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Reforming Patent Law in South Africa: Social Justice, Human Rights and Big Pharma

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PLAGIARISM DECLARATION

I declare that ‘Reforming Patent Law in South Africa: Social Justice, Human Rights and Big Pharma' is my own work, that it has not been submitted before for any degree or examination in any other university, and that all the sources I have used or quoted have been indicated and acknowledged as complete references.

Signature: A Petersen Date: 15 December 2022

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Glory be to God, the Almighty. For giving me this opportunity and carrying me through everything.

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Aqeelah Petersen

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1.1 INTRODUCTION

Intellectual property (IP) can be defined as an idea or material that is legally protected from the unauthorised use thereof by other persons, and a person who has invented a particular pharmaceutical drug or medical product will apply for a patent to protect such an invention against counterfeiting and other infringements, which means that only such an inventor can benefit from the manufacturing of a product for a certain period of time, in exchange for public disclosure of the invention. [1] IP first emerged in South Africa as a result of the colonisation of the country by the English.[2] As a result, South Africa's IP system developed to match up to that of England.[3] One of the main aims of the colonisers was to benefit themselves at the expense of the colonised.[4] Resultantly, they introduced the concept of exclusive rights and monopolies.[5] This entailed that if an invention was made, they would have the rights to the invention including the manufacturing, distribution and monetary rights.[6] This situation persisted until 1978 when South Africa enacted the South African Patents Act.

Apart from this, low standards for patents were set which resulted in multiple frivolous patents being granted.[7] Consequently, it became difficult to access patented goods, leading to social injustice.[8] It is important to note that, while South Africa now operates as a democratic state since 1994, patent laws in the country remain vastly unchanged.[9] Patent laws, in the view of this research

[1] Rivera J 'What Is Intellectual Property Theft?' available at *https://www.legalmatch.com, accessed 8-11-2021* (accessed on 23 May 2022).
[2]George J & van Staden J 'Intellectual property rights: plants and phyto-medicinals - past history, present scenario and future prospects in South Africa' (2000) 96 *South African Journal of Science* 433.
[3]Blackstock R 'Patent law reform' (1946) *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 90.
[4]Blackstock R (1946) 90.
[5]Bond P 'Globalisation, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with US Firms and Politicians' (1999) 9 *International Journal of Health Services* 766.
[6]Boldrin M and Levine DK 'Against Intellectual Monopoly' (2009) 21 *Syracuse Science and Technology Law Reporter* 131.
[7]Fix The Patent Laws Organisation 'Why we need to fix patent laws in South Africa' available at *https://www.cansa.org.za/files/2015/06/Fix-Patent-Laws-Briefer.pdf* (accessed on 22 September 2020).
[8]Fisher WW and Rigamonti CP 'The South Africa AIDS Controversy A Case Study in Patent Law and Policy' available at *https://South Africa.pdf (unibe.ch)* (accessed on 23 March 2021).
[9]Fix The Patent Laws Organisation 'Memorandum: Fix the patent laws picket, 18 March 2021' available at *https://www.fixthepatentlaws.org/memoradum-fix-the-patent-laws-picket-18-march-2021/* (accessed on 23 March 2021). The Patents Act has not changed much since before 1994. The most notable amendment, although a minor amendment, is that of s69A which stipulates that 'it shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of, or import a patented invention on a non-commercial scale and solely for the purposes reasonably related to obtaining, development and submission of information required under any law that peaqqregulates the manufacture, production, distribution, use or sale of any product.' Before 1994, and before the

paper, continue to undermine the citizens and residents of this country, foiling attempts at realising human rights and achieving social justice[10].[11] Generally, human rights are considered indivisible and interconnected.[12] This idea is recognised in paragraph 5 of the Vienna Declaration and Program of Action which was concluded at the World Conference on Human Rights in 1993.[13] This document enjoins member states to "promote and protect all human rights and fundamental freedoms."[14]

1.2 BACKGROUND

The right to health is a fundamental human right recognised in South Africa's Constitution.[15] The provisioning of this right in the Constitution also accords with South Africa's obligations in terms of its regional and international commitments.[16] The right to health is particularly important given its interconnectedness with other rights such as the rights to life, dignity and work.[17]

To crystallise this aversion, one can consider how the big pharmaceutical companies (Big Pharma) have manipulated patents in dispensing very much needed drugs, not only in South Africa, but across the globe.[18] To explain this, one can think around how Big Pharma has charged unreasonable prices on drugs which are critical for human health, across the globe, especially in

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s69A amendment, s69 stipulated that 'A declaration that the use by any person of any process, Declaration as to or the making or use or sale by any person of any article, does not non-infringement, or would not constitute an infringement of a patent, may be made by the commissioner in proceedings between that person and the patentee or an exclusive licensee mentioned in section 56.' Hence, there has only been a minor amendment in this regard.

[10] Social justice is fairness as it manifests in society. That includes fairness in healthcare, employment, housing, and more. Social justice depends on four essential goals: human rights, access, participation, and equity, ie it is justice in terms of the distribution of wealth, opportunities, and privileges within a society.

[11]Singh JA 'Do human rights matter to health?' (2007) 370 *The Lancet* 521.

[12]Nordic J 'The Justifiability of Indivisible Rights' 2003 *Nordic Journal of International Law* 3. As a member of the World Trade Organization, SA is required to uphold minimum standards of IP protection as defined by the Agreement on Trade-Related Aspects of Intellectual Property Rights, which it currently does.

[13]The Vienna Convention on the Law of Treaties 1969 (1969) 8 *ILM* 679, para 5.

[14]United Nations, Office of the High Commissioner for Human Rights, 1993 Available at *http://www.ohchr.org/EN/ProfessionalInterest/Pages/Vienna.aspx* (accessed 20 March2015)

[15]Constitution of the Republic of South Africa, Act 108 of 1996, s27.

[16]WHO 'Access to AIDS medicines stumbles on trade rules' available at*https://www.who.int/bulletin/volumes/84/5/news10506/en/#:~:text=Although%20existing%20provisions%20of%20the%20TRIPS%20Agreement%20permit,predominantly%20for%20the%20supply%20of%20the%20domestic%20market* (accessed on 23 March 2021).

[17]Fix The Patent Laws Organisation 'Why we need to fix patent laws in South Africa' available at *https://www.cansa.org.za/files/2015/06/Fix-Patent-Laws-Briefer.pdf* (accessed on 22 September 2020).

[18] Matthews D 'Intellectual Property Rights, Human Rights and the Right to Health' available at *https://pdfs.semanticscholar.org/adfb/d6ffdd1f63bf60d3410206f788cb0f6c4806.pdf?_ga=2.104384387.2069762645.1616572391-1112411838.1602835400* (accessed on 3 March 2021).

the developing country context.[19] In America, Martin Shkreli, the owner of Vyera Pharmaceuticals, charged excessive prices for ARVs.[20] He increased the price of Darapim from $13.50 to $750.[21] While he was indicted on separate charges, he was never convicted of excessive pricing for drugs.[22] In South Africa, GlaxoSmithKline had also adopted similar pricing techniques.[23] They charged four times the market value with the consequence of inaccessibility to essential ARVS which resulted in premature deaths, which were predictable and avoidable.[24] This research paper submits that there is therefore a clear link between access to essential medicine and the right to health.

Another important hallmark of Big Pharma is the ability to manipulate the patent process where a company is able to extend its exclusive rights and prevent competition from entering the market by means of "evergreening" which will be discussed later.[25] It could be argued that an option is

[19]Cullet P 'Patents and medicines: the relationship between TRIPS and the human right to health' (2003) 79 *International Affairs* 139.

[20] The Competition Act 89 of 199 prohibits excessive pricing and stipulates in s 8, "(1) It is prohibited for a dominant firm to- (a) charge an excessive price to the detriment of consumers or customers; (b) refuse to give a competitor access to an essential facility when it is economically feasible to do so; (c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive gain; or (d) engage in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act (i) requiring or inducing a supplier or customer to not deal with a competitor; (ii) refusing to supply scarce goods or services to a competitor or customer when supplying those goods or services is economically feasible; (iii) selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract; (iv) selling goods or services at predatory prices; (v) buying-up a scarce supply of intermediate goods or resources required by a competitor; or (vi) engaging in a margin squeeze.

