely, 'Compulsory Licensing Under TRIPs: An Effective Tool to Increase Access to Medicines in Developing and Least Developed Countries?' (2011) 33 EIPR 299.
[85] ibid.
[86] Charles Collins-Chase, 'The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics' (2007) 29 UPJIL 763.
[87] Fanni Weitsman, 'TRIPS, Access to Medicines and the "North-South' Conflict after Doha: The End or the Beginning?' (2006) 6 ARIBTL 67.
[88] Tolulope Adekola, 'Has the Doha Paragraph 6 system reached its limits?' (2020) 15 JIPLP 525.

of these countries. There seems to be a greater investment in the drug therapy combinations, which could possibly be related to the lack of financial return. There is scope for larger efforts in this regard and a shift in viewing pharmaceutical prices as a political issue to a humanitarian one, may help.

2.5 Case study two: malaria

Malaria is another health crisis that sparked significant debate into the effects IPRs have on the access to medicines. Malaria is a deadly tropical disease that affects over 300 million people and leads to over one million deaths yearly.[89] The developed world has mostly eradicated malaria due to access to effective medicines, chemical treatments to control mosquito populations and water system management, i.e., approaches which many countries in the developing world do not have access to.[90] In countries where malaria is prevalent, the challenges that arise are related to costs and controlling environmental and health effects of chemical parasite removal.[91] Hence IP problems arise in approaches to treatment and prevention, which are overshadowed by the differences between developing and developed nations access. In terms of a malaria vaccine, the possibility of commercialising an effective vaccine raises issues, as there are many patents that cover malaria antigens, and it is likely than more than one is necessary.[92] There is only so much that IP can do, however the underlying issue of poverty is intrinsically linked to the factors that do not allow the facilities or infrastructure to deal with malaria, possibly requiring IP to make some concessions.[93] However, with the complexity of IP law the possibility of accessing more than one antigen for a vaccine through the normal licensing route or partnering, could occur in enormous R&D costs.[94] Therefore, the potential negotiation process and access to the key patents may not even be available since different companies own the patents necessary for a malaria vaccine.[95]

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[89] Anatole Krattiger and Richard Mahoney, *Intellectual Property Management in Health and Agricultural Innovation* (1st edn, MIHR 2009).
[90] ibid.
[91] ibid.
[92] Vasee Moorthy and others, 'Malaria Vaccine Developments' (2004) 363 The Lancet 150.
[93] Francesco Ricci, 'Social Implications of Malaria and Their Relationships with Poverty' (2012) 4 MJHID e2012048.
[94] ibid.
[95] ibid.

2.6 Different NGOs Approaches:

This section is analysed through the comparison of different NGO partnerships and approaches as this best illustrates how the question of balancing rights was addressed during the malaria epidemic.

2.6.1 *MMV (Medicines for Malaria Venture)*

MMV is one of the members of the public-private partnership created by World Intellectual Property Organization (WIPO) in association with BIO Ventures for Global Health in 2011.[96] MMV is the first product development collaboration to contribute IP to the Open Innovation Against Neglected Tropical Diseases Pool.[97] The Pool was formed in 2009 by Alnylam Pharmaceuticals and GlaxoSmithKline, now also collaborating with MIT, to innovate for neglected tropical diseases and ensure public access to IP.[98] This partnership recognises there are neglected tropical diseases, including malaria, that affect the poorest people and propels the development of medicines through innovative research partnership and knowledge sharing.[99] MMV was formed to bridge the gap left by the market failure because of the lack of research for malaria and it works with those in the public and private field to create new antimalarials at lower prices.[100] The risk that exists with development of antimalarials is relieved by MMV, as they support efforts to fund projects and the involved governments and charitable sources participate collaboratively.[101]

MMV in collaboration with their partners have brought forward six new quality antimalarials and have developed two drugs.[102] Seemingly, MMV's strategy is effective and a pragmatic approach to the IP debate. As a way of balance, the pharmaceutical collaborator decides the patent strategy which Somaya details as 'a set of resource allocation decisions and underlying 'logics' of decision making about patents that primarily occur in three broad (and interdependent) domains of

[96] Sylvie Fonteilles-Drabek and others, 'Managing Intellectual Property to Develop Medicines for The World's Poorest' (2017) 16 NRDD 223.
[97] 'MMV Becomes First PDP To Make Its IP Freely Available for Neglected Diseases Research | Medicines for Malaria Venture' (*mmv.org*, 2010) <https://www.mmv.org/newsroom/press-releases/mmv-becomes-first-pdp-make-its-ip-freely-available-neglected-diseases> accessed 31 March 2021.
[98] ibid.
[99] ibid.
[100] Fonteilles-Drabek (n 96).
[101] ibid.
[102] ibid.

activity: rights, licensing, and enforcement.'[103] This increases the value of the product and the majority of MMV's antimalarials have clear IP ownership and have patent protection, encouraging the pharmaceutical industry's participation.[104] This seems to be a valuable partial answer to the debate, outlining the fact that the pharmaceutical partners and their experience in taking drugs to the market are vital, however the affordability of the antimalarial drugs is the priority.[105] These protections also allow for the antimalarials to be quality controlled in manufacturing to meet the public health goals for vulnerable populations.[106] The patent protection does not extend to malaria afflicted countries except for India, China, and Brazil, due to their extensive generic manufacturing presence.[107] Clearly, MMV has found a valid solution for the IP question, outlining the fact that both IPRs can be valued whilst addressing public health concerns.[108]