Further, s8(3) stipulates that the following have to be taken into account when determining if a product is excessively priced, "(3) Any person determining whether a price is an excessive price must determine if that price is higher than a competitive price and whether such difference is unreasonable, determined by taking into account all relevant factors, which may include- (a) the respondent's price-cost margin, internal rate of return, return on capital invested or profit history; (b) the respondent's prices for the goods or services- (i) in markets in which there are competing products; (ii) to customers in other geographic markets; (iii) for similar products in other markets; and (iv) historically; (c) relevant comparator firm's prices and level of profits for the goods or services in a competitive market for those goods or services; (d) the length of time the prices have been charged at that level; (e) the structural characteristics of the relevant market, including the extent of the respondent's market share, the degree of contestability of the market, barriers to entry and past or current advantage that is not due to the respondent's own commercial efficiency or investment, such as direct or indirect state support for a firm or firms in the market; and (f) any regulations made by the Minister, in terms of section 78 regarding the calculation and determination of an excessive price."

[21] The Guardian 'Martin Shkreli: I'm not upset about IK drug ike; it was 'woefully' underpriced' available at *Amp.theguardian.com/business/2016/oct/28/marin-shkreli-daraprim-hiv-drug-price-hike-interview* (accessed on 18 July 2022).

[22] The Guardian 'Martin Shkreli: I'm not upset about IK drug ike; it was 'woefully' underpriced' available at *Amp.theguardian.com/business/2016/oct/28/marin-shkreli-daraprim-hiv-drug-price-hike-interview* (accessed on 18 July 2022).

[23] *Hazel Tau & Others v GlaxoSmithKline & Others*, 2002 (South African Competition Commission Case No. 2002Sep226).

[24] *Hazel Tau & Others v GlaxoSmithKline & Others*, 2002 (South African Competition Commission Case No. 2002Sep226).

[25]Cullet P (2003) 140.

available to developing countries to purchase generic versions of such medication.[26] However, the argument can quickly be dispensed by noting that generic medication can only be made after 20 years due to exclusive rights which patent holders are granted by the South African Patent Act, as well as by international law.[27] As mentioned, patent holders can further extend their period of exclusivity by registering multiple patents over a single product.[28] However, in response to the latter, the World Trade Organisation (WTO) has attempted to reasonably remove the barriers to allow people to gain access to generic life-saving drugs.[29] This is vital because of the centrality of the right to health in the Constitution of the World Health Organisation (WHO).[30]

Accordingly, the WTO has attempted to deal with the matter in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS agreement).[31] The TRIPS agreement arose as an intervention by the WTO in the early 2000s when antiretroviral drugs (ARVs) which were crucial in responding to the AIDS (Acquired Immune Deficiency Syndrome) pandemic were inaccessible.[32] Clinical trials for the treatment of the virus were conducted by American pharmaceutical companies.[33] As a result, these American companies patented ARV medication.[34] The challenge was, however, that these drugs were extravagantly priced, making them unaffordable and therefore, inaccessible to many.[35] For instance, in the US, ARVs initially retailed at approximately R17 000, while the annual income of most households in South Africa during

[26]Narula S 'The rights-based approach to intellectual property and access to medicines: Parameters and pitfalls' 2011 *New York University Public Law and Legal Theory Research Paper Series, Working Paper* 12.
[27]Hlomani H 'Patents Kill Patients: A case for the future of Covid-19 treatment' available at https://www.mandelarhodes.org/ideas/patents-kill-patients-a-case-for-the-future-of-covid-19-treatment/ (accessed on 17 September 2020).
[28]Hlomani H 'Patents Kill Patients: A case for the future of Covid-19 treatment' available at https://www.mandelarhodes.org/ideas/patents-kill-patients-a-case-for-the-future-of-covid-19-treatment/ (accessed on 17 September 2020).
[29]Secer HE 'Pharmaceutical Patents and Right to Health' (2019) available at https://www.researchgate.net/publication/335689217_Pharmaceutical_Patents_And_Right_to_Health (accessed on 23 March 2021).
[30]Kiehl, J 'Trips article 31(b) and the hiv/aids epidemic' (2002) 10 *Journal of Intellectual Property Law* 145.
[31]Trade-Related Aspects of Intellectual Property Rights.
[32]Matthews D 'Intellectual Property Rights, Human Rights and the Right to Health' available at https://pdfs.semanticscholar.org/adfb/d6ffdd1f63bf60d3410206f788cb0f6c4806.pdf?_ga=2.104384387.2069762645.1616572391-1112411838.1602835400 (accessed on 3 March 2021).
[33]Fix The Patent Laws Organisation 'South Africa's Patent Laws Threaten Access toFuture Covid-19 Medicines' available at https://www.fixthepatentlaws.org/south-africas-patent-laws-threaten-access-to-future-covid-19-medicines/ (accessed on 23 September 2020).
[34]Kiehl J (2002) 145.
[35] Helfer R 'Human Rights and Intellectual Property: Conflict or Coexistence?'(2003) 5 *Intellectual Property Review* 47.

this time was approximately R44 000.[36] Hence, these drugs were very inaccessible.[37] Fortunately, to save the situation, India manufactured affordable generic ARVs, due to one of the flexibilities under the TRIPS agreement.[38] The flexibility which enabled India to do this was that they had a transition period to comply with the TRIPS agreement. The transition period had been extended three times and started in 1999 and continued until 2005. The significance of this transition period is that India was enabled to produce generic medications of patented medication which would not have been allowed until the end of the twenty-year period in which the medicinal patent would expire and distribute generic ARVs to developing countries, including South Africa.[39]

After signing the TRIPS agreement, South Africa amended its national legislation to comply with this agreement.[40] An interesting addition was the 'limited health safeguards' contained in the TRIPS agreement.[41] The inclusion of these safeguards facilitated South Africa's importation of ARVs from India.[42] However, the decision was not welcomed by the pharmaceutical companies that patented ARVs.[43] To counter this, these companies decided to institute legal proceedings against the South African government.[44] In February 1998, the South African Pharmaceutical Manufacturers Association and 39 multinational pharmaceutical companies litigated against the

[36]WHO 'Access to AIDS medicines stumbles on trade rules' available at*https://www.who.int/bulletin/volumes/84/5/news10506/en/#:~:text=Although%20existing%20provisions%20of%20the%20TRIPS%20Agreement%20permit,predominantly%20for%20the%20supply%20of%20the%20domestic%20market* (accessed on 23 March 2021).

[37]Ncube C 'The draft national Intellectual Property Policy proposals for improving South Africa's patent registration system: A review.' (2014) 9 *Journal of Intellectual Property Law & Practice* 822.

[38]Klug H 'Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic' (2012) 37 *Law & Social Inquiry* 297.

[39]Azam M (2015) 61.

[40]Fix The Patent Laws Organisation 'South Africa's Patent Laws Threaten Access to Future Covid-19 Medicines' available at *https://www.fixthepatentlaws.org/south-africas-patent-laws-threaten-access-to-future-covid-19-medicines/* (accessed on 23 September 2020).

[41]WHO 'Access to AIDS medicines stumbles on trade rules' available at *https://www.who.int/bulletin/volumes/84/5/news10506/en/#:~:text=Although%20existing%20provisions%20of%20the%20TRIPS%20Agreement%20permit,predominantly%20for%20the%20supply%20of%20the%20domestic%20market* (accessed on 23 March 2021).

[42]United Nations, Office of the High Commissioner for Human Rights, 1993 Available at *http://www.ohchr.org/EN/ProfessionalInterest/Pages/Vienna.aspx* (accessed 20 March2015)

[43]Ncube C (2014) 823.

[44]*The Pharmaceutical Manufacturers' Association of South Africa v The President of South Africa* unreported case no 4183/98 (March 2001). In this case, the applicants successfully sought an interdict which prohibited the publishing amendments of the Medicines and Related Substances Control Amendment Act no 90 of 1997 due to these sections being in conflict s 43 and s 44 of the Constitution, as it enabled the president to, amongst other things, deprive owners of intellectual property regarding pharmaceutical products.

South African government stating that its attempts to increase the availability of affordable medicines violated both the Constitution, specifically the right to health and TRIPS.[45]

The litigation caused public outcry and despite the pharmaceutical companies initially having the support of the US and certain European states, the international public outrage over Big Pharma's legal challenge against a developing country's medicine laws was "so strong and the multi-national pharmaceutical company's legal position sufficiently weak, that the case was unconditionally dropped in April 2001."