2.6.2 *Further pharmaceutical collaboration*

Furthermore, there has been progress made as in 2007 an innovative partnership between French pharmaceutical company Sanofi-Aventis and Drugs for Neglected Diseases imitative led to a new affordable non patented drug for the treatment against malaria.[109] This has been extended further to create a partnership with Faramanguinhos/Fiocruz, a public Brazilian pharmaceutical company, where they created a new non patented anti-malarial drug.[110] Many people who suffer with malaria live in countries where there is no mefloquine resistance and hence a new unpatented combination could be made to treat these people. The drug including the component, artesunate and mefloquine, created a new unpatented combination called ASMQ, which now treats people who suffer with uncomplicated falciparum malaria in Asian and South American countries.[111] This provides a

[103] Deepak Somaya, 'Patent Strategy and Management: An Integrative Review and Research Agenda' (2012) 38 JOM 1084.
[104] Melinda Anthony and others, 'The Global Pipeline of New Medicines for The Control and Elimination of Malaria' (2012) 11 Malaria Journal 316.
[105] ibid.
[106] ibid.
[107] ibid.
[108] ibid.
[109] Christine Årdal and John-Arne Røttingen, 'An Open-Source Business Model for Malaria' (2015) 10 PLOS ONE < https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0117150> accessed 31 March 2021
[110] ibid.
[111] ibid.

sustainable solution that is cheaper, quicker, and more effective for the patients suffering with malaria, demonstrating that a balance is possible.

2.7 Considerations

Chloroquine is one of the medicines used to treat malaria, although it was originally banned as a first line of treatment, it was found in some cases to be effective.[112] Chloroquine particularly, raises little debate about the patent due to its long-standing use in different treatments. In accessing chloroquine, countries like Nigeria opt to import the generic medicine through providers in India, because of their infamous lower costs. The challenge that arose in the malaria epidemic, especially in African countries, was the access to other essential drugs, which were priced dearly unlike chloroquine. It has been argued that patent protection indirectly restricts the access to vital medications and in this, creating an opposition to the implementation of IPRs and the harmonisation of international regulations.[113]

Patent regulation provides an exclusionary right thereby limiting access to certain medicines and treatment options in epidemics. This is evidenced by academics supporting the view that the patent system is 'highly distortionary and inequitable in the way in which funds to support research are raised-by charging monopoly prices, e.g., in the case of pharmaceuticals, on the sick…the patent system is the worst, given that it relies on monopolization, which entails high prices and restricted usage.'[114] Hence the proposition of harmonising patent law is not enthusiastically accepted by developing countries, as in practice they will be disproportionately impacted by the measures and this could hinder the potential of their public health systems.[115] The position of patents is secure, however there could be further discussion had about the different approaches and regulations for

[112] Onyemelukwe (n 62).
[113] Reed Beall, Rosanne Blanchet, and Amir Attaran, 'In Which Developing Countries Are Patents on Essential Medicines Being Filed?' (2017) 13 Globalization and Health 1.
[114] Giovanni Dosi and Joseph E. Stiglitz, 'The Role of Intellectual Property Rights in the Development Process, with some Lessons from Developed Countries: An Introduction' in Mario Cimoli and others (eds), *Intellectual Property Rights Legal and Economic Challenges for Development* (OUP 2014) 31
[115] ibid.

developing and developed countries. Mainly, the issue is the lack of manufacturing abilities in developing countries.

Sell argues that developing countries are becoming more aware of the negative ramifications of some TRIPS-plus provisions which is detrimental to pharmaceutical companies who strive to maintain their interests and patents.[116] The concern is that some governments do not utilise the TRIPS flexibilities to its fullest extent due to the potential hostile repercussions from patent holders or pharmaceutical companies.[117] Bird contends that the challenge developing countries face 'is not whether to issue a compulsory licence at all. Rather, the challenge is how poor governments can issue compulsory licences that both maximise drug access and avoid unwanted side effects.'[118]

Moreover, IP has entered the debates involving economic development, governance of trade and mostly importantly human rights issues. It has been argued that proliferation of the various trade agreements such as TRIPS, intended to expand IPRs and their scope, has consequently turned IP into an issue concerning socio-economic and political interest.[119] This suggests why developing countries do not favour the extension of IPRs that go beyond the TRIPS provisions.[120] These countries, mainly Sub-Saharan African and South American countries, believe that these regulations hinder their ability to meet their human right obligations, especially in situations such as the malaria outbreak.[121] The Lancet Commission report supports these claims, as it was noted that the high prices of the antimalarial were linked to the monopoly rights that is created by certain patent protections.[122] Notably, in some countries such as India, patent claims have been rejected due to the public health implications.[123]

[116] ibid.
[117] ibid.
[118] Robert Bird, 'Developing Nations and the Compulsory License: Maximizing Access to Essential Medicines while Minimizing Investment Side Effects' (2009) 37 JLME 209.
[119] Sam Halabi, 'International Intellectual Property Shelters' (2016) 90 Tulane Law Review 903.
[120] ibid.
[121] Olasupo Owoeye and Oluwabusayo Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage Through a Health Rights Lens' (2018) 40 EIPR 49.
[122] Veronika Wirtz and others, 'Essential Medicines for Universal Health Coverage' (2016) 389 The Lancet 403.
[123] ibid.

In *Novartis AG v Union of India and Others*, the Indian Supreme Court rejected a drug patent claim and highlighted the importance of patent claims not hindering generic pharmaceutical manufacturing or the government's responsibility to provide healthcare.[124] The court found the right to health can ensure that IP is not used to hinder social welfare provisions.[125] Furthermore, it has been argued that Article 30 of TRIPS can be read in a restrictive light that argues that a patent owner's rights and interests could potentially be overridden by public interest.[126]

2.8 Case study three: Ebola

Ebola further conjured up the debate surrounding IP hinderances to public health access. Ebola from 2013-2015 killed over 11,300 people and infected over 28,000.[127] It was described as one of the severest humanitarian crises in modern times which prominently affected West African countries, such as Sierra-Leone, Liberia, and Guinea.[128] The WHO found that Ebola is a severe, frequently fatal illness for humans and outbreaks have a case fatality rate of up to 90%.[129] Like previous epidemics and health crises, human rights and public health access were interlinked with IP.

2.9 Different approaches:

This section specifically analyses the entire region of West Africa due to the widespread nature of the disease in that region in addition to the lack of legislation in certain areas.

2.9.1 *West Africa*

The Ebola outbreak raised concerns about public health readiness as the pharmaceutical industry has always had a problematic history with R&D especially with the differences in the public and private sector.[130] IP shortcomings reveal the considerable problems in the policy and legal systems

[124] [2007] 4 MLJ 1153 (SC).
[125] ibid.
[126] Ben Sihanya, 'Patent Law and Practice in Kenya' (2007) 38 IIC 648.
[127] Audrey Ceschia, 'The Institut Pasteur Network: A Crucial Partner Against Ebola' (2014) 384 The Lancet 1239.
[128] ibid.
[129] 'Ebola Virus Disease' (*Who.int*, 2021) <https://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease> accessed 10 April 2021.
[130] ibid.

surrounding the need for promotion, even though patents are necessary for social advancement and innovation.[131] It is argued by utilitarian academics that whilst patents function as an incentive, the system functions well as the IP regime primarily works to exclude.[132] In the area of biopharmaceutical innovation, the R&D costs and the risks are heightened which causes underfunding hence why the field of vaccines needs significant support.[133]

Most of these infectious diseases do not normally challenge the global north and the Ebola virus outbreak further outlined this difference.[134] The vaccine candidate for the Ebola virus was in development for years but without the lucrative potential, the vaccine was shelved and left in storage without clinical testing.[135] At the time there was no market for an Ebola vaccine and economically it made no sense for private pharmaceuticals to invest in the R&D stage.[136] The Coalition for Epidemic Preparedness Innovations tried to fill the gap by forming a large public and private partnership during the Ebola crisis.

The Medicines Patent Pool created by UNITAID offered countries in West Africa an effective alternative to accessing antimicrobial resistance drugs and medicines and although this has been successful, it is entirely dependent on the cooperation and willingness of patent holders to work in collaboration with the generic pharmaceutical industry.[137] This has proved a challenge, as the patent holders must submit their IP and their interest to the pool.[138] The question raised alongside this, is where the line is drawn between balancing pharmaceutical patent protections and ethical considerations.[139] Academics have contended in literature that whilst the aspirations of TRIPS are to be commended, the practicality found that TRIPS has failed to strike the correct balance between

[131] ibid.
[132] William Landes and Richard Posner, *The Economic Structure of Intellectual Property Law* (1st edn, HUP 2003)
[133] Stanley Plotkin and others, 'Establishing a Global Vaccine-Development Fund' (2015) 373 NEJM 297.
[134] Denise Grady, 'Ebola Vaccine, Ready for Test, Sat On the Shelf' *The New York Times* (2014).
[135] ibid.
[136] ibid.
[137] Jorge Bermudez and Ellen 't Hoen, 'The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good' (2010) 2 Open AIDS J 37.
[138] ibid.
[139] Tolulope Adekola, 'Should COVID-19 Treatment be patented? Rethinking the Theoretical Justification for the Grant of Pharmaceutical Patent' (2020) 42 EIPR 695.

patent holders' rights and the rights of those who require access to essential technologies and medicines.[140]

High pharmaceutical prices and IPRs may often supress innovations and 'because Ebola has been, historically, geographically confined to poor African nations…the R&D incentive is virtually non-existent. A profit-driven industry does not invent in products for markets that cannot pay'.[141] The attempts to bring a vaccine to market began to grow in late 2015 and hence the successful approval of Ervebo can be classified as a public health win.[142] Moreover, in 2019 the landmark vaccine Ervebo was approved and became the first commercially available vaccine to treat an Ebola virus.[143] Børge Brende argued that the '[e]valuations of the Ebola response highlight that the global community must rethink how vaccines, diagnostics, and drugs for emerging infections are developed given their lack of commercial profitability'.[144]