The South African case was particularly significant because it showed how the flexibilities contained in the TRIPS Agreement, and their use for public health purposes, needed to be clarified.[46] In response to this, developing member states of the WTO asked for the organisation to convene and address the challenges at hand.[47] This resulted in the Doha Declaration on TRIPS.[48]

This Declaration reinforced the stance adopted in TRIPS that countries should have access to generic medication in certain instances in order to address healthcare needs.[49] Although the Doha Declaration confirmed member states' freedom to issue compulsory licenses and make use of parallel imports as an alternative source for cheaper medications,[50] it did not address issues of sourcing for developing states that could not produce their medications.[51] Furthermore, large quantities of medications could also not be exported to these countries as TRIPS limited the amount of exports allowed.[52] This problem was eventually resolved by the members of the WTO with the Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (the Paragraph 6 decision); in which the exporting limitations were removed.[53] Therefore, there are various legal flexibilities under TRIPS that enable

[45] *The Pharmaceutical Manufacturers' Association of South Africa v The President of South Africa* unreported case no 4183/98 (March 2001).
[46]Pouris A 'Patents and economic development in South Africa: Managing intellectual property rights' available at *http:// dx.doi.org/10.4102/sajs.v107i11/12.355* (accessed on 23 March 2021).
[47]Azam M (2015) 62.
[48]Abbott FM 'The Doha Declaration on the TRIPS Agreement and public health: lighting a dark corner at the WTO' (2002) 5 *Journal of International Economic Law* 469.
[49]Klug H (2012) 303.
[50]Klug H (2012) 303.
[51] Abbott FM (2002) 469.
[52]Abbott FM (2002) 469.
[53] Decision of 30 August 2003: Implementation
of Paragraph 6 of the Doha Declaration on the TRIPS Agreement.

persons to access medication.[54] However, South African law does not incorporate all of this into its legislation as it only makes provision for compulsory licensing in section 56 of the Act and the 'bolar exception' in section 69(A) of the Act. The 'bolar exception' aims at hastening the approval of generic medications upon the expiry of the patented medicine. The reason for this is that if a manufacturer of a generic medicine is to wait until the patent expires before obtaining approval from the patent holder, it will hinder access to affordable medication.[55]

As with the AIDS outbreak and the inaccessibility of ARVs, the Covid-19 outbreak and the access to vaccinations have also been problematic.[56] This is due to poor production and distribution of vaccines to certain countries. Activist have now coined this challenge as "vaccine apartheid".[57] In December 2020, 450 million people were vaccinated around the globe.[58] Contrastingly, in the early parts of the pandemic during the vaccine roll-out, most African countries did not receive a single dose.[59]

This was due to agreements made by developed countries and vaccine manufactures for the purchasing of successful vaccines such as Johnson and Johnson and Pfizer. Some of these developed countries financially backed certain vaccines while others made advance payments for these. For example, the United Kingdom and had more than five doses per person on order.[60] This

[54]Attaran A 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, under WTO Law' (2002) 12 *Fordhum Intellectual Property, Media and Entertainment Law Journal* 859.
[55]Attaran A (2002) 859.
[56]Hogson TF and De Falco R 'Human Rights and Universal Access to COVID-19 Vaccines: Does the Human Rights Council Resolution go far enough?' available *at* *http://opiniojuris.org/2021/03/23/human-rights-and-universal-access-to-covid-19-vaccines-does-the-human-rights-council-resolution-go-far-enough/* (accessed on 29 March 2021).
[57]Kashyap A 'Whoever finds the vaccine must share it' available at *https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency* (accessed on 30 March 2021).
[58]Guardia AB and Hirsch C 'Coronavirus vaccination in Europe — by the numbers' available at*https://www.politico.eu/article/coronavirus-vaccination-europe-by-the-numbers/*. (accessed on 30 March 2021).
[59]Olowolagba F 'Covid-19: Terrible consequences await African countries without vaccine – AU, CDC' available at*https://dailypost.ng/2020/12/10/covid-19-terrible-consequences-await-african-countries-without-vaccine-au-cdc/* (accessed on 30 March 2021).
[60] The Guardian 'Canada and UK among countries with most vaccine doses ordered per person' available at *https://www.theguardian.com/world/2021/jan/29/canada-and-UK-among-countries--with-most-vaccine-doses-ordered-per-person* (accessed on 18 July 2022).

left African countries such as Zimbabwe, to make arrangements with countries such as China and Russia for vaccines with an unproven record.[61]

One of the main causes of this is intellectual property regimes as well as states not making use of the TRIPS agreement which allows states to "grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted in the specific context of public health emergencies" such as the Covid-19 pandemic.[62] This pandemic has resulted in a state of national disaster, which is the type of situation that warrants extreme urgency as envisioned by Article 31 of TRIPS. Article 31 allows for states to use patents without requiring any negotiations with the patent holder.[63] This means that the South African government could be permitted to utilise patents without authorisation from the patent owner and without prior negotiations, but subject to the payment of reasonable remuneration and other terms as agreed upon or as deemed by a court. This may include manufacturing, utilising, exercising, and importing patented products that are deemed necessary to combat the pandemic.[64]

As mentioned above, the Covid-19 pandemic has not been the first instance whereby many lives are lost due to inaccessible treatments.[65] Therefore, countries such as India and South Africa called for the waiver on "the application of intellectual property rights for Covid-19 diagnostics, therapeutics and vaccines."[66] However, this waiver was not welcomed by developed states who had already secured vaccines.[67] In response to this, the United Nations Human Rights Council adopted a resolution on access to vaccines.[68] The resolution states that vaccines should be

[61] The Guardian 'Canada and UK among countries with most vaccine doses ordered per person' available at *https://www.theguardian.com/world/2021/jan/29/canada-and-UK-among-countries--with-most-vaccine-doses-ordered-per-person* (accessed on 18 July 2022).
[62]Hogson TF and De Falco R 'Human Rights and Universal Access to COVID-19 Vaccines: Does the Human Rights Council Resolution go far enough?' available at *http://opiniojuris.org/2021/03/23/human-rights-and-universal-access-to-covid-19-vaccines-does-the-human-rights-council-resolution-go-far-enough/* (accessed on 29 March 2021).
[63] TRIPS, Article 31.
[64] TRIPS, Article 31.
[65]Ward KJ and Hickey EJ '*Legal Issues in Covid-19 Vaccine Development*' available at *https://heinonline-org.ezproxy.uwc.ac.za/HOL/P?h=hein.crs/govdbux0001&i=1* (accessed on 29 March 2021).
[66]Sandor J 'Rebalancing Human Rights at the Time of Covid-19 Pandemic' (2020) 11 *Union University Law School Review* 386.
[67]Sandor J (2020) 386.
[68]Nebehay S 'Top U.N. rights body calls for fair, affordable access to COVID-19 vaccines' available at *https://www.reuters.com/article/us-health-coronavirus-un-rights-idUSKBN2BF29B* (accessed on 31 March 2021).

"equitable, affordable, timely, and universal access by all countries and reaffirms vaccine access as a protected human right and openly acknowledges unequal allocation and distribution among countries."[69] However, the challenge is that the resolution merely restates that countries are allowed to make use of the flexibilities provided in the TRIPS agreement.[70] It also endorses measures of best practices, instead of putting measures of best practice in place which could realise the right to health, as opposed to merely endorsing such measures.

It is against this backdrop, that this research paper discusses current patent laws and practices in South Africa and globally. It considers the question whether human rights should trump patent rights. To do this, the paper traverses various laws and treaties and considers the shortfalls of them. The main argument raised in the research paper is that human rights achieve superiority in theory but superiority in practice. This is supported by the evidence of current practices resulting in inaccessibility to life-saving medicine due to patents being overly protected. Challenges to this argument considered in the paper include measures taken to enable medicine to be accessed by more people as well as certain case law. The research paper makes the eventual finding that patent laws, specifically in South Africa, have to be reformed in order to realise the right to health and for the achievement of social justice. These findings are qualified in detail in chapter 5 where the conclusion and recommendations are presented. The research paper makes a contribution to scholarship by advocating for the realisation of human rights and social justice in the context of big pharma and provides innovative recommendations on ways in which to realise the right to health and achieve social justice

1.3 RESEARCH QUESTION

The question posed by this research paper is: whether patent law in South Africa should be reformed in a quest for social justice and the realisation of human rights?