2.10 Considerations

This outbreak emphasised how the lack of access to medicines creates a ricochet effect on different regions.[145] Only eight of 1233 (1%) drugs that were licensed globally from 1975-1997 were developed expressly for tropical diseases in humans.[146] In the Ebola virus health crisis, the insufficient access to medicines resulted in the outbreak spreading to other regions such as the US and Europe, which outlined how if not treated and contained, viruses could quickly turn into epidemics, a foreshadowing of the Covid-19 pandemic.[147] As aforementioned, the current legislative frameworks for IP protection generates issues in the dealing of the global health

[140] Wenwei Guan, *Intellectual Property Theory and Practice: A Critical Examination of China's TRIPS Compliance and Beyond* (1st edn, Springer 2014)
[141] ibid.
[142] Claire Sykes and Miriam Reisman, 'Ebola: Working Toward Treatments and Vaccines' (2015) 40 Pharmacy & Therapeutics 521.
[143] Ana Rutschman, 'The Intellectual Property of Vaccines: Takeaways from Recent Infectious Disease Outbreaks' (2020) 118 MLRO 170.
[144] ibid.
[145] Olasupo Owoeye and Jumoke Oduwole, 'Development, Access to Medicines and the Ebola Virus Epidemic in West Africa' (2017) 24 JLM 722.
[146] Bernard Pecoul, 'Access to Essential Drugs in Poor Countries: A Lost Battle?' (1999) 281 JAMA 361.
[147] ibid.

climate.[148] The current frameworks are centred on the traditional diplomatic principles, i.e. good faith and international diplomacy measures and while it was theoretically balanced, it began the elevation of IP law in the international sphere. The regulations have advanced and improved patent protections, it has also allowed for public health law to be somewhat subordinate to IP law, which is not appropriate when dealing with a virus outbreak. It has been argued that these regulations should be better formulated in a way that is conducive to the attainable access of medicines and the socio-economic responsibilities of developing countries.[149]

The concern that derives from the development of vaccines is the different patented genetic sequences and proteins of viral pathogens that are involved in the formulation.[150] In addition to this, when the outbreaks originate in developing countries, countries are reluctant to send samples for clinical testing or trials as these once patented and developed into vaccines, become expensive to purchase.[151] Therefore, these countries become unwilling to share disease samples or data necessary for research. During the Ebola outbreak drugs such as Zmab and FX06 were used in clinical trials and treatment, the problem that occurred was wealthier countries stockpiling certain medicines, which created an access issue for those developing countries dealing with the outbreak.[152] In circumstances like this, it calls for organisations such as the WHO to step up and ensure that there is affordable access to medicines and treatments.[153] Eventually, the WHO stepped in and ensured no IP barriers during the Ebola outbreak.[154]

This substantial debate clearly needed to be addressed in order to prevent future health crises similar to the Ebola crisis and it demonstrated the need for action to be taken in fighting diseases

[148] Lo Gostin, 'Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health' (2008) 96 GLJ 331.
[149] Owoeye (n 145).
[150] Eileen Kane, 'Achieving Clinical Equality in an Influenza Pandemic: Patent Realities' (2009) 39 SHLR 1137.
[151] ibid.
[152] ibid.
[153] Catherine Saez, 'WHO: Fight Ebola Now, Solve Patent Issues Later - Intellectual Property Watch' (*Intellectual Property Watch*, 2014) <http://www.ip-watch.org/2014/09/06/who-fight-ebola-now-solve-patent-issues-later/> accessed 10 April 2021.
[154] ibid.

directly and largely afflicting developing countries.[155] As evidenced by the lessons learned from the Ebola crisis, more attention should be given to creating more collaborative avenues for developing drugs and vaccines that help treat diseases and viruses unreasonably affecting developing countries.[156] Furthermore, there should be more partnership and transparency between these humanitarian organisations whilst also endeavouring to involve affluent governments to help supply these vaccines and pharmaceuticals to those regions in need.[157] This debate leads directly into the Covid-19 pandemic which turns these concerns from a hypothetical into a real conversation and issue, which will be discussed in Chapter 3.

[155] Saez (n 153)
[156] ibid.
[157] ibid.

Chapter Three:

Is there a balance between intellectual property rights and the access to public health during the current Covid-19 pandemic?

3.1 Introduction

The Covid-19 pandemic is the most unprecedented health crisis in modern times and has further explored the deplorable relationship that public health access has with the pharmaceutical industry. The ongoing debate surrounding the balancing of IPRs and public health access was not only heightened but also allowed both sides to reconsider their approaches and possibly learn from the mistakes made in previous epidemics. As previously established in this paper, major pharmaceutical companies are key to combatting health crises. At the beginning of the current pandemic countries took initiative and pre-exemptive steps to tackle the potential crisis ahead, for example, Canada adopted a legislative measure that would permit their Commissioner of Patents to grant compulsory licenses without negotiations, as required under TRIPS.[158] Germany opted to allow their federal health minister to make executive decisions in accessing and making medication available in exchange for adequate compensation, whilst France for example amended their patent law to state that 'amicable negotiations' with patent holders were not necessary if there is urgency, like the Covid-19 situation.[159]

Furthermore, wealthier countries and several companies avowed to support the vaccine scheme called 'COVAX', which was established by Gavi, the Vaccine Alliance, the Coalition for Epidemic Preparedness Innovations, and the WHO. It secured over 1 billion doses and is headed for a 2 billion target in 2021, to vaccinate 20% of the vulnerable groups in 92 low and middle-income countries requiring assistance.[160] Although COVAX has promising aims, they may have failed to evaluate

[158] Jacopo Cusinato and others, 'Repurposing Drugs for The Management Of COVID-19' (2020) 31 EOTP 295.
[159] Martina Dani, 'Public Health Comes First' (2020) 15 JIPLP 865.
[160] Megan Scudellari, 'The Sprint to Solve Coronavirus Protein Structures — And Disarm Them with Drugs' (*Nature.com*, 2021) <https://www.nature.com/articles/d41586-020-01444-z> accessed 16 April 2021.

the level of ‘vaccine nationalism’ that would occur in the early stages of 2021, which has resulted in the COVAX’s potential being hindered.[161]

The WHO also proposed the Covid-19 Technology Access Pool (C-TAP), which was created to support IPRs sharing under a technology transfer to permit international equitable access to the health technologies related to the pandemic.[162] In addition to this, the Open Covid Pledge was created in April 2020 to further voluntarily licensing and sharing of technologies and patents related to Covid-19 on a provisional royalty-free basis.[163] However, the Open Covid Pledge and the C-TAP, were met with some initial opposition from countries like the UK and US in addition to remarkably low numbers of endorsements, outlining a shortcoming of the voluntary pool system.[164] Notably, neither voluntary pool has been availed of or updated since May 2020, which ultimately defeats the purpose of the pool and slows down the access to patent protected information and technology indicating the hostility towards supporting public health initiatives.[165] Even with persuasion from countries such as the UK, pharmaceutical companies have failed to engage with the patent sharing platform, which could be attributed to the argument that IPRs are hindering public health access. Nevertheless, the issue of wealthier countries playing into ‘vaccine nationalism’ has proved to be a serious hinderance in global access to vaccines.

3.2 Vaccine Nationalism

Vaccine nationalism refers to the term that describes the phenomenon of bulk buying emergency vaccines through pharmaceutical contracts by a limited number of countries, which has consequences.[166] The development and approval of vaccines are vital and research indicates that the early aggressive procurement of vaccine contracts is directly linked to the formidable hindrances

[161] Lynn Eaton, 'Covid-19: WHO Warns Against “Vaccine Nationalism” Or Face Further Virus Mutations' (2021) 372 BMJ <https://www.bmj.com/content/372/bmj.n292> accessed 16 April 2021.
[162] 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.
[163] ibid.
[164] ibid.
[165] Michael Safi, 'WHO Platform for Pharmaceutical Firms Unused Since Pandemic Began' *The Guardian* (2021)
[166] David Fidler, ‘Vaccine nationalism’s politics’ (2020) 369 Science 749.

faced by lower income countries in dealing with Covid-19.[167] Similarly, in the HIV/ADIS epidemic low-income countries could not access antiretrovirals due to heinously high prices set by the pharmaceutical industry. Unlike previous epidemics, this current health crisis is a pandemic with the devastating impact being felt in every country.

The question of transparency comes into play in this debate, and it can be argued that there should be transparency in the accessing of vaccines, especially by wealthier countries. The Belgian Secretary of State temporarily released the prices each manufacturer was charging the EU.[168] Upon this revelation, it was found that the EU was paying €1.78 per dose of the Oxford/AstraZeneca vaccine versus South Africa's €4.321 and this indicates the lack of transparency in pharmaceutical licenses and contracts.[169] The European Commission (EC) later published their agreement with Oxford/AstraZeneca, and this can be regarded as a success for transparency as it supports low-income countries in their own negotiations.[170] Much of the funding for these patents and clinical trials are from public bodies and this begs the question of whether a greater level of transparency is expected.[171] The publishing of the EU deal shed light on the licensing of the clinical trial data and IPRs of Covid-19 vaccines and it can be argued that this level of transparency may prove beneficial when assessing the fairness of royalties, which are linked to vaccine pricing.[172]

With most of the vaccines being messenger RNA (mRNA) based, an agent between protein and DNA, these vaccines therefore are subject to a dense number of patents that cover almost every component from development to manufacturing.[173] Considering this and the patented lipid nanoparticles technology used, potential legal disputes could arise for countries wishing to develop

[167] Ingrid Katz and others, 'From Vaccine Nationalism to Vaccine Equity — Finding A Path Forward' (2021) 384 NEJM 1281.
[168] Bryan Mercurio, 'WTO Waiver from Intellectual Property Protection For COVID-19 Vaccines and Treatments: A Critical Review' (2021) 1 VJILO <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820> accessed 25 April 2021
[169] ibid.
[170] Paul Hunter and Julii Brainard, 'Estimating the Effectiveness of The Pfizer COVID-19 Bnt162b2 Vaccine After A Single Dose. A Reanalysis of a Study Of 'Real-World' Vaccination Outcomes from Israel' (*MedRxiv*, 2021) <https://www.medrxiv.org/content/10.1101/2021.02.01.21250957v1> accessed 20 April 2021
[171] ibid.
[172] ibid.
[173] Sven Bostyn, 'Access to Therapeutics and Vaccines in Times of Health Pandemics: How Exclusivity Rights Can Affect Such Access and What We Can Do About It' (2020) 4 IPQ 227.