1.4 RESEARCH OBJECTIVES

To achieve the ideals set out in the research question, several objectives will be utilised to guide the process:

[69]Sarnoff JD 'Negative Emission Technologies and Patent Rights after Covid-19' (2020) 10 *Climate Law* 225.
[70]Sarnoff JD (2020) 225.

1) Identifying the intersection of human rights and social justice with the evolution of patent law;
2) Critically discussing current patent laws and practices and identifying its shortfalls; and
3) Identifying how to rectify these shortfalls in order to realise the right to health and achieve social justice.

1.5 SIGNIFICANCE OF THE STUDY

This study is important in that it traverses the important question of whether patent law in South Africa should be reformed to realise the right to health and also achieve social justice. This research is important because while studies have been done in the past in similar areas, the emphasis on social justice has been lacking. Given South Africa's tumultuous history, social justice is vital in redressing historical injustices. Accordingly, the research hopes that, in so undertaking, recommendations can be suggested which contribute substantially to how patents concerning health goods are currently being dealt with. This research will be useful to researchers, lecturers, students, policymakers and practitioners in the area.

1.6 RESEARCH METHODOLOGY

This is a desktop study that utilises both primary and secondary sources. In terms of primary sources, the research paper refers to conventions, treaties, legislation and case law. In terms of secondary sources, the research paper makes use of sources such as journal articles, books, discussion papers, internet publications as well as any other relevant documents. The study utilises a mixed methodology in attempting to engage the main research question. A legal historical approach is employed in tracing the historical development of patent law. Thereafter, a legal analytical method is used to analyse and critique the relevant frameworks on patents at a domestic, regional and international level.

1.7 LIMITATIONS OF THE STUDY

The study is limited to patents as they relate to Big Pharma and the right to health. Further, while some many more angles and issues could be raised concerning the challenges of patent laws in South Africa, the study limits the debate to human rights and social justice perspectives.

1.8 CHAPTER OVERVIEW

This research paper consists of 4 chapters including this one.

Chapter 2: Traces the evolution of patent law, exposing the points at which human rights and social justice debates became pertinent in patent debates**.** It further discusses regional patent laws and international patent laws.

Chapter 3: Critically analyses South Africa's patent laws.

Chapter 4: Concludes and provides recommendations.

CHAPTER 2

EVOLUTION OF PATENT LAW

2.1 INTRODUCTION

This chapter will discuss the evolution of patent law and argues that human rights must trump proprietary rights. It seeks to introduce a social justice perspective on the human rights/intellectual property debate. It begins by reviewing the competing paradigms of the right to health versus proprietary intellectual property rights, showing how the human rights regime has achieved superiority in theory, but inferiority in practice. The chapter will further discuss regional patent laws by illustrating how patent laws operate in the African Regional Intellectual Property Organization (ARIPO) and how it operates in The African Intellectual Property Organization (OAPI). It illustrates why human rights should trump IP in the context of African states. It further discusses shortfalls as well as providing possible solutions to these shortfalls.

2.2 THE EARLY HISTORY AND DEVELOPMENT OF PATENT LAW

2.2.1 General Patents

The first codified system of patent law can be traced backed to Europe, specifically in the republic of Venice.[71] Consequently, the oldest known patent law is the Venetian Statute of 1474. Interestingly, despite the age of this document, it contains some of the fundamental aspects of the current patent system.[72] In the same period, patent laws also developed in other places. Predominantly, there was a need to encourage entrepreneurs to create new industries within these territories – the process of which required the protection of intellectual property.[73]

At the same time, the idea of granting patents was aimed at encouraging business-persons in acquiring greater risk for greater reward.[74] These patents were considered trade monopolies as they granted exclusive rights to a person to practice a certain art to make, use, or sell a certain

[71] McEniery B 'Patent Eligibility and Physicality in the Early History of Patent Law and Practice.' (2016) 38 *Little Rock Law Review* 175.
[72] McEniery B (2016) 178.
[73] Holdsworth SW *A History of English Law* 3 ed 360-371.
[74] Mandich G 'Venetian Origin of Inventors' Rights' (1960) 175. 166.

article.[75] The objective of emperors was therefore to promote the creation of new industries that would equip their territories with new and inventive products made within their realm, therefore, reducing the need to import goods. [76] As a result, they granted trading monopolies.

The Venetian model emerged in several areas of Western Europe in the fifteenth and sixteenth centuries due to its success as it adequately regulated the market in relation to new inventions which were previously regulated by artisanal guilds.[77] Furthermore, the English also adopted this approach with a view to embolden new manufacturers within their territories.[78] From this, modern patent law has been developed. Accordingly, in *King v Wheeler*, the King's Bench took the view that:

> "The origins of modern patent law and the legal concepts of invention and patentability lie in the custom of the English Crown awarding monopoly rights by letters patent provide specific services."[79]

Importantly, the point must be taken that, at the time of these initial developments, patents were not interpreted to have the technical meanings that they have gained over the past 200 years. Rather, as discussed above, they involved the rudimentary concept involving the granting of monopoly rights to certain businesses to create.[80] This was seen in the early English practice of granting patent letters to stimulate innovation and cultivate the creation of new trades and industries as well as encourage foreign tradesman to settle in English territories (in a manner of importing their skills). [81]

The above notwithstanding, the system had its own shortcomings. Predominantly, there were abuses of power, as they practiced nepotism and the granting frivolous patents to those that were aligned to them.[82] Resultantly, there was litigation that arose to contest these practices. A case in

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[75] Trading monopolies is a market structure characterised by a single seller, selling a unique product in the market, which is what the Venetian system comprised of as when a patent was granted, an exclusive right was granted to a single person over a particular invention.
[76] Fox HG *Monopolies & Patents A Study of the History and Future of the Patent Monopoly* 350.
[77] McEniery B 'Patent Eligibility and Physicality in the Early History of Patent Law and Practice.' (2016) 38 *Little Rock Law Review* 180.
[78] Fox HG *Monopolies & Patents A Study of the History and Future of the Patent Monopoly* 350.
[79] *The King v. Wheeler* (1819) 2 B.
[80] Ostergard RL 'Intellectual Property: A Universal Human Right?' (1999) 21 *Human Rights Quarterly* 156-178.
[81] Fox HG *Monopolies & Patents A Study of the History and Future of the Patent Monopoly* 350-388.
[82] Hulsebosch DJ 'The Ancient Constitution and the Expanding Empire: Sir Edward Coke's British Jurisprudence'. Available at *https://doi.org/10.1057/9780230501584_12* (accessed on 4 June 2021).

point is that of *Darcy v Allen* which took place in England. The case involved the granting of an exclusive right to a plaintiff on an arbitrary ground.[83] The right was issued in 1598 for the manufacture of playing cards.[84] Pursuant to this, the applicant had the exclusive right to produce, sell and import playing cards in English territories, regardless of whether the manufacture of such playing cards was regarded as being 'an established industry'.[85] The contestation was that this was in violation of the common law.[86] Consequently, the defendant sought the prayer that they be allowed to participate in this industry, despite this exclusive right.[87]

In dealing with this matter, it was considered whether monopolies were generally contrary to English law. The thinking in this regard surrounded whether they were to the benefit of the territory as they often led to increased prices.[88] The argument raised by the defendant was that there was an established common law rule against monopolies, which the court taken into account and on this basis, the court determined the patent to be void .[89] Although at this time the Privy Council in England retained jurisdiction for hearing patent validity cases and those for prolongation of the monopoly period, *Darcy v Allen* established the right of the common law judges to determine patent disputes and this demonstrates the common law at work twenty-two years before Parliament's intervention in 1624 in which the Statute of Monopolies was enacted.