their own generic version of the vaccines with the patents usages.[174] Large companies such as CureVac, GSK, BioNTech and Moderna together own nearly half of all the mRNA vaccine patent applications, leaving little room for low-income countries to access the technology and information to develop their own vaccines.[175]

Several different countries placed export bans on either raw materials or vaccine doses, and this exhibits another form of vaccine nationalism. The vaccine dose export ban introduced by the EU in early 2021 was criticised, especially since the rules on exporting were tightened when countries like Australia relied on those exports.[176] These bans hinder the access to crucial vaccines and equipment by low-income countries. The ban that India introduced was particularly a blow for many developing countries as previously stated India is one of the largest manufacturers and without this access, several countries are in a desperate situation in addition to the COVAX scheme.[177] This creates a serious problem, which has recently begun to become significantly worse, where countries such as Brazil and India are left without the support they require. With this as the current backdrop, the US is being persuaded into sending raw materials required for India to continue its production of the Oxford/AstraZeneca vaccine.[178]

Over 8.6 billion doses of a combination of the different vaccines have been ordered worldwide by different countries but over 6 billion of these will be for wealthier countries, which is illogical as 80% of the world's population is accounted for by lower income countries, meaning they will only have access to one third of the vaccines.[179] The refusal to distribute any excess vaccine doses across national borders causes a problem for developing countries, as most of the wealthier countries pre-orders can vaccinate their population several times over. Many believe that

[174] ibid.
[175] Cecilia Martin and Drew Lowery, 'Mrna Vaccines: Intellectual Property Landscape' (2020) 19 NRDD 578.
[176] Matina Stevis-Grindeff, 'E.U. Will Curb Covid Vaccine Exports For 6 Weeks' *The New York Times* (2021)
[177] Stephanie Findlay, Michael Peel and Donato Mancini, 'India Blocks Vaccine Exports in Blow to Dozens of Nations' *Financial Times* (2021)
[178] ibid.
[179] Mercurio (n 168).

manufacturing and supply should be more evenly distributed, hence India and South Africa applied for an IP waiver from the WTO.

3.3 Waiver

The waiver brought forward by South Africa and India to the WTO in October 2020, ignited further debate into whether an IP waiver for Covid-19 vaccines would assist in the issues blocking access to different vaccine elements.[180] They argued this would apply to patents and be beneficial as the shared information would permit countries to produce their own vaccines and elevate the pressure on the current manufacturing structure. The International Federation of Pharmaceutical Manufacturers & Associations noted that 'diluting national and international IP frameworks during this pandemic is counterproductive…IP enables R&D and ensures that the next generation of inventors and investors will remain engaged.'[181] However, this waiver had significant backing from developing countries but fiercely opposed by countries such as USA, UK, and the EU.

3.3.1 *Arguments for:*

Various voluntary initiatives are not being utilised and therefore the ability to access information to increase production of vaccines is severely being hindered. The waiver was intended to cover section 1,4 and 5 of the TRIPS Agreement and the justification behind this was the limitations that TRIPS presented in the current pandemic. There has already been significant criticism towards TRIPS, and it was argued that this would be further exacerbated by the pandemic. It was contended that within the current framework smaller low-income countries would struggle to meet the principles outlined in TRIPS, due to inadequacies in their domestic system and regardless of the flexibilities available, this still posed an issue.[182] Regardless of the flexibilities, compulsory licensing measures require a case-by-case approach, which could cause issues during a pandemic and considering these requirements are complex, this is not sustainable. Additionally, with the

[180] ibid.
[181] IFPMA, 'Pharma Delivers COVID-19 Solutions, But Calls for The Dilution of Intellectual Property Rights Are Counterproductive' (*IFPMA*, 2020) <https://www.ifpma.org/resource-centre/pharma-innovation-delivers-covid-19-solutions-beyond-expectations-but-calls-for-the-dilution-of-intellectual-property-rights-are-counteproductive/> accessed 27 April 2021.
[182] Mercurio (n 168).

compulsory licensing measures, countries could experience strong pressure from wealthier countries and pharmaceutical companies due to the potential importing measures. These arguments correctly outline that in a pandemic resource is scarce and these constraints could further restrict manufacturing, undermine potential competition that could lead to lower prices and a lack of varied suppliers.[183]

3.3.2 *Arguments against:*

On the other hand, despite the potential introduction of this waiver, the reality is that it would not bring about the instant changes expected as several other factors come into play.[184] The suspension of the protections of the mRNA technology would do little to alleviate the pressures to local production, as these technologies are complicated and require specific capabilities that many low-income countries do not have access to, regardless of IPRs.[185] Furthermore, the proposal brought forward lacks any additional evidence or explanation as to the problems with TRIPS, rather outlining domestic issues and the current prices proposed by Oxford/AstraZeneca and Pfizer/BioNTech, the two main suppliers, are rather reasonable.[186] Regardless of the slight difference in the pricing given to the UK and South Africa, these prices still prove to represent a value for money.

Theoretically suspending patent protections does little for countries who do not have the specific registered patents in their country, therefore the waiver would prove useless. In their case, a lack of capacity for production would be the real issue which IP has no control over. For the countries with capacity, there still lies an issue in importing the correct materials and the main benefactors would be larger established generic manufacturers. While some voluntary initiatives are not successful, the COVAX vaccine scheme is still progressing, however the challenges faced by India in April 2021 could pose another issue for this initiative.

[183] ibid.
[184] ibid.
[185] ibid.
[186] ibid.

3.4 Potential Patent Disputes

This pandemic has raised considerable questions and created tension surrounding patent protection and access. This is due to the potential patent disputes that could arise from the need to procure several different medicines and vaccines. Towards the beginning of the pandemic, Israel permitted a compulsory license for the importing of AbbVie's Kaletra from India for the treatment of Covid-19.[187] This measure led to AbbVie declaring that for the duration of the pandemic, they would not be enforcing their patents on Kaletra globally which created the possibility for a supplier to create generic versions without fear of patent infringement measures.[188] AbbVie was the first pharmaceutical company to surrender their patent protections for ritonavir/lopinavir, which at the time were thought to be possible therapies to Covid-19. Israel's use of compulsory licensing likely propelled their decision to do this, illustrating that if countries pursue action, pharmaceutical companies may follow suit.

Gilead obtained a patent for the active substance of remdesivir in 2018 and when it was still thought to be a potential treatment in early 2020, concerns were raised about the potential access to it due to Gilead's rights.[189] However, Gilead considered the potential of remdesivir and opted to grant voluntary licensing to manufacturers in India, Pakistan, and Egypt, which was an extremely positive decision, considering patent usage is entirely at the discretion of the patent holder. This raised another issue in relation to the transparency of pricing, as when remdesivir was assumed to be a treatment method, there were questions regarding the discrepancy in production price. For example, in the US, it was reported that it would cost $3200 per a 6-day treatment, when the production price was estimated at less than $6 for the same timeline.[190] This raises issues from previous epidemics and is still difficult to assess as in countries such as the USA these contracts are confidential, and the balance of power lies ultimately with the patent holder.

[187] McMahon (n 162).
[188] ibid.
[189] Bostyn (n 173).
[190] McMahon (n 162).

3.5 Alternatives and Recommendations

It could be argued that the only plausible alternative is voluntary licensing. While it may be asserted that pharmaceutical companies oppose this, it can be observed that many companies are actively involved in negotiating voluntary licenses from patent holders. These licenses allow for various generic medicine manufacturers to increase their scale of production to deal with the ongoing health crisis. This is evidenced by Gilead issuing a nonexclusive voluntary license to generic producers in Pakistan, India, and Egypt.[191]

Furthermore, Oxford/AstraZeneca announced that they were granting a voluntary license for their vaccine in developing countries.[192] They also signed a sublicense agreement with numerous generic manufacturers, including the Serum Institute of India, one of the largest vaccine manufacturers.[193] Arguably, this is a massive step that emphasises the point that pharmaceutical companies can find alternative routes and can strike a balance with generic manufacturers. Due to this, Fiocruz in Brazil, R-Pharm in Russia, and BioKangtai in China have also been able to contribute to the large-scale production of affordable generic vaccines which supply lower income countries once approved.[194] This is a huge victory moving forward and with the current export bans being potentially lifted from wealthier countries, these productions will continue to increase and potentially assist greatly in the Covid-19 pandemic.

Finding a balance between respecting patent holders rights and ensuring equitable public health access is a complex undertaking and the current pandemic poses the possibility of changed attitudes towards the access to life saving medicines and vaccines. Recently, the Canadian pharmaceutical manufacturer Biolyse proposed to AstraZeneca and Johnson & Johnson, that in exchange for the recipe for their vaccines, they would produce 20 million doses for countries in the global south.[195] Additionally, they also approached the Canadian government for assistance with compulsory

[191] Mercurio (n 168).
[192] ibid.
[193] ibid.
[194] ibid.
[195] Stephen Buranyi, 'The World Is Desperate for More Covid Vaccines – Patents Shouldn't Get in The Way' *The Guardian* (2021)

licensing, which would provide them with the authorisation to go through with their proposal. Interestingly, it appears that neither company has taken this offer, which begs the question of whether any real progress has been achieved in IP law.