Due to the absence of substantial parliamentary intervention in relation to patent law, the Statute of monopolies consisted of a coherent set of patent law precedents and principles.[90] Additionally, perhaps in response to the pressures of rapid industrialisation, judges developed novel remedies for the enforcement of alleged patent infringements.[91] The Statute of 1624 further outlined the circumstances of exception to the existing general prohibition on monopolies that could be made

[83] *Darcy v Allen* (1603) 11 Eng. Rep. 84
[84] *Darcy v Allen* (1603) 11 Eng. Rep. 87
[85] Ostergard RL (1999) 160.
[86] *Darcy v Allen* (1603) 11 Eng. Rep. 87
[87] Hulsebosch DJ 'The Ancient Constitution and the Expanding Empire: Sir Edward Coke's British Jurisprudence'. Available at https://doi.org/10.1057/9780230501584_12 (accessed on 4 June 2021).
[88] Coke E *The third part of the Institutes of the laws of England : concerning high treason, and other pleas of the crown, and criminal causes* 16-36.
[89] Coke E *The third part of the Institutes of the laws of England : concerning high treason, and other pleas of the crown, and criminal causes* 16-36.
[90] McEniery B (2016) 180.
[91] The Statute of Monopolies 1623.

for an invention.[92] Until its amendment by the Patent Law Amendment Act of 1852, the Statute stood in place for over 200 years.[93]

The Act provided more set rules in comparison to the Statute which was mostly principles established from case law.[94] Its strength over the Statute was that it dealt with the pressures of rapid industrialisation at the time which the Statute did not.[95] Nonetheless, the Act set out the barest of principles which the courts had to consider in their judgements, but the subject matter of emerging railway technology was unique, and required judges to create a new set of patent precedents. [96] Hence, it was in fact the judiciary who played a pivotal role in developing patent law in England, contrary to many scholarly beliefs that the Statute and the Act formed the foundation of patent law in England.[97] Hutcheson emphasises the important role of the speculation, intuition and insight of judges.[98] It is further argued that later judges such as Lord Mansfield and others, brought these qualities to the determination of patent disputes which shaped English common law.[99]

The Statute of Monopolies of 1624 was introduced into early South African patent law by virtue of British occupation and the influence of English law contributed to the development of the patent system in South Africa.[100] Subsequent to South Africa attaining its independence, it became a signatory to the Paris Convention and the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement TRIPS.[101]

The Paris Convention sought to protect intellectual property, however, it failed to protect pharmaceutical patents.[102] Multi-national pharmaceutical companies highly opposed this and their

[92] Pocock JG *The Ancient Constitution and the Feudal Law: A Study of English Historical Thought in the Seventeenth Century: A Reissue with a Retrospect* 49-54.
[93] Pocock JG *The Ancient Constitution and the Feudal Law: A Study of English Historical Thought in the Seventeenth Century: A Reissue with a Retrospect* 49-54.
[94] Holdsworth SW A History of English Law 3 ed 360-371.
[95] McEniery B 'Patent Eligibility and Physicality in the Early History of Patent Law and Practice.' (2016) 38 *Little Rock Law Review* 180.
[96] McEniery B (2016) 180.
[97] Castree S 'The Universal Destination of Pharmaceutical Patents: Reflecting on TRIPS through the Lens of Aquinas (2014) 53 *Journal of Catholic Legal Studies* 6.
[98] Castree S (2014) 6.
[99] McEniery B (2016) 181.
[100] Sutherland D 'Conquest and Law' (1972) 15 *Studia Gratiana* 33.
[101] Fox HG *Monopolies & Patents A Study of the History and Future of the Patent Monopoly* 350-388.
[102] Berman HJ 'The Origins of Historical Jurisprudence: Coke, Seiden, Hale' (1994) 103 *Yale Law Journal* 1652.

bases for objection were on moral and economic terms.[103] They argued that the unfettered copying of pharmaceutical products was a competitive disadvantage for industrialised economies and a deplorable form of modern-day piracy.[104] These arguments resonated with modern states, who recognised the strategic importance of intangible knowledge goods for economic growth and international trade."[105]

Furthermore, in the 1980s, pharmaceutical companies launched a campaign for stringent and stronger IP rights.[106] Leading American pharmaceutical companies lobbied the US and certain European countries to issue sanctions against states which failed to protect these rights.[107] This was due to the pharmaceutical industry being a major contributor to the economies of these countries.[108]

Accordingly, normative contestations played out around broader IP rights across the globe in the first half of the 1980s.[109] These contestations culminated into diplomatic conversations surrounding the revision of the Paris Convention at the World Intellectual Property Organisation (WIPO).[110] The aim of the Paris Convention was to "promote the protection of intellectual property throughout the world".[111] The changes to the document which took place in light of this aim, were in fact a success. However, various commentators who have analysed this document noted that it did not fully address the issues faced by pharmaceutical giants and it did not quell the robust debate surrounding intellectual property measures.[112] At the same time, countries such as India and members of the Andean Pact introduced a proposal that sought to afford preferential treatment to developing countries that were signatories to the Paris Convention in order to have less stringent

[103] Berman HJ (1994) 1659.
[104] Sutherland D 'Conquest and Law' (1972) 15 *Studia Gratiana* 33
[105] Sutherland D 'Conquest and Law' (1972) 15 *Studia Gratiana* 38.
[106] Judd PL 'Retooling TRIPS' (2014) 1 *Virginia Journal of International Law* 118.
[107] Sutherland D (1972) 37.
[108] Judd PL (2014) 121.
[109] Klug H'Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic' (2012) 37 Law & Social Inquiry 297.
[110] Gerhart PM 'The tragedy of trips' (2007) 1 *Michigan State Law Review* 146.
[111] Paris Convention for the Protection of Industrial Property (1883), 9.
[112] Slade A 'Good faith and the TRIPS Agreement Good faith: putting flesh on the bones of the TRIPS Objectives' (2014) 63 The International and Comparative Law Quarterly 353.

laws for less developed countries. If implemented, "this revision would dilute the Paris Convention including new laws relating to pharmaceuticals."[113]

Unsurprisingly, this proposal was opposed by most developed member states who advanced their own proposals to make patent laws increasingly stringent.[114] By 1985, the debate between developed countries and developing countries reached a deadlock.[115] Disappointment with the revisions that were made to the Paris Convention and for WIPO itself gave countries a basis for drastically reforming the institutional arrangement of the international patent law regime.[116] In 1994, the developed nations scored a massive win over the developing countries through the conclusion of the TRIPS Agreement which significantly strengthened patent laws.[117]

The object of the TRIPS agreement is "the protection and enforcement of intellectual property rights and to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, that is to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." [118]

The conclusion of TRIPS resulted in minimum international standards being introduced for the enforcement and protection of patents. [119] One of the most important provisions of the agreement stipulates that signatory states are obliged to grant exclusive rights to patent holders for at least 20 years. [120] This includes inventions of a pharmaceutical nature or the process thereof that satisfies the criteria of "novelty, inventive step and industrial applicability."[121] Another key provision which brought phenomenal change to international patent laws is the outlawing of discrimination

[113] Gerhart PM (2007) 145.
[114] Bravo G 'From Paris Convention to TRIPs: A Brief History'(2001) 1 *Journal of Contemporary Legal Issues* 446.
[115] Bravo G (2001) 447.
[116] Crowne E 'Fishing trips: look at the history of the agreement on trade-related aspects of intellectual property' (2011) 2 *Creighton International and Comparative Law Journal* 77.
[117] Crowne E (2011) 79.
[118] TRIPS, Article 7.
[119] TRIPS, Article 8.
[120] TRIPS, Article 14.5.
[121] TRIPS, Article 14.5.

between different industries, for instance, the previous exclusion of pharmaceuticals from patent regimes. [122]

Furthermore, TRIPS no longer allows discrimination against imports and the favouring of products produced locally.[123] Therefore, pharmaceutical companies are enabled to control the locations of production sites. [124] One of the most important changes brought upon by the TRIPS agreement is that pharmaceutical multinationals have succeeded in consolidating their monopoly power globally.[125] Furthermore, they also have the right to preclude others from manufacturing, making use of, importing or selling medicines that are patented.