The *Actavis Group PTC EHF and others v ICOS Corporation and another* case further advanced the balancing of public health rights and IPRs which has proved useful in the current pandemic but also outlined the need for further reform.[196] The case outlined the need to promote and reward contribution towards patent innovation whilst also respecting the EC's principles of attaining a high level of human health protection. Many could assert reading this judgment in the confines of the facts and support deterring the EPO from following it however, it is suggested that this result has created significant discussion which has promoted potential patent law modification.[197]

3.6 Conclusion

Previous epidemics and health crises have illustrated the continuous moral failings by the pharmaceutical industry but with a pandemic such as Covid-19, it seemed that there was an opportunity to derail from the standard and consider the humanitarian aspect. A stark difference between past health crises is the united position on seeking a vaccine, which is proving to be the correct course of action. Patent holders have been battling the right to public health access for decades and whilst previous epidemics have sparked debate and academic commentary, it seems that this current pandemic may be the catalyst for significant change. The vaccine race that began in mid-2020 illustrated the difference in the treatment of R&D incentives when the crisis occurs in the global north. It cannot be ignored that this pandemic was treated differently by all parties involved, the pharmaceutical companies, international organisations as well as the wealthier western countries. It perpetuated the ongoing debate into the different treatments of epidemics, due to their geographical locations.

[196] [2019] UKSC 15.
[197] ibid.

The current legislative frameworks, specifically TRIPS, were contested during each epidemic and the HIV/AIDS epidemic specifically sparked reform in the form of the Doha Declaration. It outlined the need for patent law to align itself with the urgency of health crises and the requirement for an effective response. It also paved the way for the argument in favour of having affordable and timely access to vaccines. The importance of the approach taken in a health crisis proved vital in all epidemics discussed in this paper. Whilst South Africa and India did raise crucial problems with TRIPS, they failed to supply the correct amount of evidence to support their waiver. Unlike the Ebola crisis where there was a patent for a plausible vaccine and no development was made due to the lack of interest, the Covid-19 vaccine was speedily researched and developed by major pharmaceutical companies.

HIV/AIDS was the first epidemic to highlight the crucial role vaccines and the patents attached to them play. It was suggested that the diverse approaches taken by various countries yielded different results. Moreover, the epidemic was treated without the consideration of time in the approach, and this proved consequential. The Brazilian approach worked well due to the lack of patent legislation and hence no restrictions in supplying antiretrovirals speedily to their citizens. It is contended that TRIPS plays a vital role in the international patent law, but the approach taken by Brazil highlights its shortcomings, as after its introduction the government faced challenges in accessing the same antiretrovirals, leading one to question whether a harmonised approach is necessary. On the contrary, the South African approach to the crisis was more reserved due to its existing patent framework. This led to them pursuing compulsory licensing which did involve several complications. In their case the obstacles from the pharmaceutical companies were overcome through public support and campaigning. Moreover, India established themselves as the leading generic manufacturer and outlined that the compulsory licensing system is complex and time consuming, which are elements not conducive to an emergency health crisis.

In comparison, the malaria epidemic resulted in countries taking several different approaches and legislative measures, hence it is analysed in an international capacity. This disease no longer affects the global north, and a recurring theme is that when it does not affect the global north there

is a lack of incentive to develop vaccines or drugs. During the malaria epidemic the international community tried to step up and introduce an open patent pool for neglected diseases. One stark difference in dealing with this epidemic is that most of the production of antimalarials were in countries such as Brazil, India, and China, where there were no patent protections. This further illustrated the need for a balance of patent protections and public health access, as the key in tackling the epidemic was the collaboration between international organisations in countries without patent protections. This suggests that the opposition developing countries have against the harmonisation of patent law has merit. This epidemic demonstrated the negative aspects of TRIPS and emphasised that whilst compulsory licensing is an option, it is not the most plausible choice for developing countries. It should not be forgotten that pharmaceutical companies and patent holders yield a significant amount of bargaining power and countries may face ramifications trying to implement some of the TRIPS flexibilities. Developing countries have substantial human rights obligations and do not have the same access to technology and resources that their wealthier counterparts do. It is suggested that patent holder's rights should not interfere with human rights obligations.

Furthermore, the Ebola crisis was mostly centralised to one region, West Africa, and hence was analysed accordingly. The approach taken was the treatment rather than a vaccine which would have been significantly more effective. It was outlined that there was in fact a vaccine patent candidate available but was not developed due to the lack of potential profitability and this resulted in the vaccine being released four years after the epidemic. This raised another issue about the access to patented information and how the lack of this information could prove detrimental in some cases. The combination of the coalitions created and UNITAID allowed for affordable antimicrobial resistant drugs to be accessible. It is also contended that TRIPS needs to be re-evaluated to be more conducive to the requirements, access, and resources of developing countries. Compulsory licensing and the requirement for decisions to be decided on a case-by-case basis, is not favourable to the conditions of a health crisis and it is suggested that there should be more support towards the use of generic manufacturers.

It can be argued that the most beneficial balance between patent holder's rights and the need for sufficient public health access, is the expansion of competition by introducing nonexclusive voluntary licenses. Voluntary licensing already exists but previous epidemics mistakes and the current Covid-19 pandemic prove its necessity and should be utilised more. This framework caters to public health responsibilities without forcefully infringing on the rights of patent holders and it can be argued that under the current frameworks voluntary licensing is the best option, however the discussed health crises show there is a need for further reform. In conclusion, it seems that a balanced approach to the IP debate, is through voluntary licensing as this strikes a solid balance between protecting patent rights and ensuring equitable public health access. However, to ensure maximum success, the international community should reform the current frameworks to be more favourable to all countries not simply the wealthier and resourceful ones.

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