Hence, TRIPS grants exclusivity to patent holders of medications and only patent holders are allowed to produce, sell and import lifesaving medications. As mentioned, these medications are often extravagantly priced and therefore inaccessible to many people, which indirectly denies them access to healthcare. [126]

TRIPS goes even further and protects undisclosed information, such as data from clinical tests that under certain interpretations impede the registration of generic drugs.[127] For instance, the US interprets Article 39(3) of TRIPS to necessitate a timeframe in which data is exclusive, and prohibits drug regulating authorities from relying on an inventor's clinical data when testing the beneficial equivalence of generic medication.[128] This is disadvantageous as repeating clinical trials are time-consuming and costly.[129] Furthermore, repeating clinical trials would violate human subject guidelines.[130] Hence, this provision of TRIPS acts as a barrier to generic registration. This research paper submits that this is even more disadvantageous for developing counties due to

[122] TRIPS, Article 27.
[123] TRIPS, Article 27.
[124] Slade A 'Good faith and the TRIPS Agreement Good faith: putting flesh on the bones of the TRIPS Objectives' (2014) 63 The International and Comparative Law Quarterly 353.
[125] Slade A (2014) 355.
[126] Klug H'Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic' (2012) 37 Law & Social Inquiry 297.
[127] TRIPS, Article 39.3.
[128] TRIPS, Article 39.3.
[129] George J & van Staden J 'Intellectual property rights: plants and phyto-medicinals - past history, present scenario and future prospects in South Africa' (2000) 96 South African Journal of Science 439.
[130] George J & van Staden J (2000) 440.

developed countries' comparative advantage in research and development.[131] Academics therefore opine that the developed world secured near-absolute competitive advantage over the developing world's intellectual property-related industries via TRIPS. [132] Further, the TRIPS Agreement brings problems for developing countries, regarding the provision of drugs. For instance, if an invention meets the technical requirements of patentability, such a patent should still be granted even if it could adversely affect the accessibility of drugs. Academics opine the impact of this is that medicines become inaccessible as patent rights are protected over those of human rights, specifically the right to health as medicines become increasingly inaccessible, which this research paper agrees with.

It is important to note that although TRIPS has made pharmaceutical patents more stringent, flexibilities called public health safeguards have been included in TRIPS which will be discussed in the next chapter.[133]

2.3 THE INTERSECTION OF HUMAN RIGHTS AND SOCIAL JUSTICE WITH THE EVOLUTION OF PATENT LAW IN SOUTH AFRICA

As mentioned above, TRIPS contains public health safeguards or flexibilities, and the first flexibility is compulsory licensing. This was confirmed in the Doha Declaration on TRIPS and further in the Decision of 30 August 2003: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.[134] TRIPS allows for the granting of compulsory licenses by a competent national authority which permits that national authority to manufacture a product which is patented, without requiring authorisation from the patent holder. [135]

However, the basis for the issuance of such licenses under the said provision is vague, which allows developing countries to have a wide discretion over the use thereof. [136] Furthermore, it is important to note that although developing countries have a wide discretion in issuing compulsory licenses,

[131] Oriola TA (2007) 291.
[132] Klug H (2012) 299.
[133] Abbott FM 'The WTO trips agreement and global economic development'(1996) 72 *Chicago-Kent Law Review* 385.
[134] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc.
[135] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc.
[136] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc.

the reliance on Article 31 has been problematic due to complex procedures involved in the issuance thereof as they may go beyond the existing institutional capacities of developing countries.[137]

Another flexibility contained in TRIPS is antic-competitive contractual licenses. [138] The aim of this is for it to be a cooperation mechanism for competition control for patented products. "Articles 40.3 and 40.4 provide for consultation and cooperation on a case-by-case basis regarding the enforcement of control of anticompetitive practices in contractual licenses." [139] Furthermore, Article 67 obliges developed countries to give technical cooperation to developing nations in order to help them prepare laws which protect and enforce patents.[140] However, these provisions are not clear and also contain shortcomings. For instance, technical cooperation regarding the deterrence of intellectual property abuses by developed states may be unsuitable for the circumstances of developing states.

It is important to note that Article 67 mainly focuses on the provision of cooperation regarding the protection and enforcement of patent laws.[141] This provision, however, does not put obligations on developed states in order to help developing states in enforcing their local competition laws to circumvent patent law abuses.[142]

The TRIPS Agreement does, however, allow member states of the WTO to take the necessary measures to protect public health when formulating or amending their IP laws as stated in Article 8 of the TRIPS Agreement.[143] This research paper therefore submits that the TRIPS Agreement acknowledges that IP is directly linked and relevant to public health.

Further, the preamble of the Constitution of the WHO clearly states that the enjoyment of the right to health is one of the indiscriminative fundamental rights of every human being.[144] In this context, the right to health is a right afforded to every human being, a right related to other rights and, it is

[137] TRIPS, Article 31.
[138] TRIPS, Article 40.3
[139] TRIPS, Article 40.4
[140] TRIPS, Article 67.
[141] TRIPS, Article 67.
[142] TRIPS, Article 67.
[143] TRIPS, Article 8.
[144] Agreement Establishing the World Trade Organisation, i.

also more than just a political or civil right.[145] The Constitution of South Africa (the Constitution) is the supreme source of law in the land and provides for the right to access health care services.[146] Additionally, another important human right related to the right to health, the right to life, is also stated in the Constitution.[147]

There therefore exists a hierarchy of laws and a hierarchy of rights, as stated in *Minister of Health and Others v Treatment Action Campaign and Others* regarding the importance of the right to health.[148] In this case, the Constitutional Court held, *inter alia*, that the conduct of restricting the distribution of antiretroviral drugs to HIV positive pregnant women by the South African government was a violation of the constitutional right to health, which means that if indeed the right to IP was to be deemed a human right for example, in the context of the UDHR, *inter alia*, then the right to health would trump the right to IP for a number of reasons.[149]

One of the reasons referred to is the fact that IP rights depend on legislative promulgation. These rights are of a temporary nature which can be licensed, assigned to persons, as well as being amended if necessary, and forfeited.[150] The link and relevance of IP, particularly patents, to public health is directly evidenced by the increased well-being of the public, while the relevance of same to the economy is evidenced by the sales of the manufactured product.[151] As mentioned earlier in the paper, IP rights are monopolistic in nature, which means that their prices of sale may be higher than what poor people can afford, thereby directly impacting their right to health negatively. This therefore shows the direct link and relevance that IP has to public health and the right to health.

Furthermore, one of the reasons in favour of IP protection is for the promotion of creativity and to generate profit in order to foster further research and innovation. Research and innovation are important because new viruses and illnesses are always emerging. The pharmaceutical industry,

[145] WTO 'Responding to Least Developed Countries' Special Needs in Intellectual Property' available at *https://www.wto.org/english/tratop-e/trips-e/ldc-e.htm* (accessed on 10 June 2021).

[146] The Constitution of South Africa, 1996, s27.
[147] The Constitution of South Africa, 1996, s27.
[148] *Minister of Health and Others v Treatment Action Campaign and Others* (1) 2002 (10) BCLR 1033 (CC), 98.
[149] *Minister of Health and Others v Treatment Action Campaign and Others* (1) 2002 (10) BCLR 1033 (CC), 109.
[150] Pavone I 'The hiv/aids pandemic and international human rights law.' (2009) (1) LAWASIA Journal 99.
[151] Pavone I (2009) 99.

therefore, needs to be prepared and such preparation is done by conducting research. Since illnesses and viruses are referred to as "life-threatening", it shows that an invention, which targets such illness or virus has a direct impact on public and this is therefore an indication of how IP is relevant and linked to public health. [152]

To contextualise this situation, one can have a look at the debate around the HIV and AIDS pandemic. When the HIV/AIDS pandemic broke out, by 2007, an estimated 350 000 people had become casualties of the virus.[153] A number of reasons could be advanced for these fatalities which include:

(1) an inequitable health system,

(2) HIV/AIDS denialism of the virus by the ANC government led by former President, Thabo Mbeki, and

(3) global factors such as the intellectual property hegemony and the impact of Bretonwoods-backed policies such as structural adjustments.[154]

A fair amount of the deaths were as a result of the inaccessibility of the life-saving ARVs.[155] When available, these drugs were also priced at a point beyond the reach of the majority.[156] This led to an uproar from various activists and communities who cited that the price of ARVs were priced at more than what the most vulnerable South Africans made in a year; and with the number of deaths due to this virus increasing, the government was forced to take measures to respond to the public debate and outcry. [157]

[152] Pavone I (2009) 99.

[153] SAHO 'HIV/Aids in South Africa' available at https://www.sahistory.org.za/article/hivaids-south-africa#:~:text=HIV%2FAids%20is%20becoming%20the%20most%20devastating%20disease%20humankind,died%20from%20AIDS%20in%20South%20Africa%20in%202007 (accessed on 15 June 2021).

[154] Pechacek JT (2012) 190. Regarding the ANC's denialism on AIDS, Thabo Mbeki believed that HIV could not cause AIDS and would therefore not sufficiently address the problem that the country was facing at the time, further he delayed providing treatment to people with HIV/AIDS. As a result, there were more than 300,000 avoidable deaths that occurred. It also resulted in an estimated 35,000 babies being born with HIV who would not otherwise have been HIV positive. In 2016, Thabo Mbeki further stated that as AIDS is a syndrome, i.e. a collection of well-known diseases, with well-known causes and that they are not, together, caused and cannot be caused by one virus but HIV might be a contributory cause of immune deficiency.

[155] Pavone I (2009) 98.

[156] Helfer LR 'Pharmaceutical Patents and the Human Right to Health The Contested Evolution of the Transnational Legal Order on Access to Medicines' 2015 Duke Law School Public Law and Legal Theory Series 314.

[157] SAHO 'HIV/Aids in South Africa' available at https://www.sahistory.org.za/article/hivaids-south-africa#:~:text=HIV%2FAids%20is%20becoming%20the%20most%20devastating%20disease%20humankind,died%20from%20AIDS%20in%20South%20Africa%20in%202007 (accessed on 15 June 2021).

One of the measures taken was the purchase of ARV drugs from India to treat persons living with HIV/AIDS.[158] As noted in chapter 1, this was not welcomed by certain sectors of the developed countries, particularly the US and the EU. The US was particularly outspoken on the matter because it was the first country to conduct clinical trials and patented the first ARVs.[159] As a result, they threatened to sanction South Africa and India. However, these countries argued that, pursuant to TRIPS flexibilities, they were within their rights to manufacture and make use of generics HIV/AIDS drugs in order to address healthcare emergencies.[160]

Pharmaceutical companies, from these countries and others, therefore decided to institute legal proceedings against the South African government.[161] Their cause of action was that the clauses that allowed for generic medications should be revoked.[162] In response to this, members of developing states in the WTO requested that the organisation convene an emergency meeting to resolve the conflict.

At the meeting that took place in Doha, in the United Arab Emirates, the conversations surrounded generic medications, and the flexibilities contained in TRIPS. The main points raised at this meeting were compulsory licenses, parallel imports and other exceptions as stated in Article 31 of TRIPS, could be used as alternative sources for cheaper medications.[163] The declaration which reinforced TRIPS flexibilities, and was in favour of developing countries, further advocated the stance that developing member states should have access to generic medication in certain

[158] Gathii J 'Rights, patents, markets and the global aids pandemic' (2002) 14 *Florida Journal of International Law* 261.
[159] Gathii J (2002) 264.
[160] WTO 'Responding to Least Developed Countries' Special Needs in Intellectual Property' available at https://www.wto.org/english/tratop-e/trips-e/ldc-e.htm (accessed on 10 June 2021).
[161] *The Pharmaceutical Manufacturers' Association of South Africa v The President of South Africa* unreported case no 4183/98 (March 2001). In this case the applicants successfully sought an interdict which prohibited the publishing amendments of the Medicines and Related Substances Control Amendment Act no 90 of 1997 due to these sections being in conflict s 43 and s 44 of the Constitution, as it enabled the president to, amongst other things, deprive owners of intellectual property in regard to pharmaceutical products.
[162] Pouris A ' Patents and economic development in South Africa: Managing intellectual property rights' available at http:// dx.doi.org/10.4102/sajs.v107i11/12.355(accessed on 23 March 2021).
[163] Abbott FM 'The Doha Declaration on the TRIPS Agreement and public health: lighting a dark corner at the WTO' (2002) 5 *Journal of Internation Economic Law* 469.

instances, in order to address healthcare needs.[164] In South Africa's instance, it was required in order to prevent further deaths and realise the right to health and achieve social justice by making ARVs accessible and equally accessible to the majority of society who were people from vulnerable groups or previously disadvantages groups.[165] In this way, there was a sense of social justice being achieved as persons who were disadvantaged by South Africa's inequitable healthcare system, received life-saving medication.[166]

As with the AIDS outbreak and the inaccessibility of ARVs, the Covid-19 outbreak and access to vaccinations have also been a challenge.[167] This was due to poor production and distribution of vaccines to certain states.[168] Importantly, over the past three years, over 102 550 people in South Africa have lost their lives to the deadly Covid-19 pandemic.[169] Had the availability of vaccines been equitable, especially in the initial phases of the pandemic, as discussed in chapter 1, the amount of lives lost would have been significantly reduced.[170] Consequently, South Africa has called for the waiver "of the application of intellectual property rights for Covid-19 diagnostics, therapeutics and vaccines."[171] However, this waiver was not welcomed by certain states.[172]

In response to this, the United Nations Human Rights Council adopted a resolution on access to vaccines which states that vaccines should be accessible to all states, as well as being inexpensive, and should be provided timeously.[173] Further, they argue that having access to vaccines is a human right, specifically, a right to health and they are aware that there has been unequal allocation and

[164] TAC 'Dying for Treatment. TAC Briefing Document on the Civil Disobedience Campaign' available at *http://www.tac.org.za/Documents/CivilDisobedience/briefingdocument.html.* (accessed on 10 June 2021).
[165] TAC 'Dying for Treatment. TAC Briefing Document on the Civil Disobedience Campaign' available at *http://www.tac.org.za/Documents/CivilDisobedience/briefingdocument.html.* (accessed on 10 June 2021).
[166] Baker JH *An Introduction to English Legal History* 3ed 14-62.
[166] Castree S 'The Universal Destination of Pharmaceutical Patents: Reflecting on TRIPS through the Lens of Aquinas' (2014) 53 *Journal of Catholic Legal Studies* 4. 5.
[167] WHO 'South Africa WHO Coronavirus Disease Dashboard' available at *https://covid19.who.int/region/afro/country/za* (accessed on 5 June 2021).
[168] Saha S 'Patent law and trips: Compulsory licensing of patents and pharmaceuticals' (2009) 91 *Journal of the Patent and Trademark Office Society* 36.
[169] WHO 'South Africa WHO Coronavirus Disease Dashboard' available at *https://covid19.who.int/region/afro/country/za* (accessed on 5 June 2021).
[170] Capling A *Intellectual Property, Trade Politics: International, domestic and regional perspectives* 56-75.
[171]Sandor J 'Rebalancing Human Rights at the Time of Covid-19 Pandemic' (2020) 11 *Union University Law School Review* 386.
[172]Sandor J (2020) 386.
[173] Baker BK 'International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) New York Law School Review 307.

distribution of vaccines, in which preference was given to developed nations. [174] Unfortunately, this resolution does not change any existing property laws as it merely reiterates that states are allowed to make use of the TRIPS safeguards.[175] Furthermore, it endorses measures of best practices, but does not of put any measures of best practice in place which could help realise the right to health.[176]

Another shortfall of this resolution is that it does not provide that vaccines should be medically safe.[177] Instead, developed member states have urged the WTO to fast-track vaccines to African states.[178] Although these fast-tracked vaccines have been approved, it only took a year for them to be approved and sourced to Africa, whereas a vaccine usually takes up to ten years to be approved.[179] As a result, some people have been experiencing crippling side effects of the vaccine.[180] Some side effects include paralysis, short-term memory loss, and uncontrolled movement of limbs.[181] Hence, the resolution on access to vaccines should provide for access to safe vaccines, with more clinical trials and less severe side-effects as pharmaceutical companies have been given indemnity from any lawsuits, if the vaccines which they produce are damaging to people.[182] Furthermore, in Africa there have been claims of herbal cures for the virus, or means of reducing serious symptoms of the virus, with little to no side-effects.[183] However, the WHO has shunned these methods instead of testing them.

[174]Sarnoff JD 'Negative Emission Technologies and Patent Rights after Covid-19' (2020) 10 *Climate Law* 225.
[175]Sarnoff JD (2020) 225.
[176] Nhemachena A 'COVID-19 and the Eternal Return of Empire? Fast-Tracking Nothing Else But Vaccines?' available at *https://www.researchgate.net/publication/351637531_Artwell_Nhemachena_2021_COVID-19_and_the_Eternal_Return_of_Empire_Fast-_tracking* (accessed on 10 June 2021).
[177] Nhemachena A 'COVID-19 and the Eternal Return of Empire? Fast-Tracking Nothing Else But Vaccines?' available at *https://www.researchgate.net/publication/351637531_Artwell_Nhemachena_2021_COVID-19_and_the_Eternal_Return_of_Empire_Fast-_tracking* (accessed on 10 June 2021).
[178] Gakpo JO 'Africa launches its first human trial for COVID-19 vaccine' available at *https://alliance-forscience.cornell.edu/blog/2020/07/africa-launch* (accessed on 6 June 2021).
[179] Gakpo JO 'Africa launches its first human trial for COVID-19 vaccine' available at *https://alliance-forscience.cornell.edu/blog/2020/07/africa-launch* (accessed on 6 June 2021).
[180] Bugos C 'A Timeline of COVID-19 Vaccine Side Effects' available at *https://www.verywellhealth.com/when-to-expect-covid-19-vaccination-side-effects-5176621* (accessed on 10 June 2021).
[181] Bugos C 'A Timeline of COVID-19 Vaccine Side Effects' available at *https://www.verywellhealth.com/when-to-expect-covid-19-vaccination-side-effects-5176621* (accessed on 10 June 2021).
[182] Nhemachena A 'COVID-19 and the Eternal Return of Empire? Fast-Tracking Nothing Else But Vaccines?' available at *https://www.researchgate.net/publication/351637531_Artwell_Nhemachena_2021_COVID-*
[183] Komesaroff P, Kerridge, I and Gilbert L 'The US is fast-tracking a coronavirus vaccine, but bypassing safety standards may not be worth the cost' available at *https://theconversation.com/the-us-is-fast-tracking-a-coronavirus* (accessed on 10 June 2021).

Studies have further shown that western medical professionals are reluctant to utilise traditional medicine due to several reservations, such as the lack of scientific basis for traditional medicine.[184] However, in South Africa the Traditional Health Practitioners Act 2007 has been designed to regulate the registration, training and practices of traditional health practitioners, and serve and protect the interests of members of the public who utilise their services. [185] Further, South Africa attempted to provide protection for indigenous knowledge by means of the 2013 Intellectual Property Laws Amendments Act (IPLAA).[186]

IPLAA provisions provide protection under the existing copyright, trademark, designs and performer's protections trademark, designs and performer's protections acts for traditional works, and designs, and create a national trust fund, council and database for Indigenous knowledge. "This was widely criticised, for not adequately recognising the unique nature of Indigenous knowledge and due to it adding an overlay to the existing IP system that will not provide the most effective protection." [187]

In 2018, the Western Cape parliament approved a negotiating mandate to support the adoption of the Indigenous Knowledge Protection Bill and proposed that the IPLAA "be repealed as it does not appear to be compatible" with the Indigenous Knowledge Protection Bill.[188] However, the IPLAA repealed language was removed from the final mandate. The Indigenous Knowledge Protection Bill provides protection for this same subject matter as the IPLAA, but under a *sui generis* regime.[189]

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[185] *Traditional Health Practitioners Act 2007.*

[186] Alvez A 'The Protection Of Traditional Knowledge In Africa' Available at *https://www.mondaq.com/southafrica/trademark/841656/the-protection-of-traditional-knowledge-in-africa* (accessed on 13 December 2022).

[187] Hardy A 'The Integration of Traditional and Western Medicine' available at *https://digitalcollections.sit.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1568&context=isp_collection* (accessed on 13 December 2022).

[188] Mokgobi M 'Towards integration of traditional healing and western healing: Is this a remote possibility?' available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4652795/* (accessed on 14 December 2021).

[189] Hardy A 'The Integration of Traditional and Western Medicine' available at *https://digitalcollections.sit.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1568&context=isp_collection* (accessed on 13 December 2022).

While the IPLAA was initially seen as possibly incompatible with the Indigenous Knowledge Protection Bill, it is now believed that by implementing only complementary provisions of the IPLAA, a more holistic protection system for indigenous knowledge can be achieved than through the Indigenous Knowledge Protection Bill alone.[190] It is evident that South Africa recognises the importance of traditional medicine and indigenous knowledge in African communities and does not discredit it as the WHO and western medicine does.[191] The WHO should be more open to finding and secure medicines apart from western medicines and put traditional African medicine on an equal footing with western practices.

Given these above debates, it has been crystallised how the interface between intellectual property rights and the right to health has been problematic. One of the takeaways from this debate is the long-noted debate on competing human rights. There should be processes, at higher levels to resolve such conflict of rights. Generally, the resolution of such a conflict involves a balancing exercise.[192] This entails the balancing of human rights such as the right to health with the right to property, whereby the right to life and health takes preference as mentioned in this chapter due to there being a hierarchy of rights and it would be a violation of the constitutional right to health if certain medicines were inaccessible due to IP rights. As mentioned, this means that if the right to IP was deemed to be a human right then the right to health and the right to life would trump IP rights.

Furthermore, at this point, it also becomes vital to note the indivisibility and interdependence of rights. While rights sometimes conflict, they are still connected. Discussing this connection, the Special Rapporteur on the right to health stated that everyone should be entitled to the enjoyment of the highest attainable standard of physical and mental health and the obstacles in achieving this, with a main contributor being laws, policies, practices and obstacles, that are not promoting and

[190] Sheridan R 'Does Madagascar's herbal remedy, COVID-Organics work' available at *https://www.researchgate.net/publication/342654901* (accesed on 10 June 2021).
[191] Alvez A 'The Protection Of Traditional Knowledge In Africa' Available at *https://www.mondaq.com/southafrica/trademark/841656/the-protection-of-traditional-knowledge-in-africa* (accessed on 13 December 2022).
[192] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).

protecting this right and enhancing public health.[193] It was further noted in the Special Rapporteur that the Doha Declaration reflects human rights perspectives, especially the right to health and the right to enjoy the benefits of scientific progress, which is a balancing act, that must take place at the national level and the value of the flexibilities contained within TRIPS will depend mainly on the manner in which it is actually implemented by states.[194]

Furthermore, the High Commissioner for Human Rights in her 2001 report examined the relationship between TRIPS and the right to health, and found that the starting point for a human rights analysis of the TRIPS Agreement is Article 15 of the ICESCR and Article 27 UDHR, which recognises "the right of everyone to the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author and the right of everyone to enjoy the benefits of scientific progress and its applications." [195] Article 15 of the ICESCR also identifies the need to balance promoting general public interests in accessing new knowledge and protecting the interests of authors and inventors in such knowledge and binds States Parties to achieve such a balance when designing an IP system.[196]

However, it is important to note that balancing interests is not new to IP laws.[197] For instance, in regard to patents, the monopoly position granted to a right holder is for a limited period and non-renewable, which is intended to provide inventors with the ability to retrieve research and in which inventors must thereafter divulge their inventions, which has been a fundamental element of patent law since its inception.[198] Therefore, patents aim to guarantee access to knowledge in the short

[193] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).
[194] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).
[195] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).
[196] ICESCR, Article 15.
[197] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).
[198] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).

term and access to the physical invention, in the long term. Resultantly, the Commissioner found a degree of compatibility between Article 15 and IP but posed the vital question of 'where to strike the right balance'. [199]

As mentioned that Article 15 of the ICESCR and Article 27 UDHR, recognises "the right of everyone to the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author and the right of everyone to enjoy the benefits of scientific progress and its applications."[200] Based on this, it can also be contended that essential medicine be declared as essential public goods which could contribute to social justice and the fair distribution on essential medication in order to realise the right to health.[201]

In this context of social justice which involves the equal distribution of resources within society, including fairness as it manifests in society; it is important to note that the increasing privatisation of knowledge and the products that are produced as a result of this knowledge, have been a significant feature of the capitalist system which fences off public spaces and brings them under private control of private entities.[202] In recent times, the harmonisation and integration of IP rights, through the WTO, WIPO and TRIPS, signify that intellectual property right protection has a global reach.[203] Advocates in favour of this have argued that "this property regime has given rise to unparalleled expansion of productive possibilities".[204] However, this has mainly benefitted the minority, who are multi-national pharmaceutical companies as essential medications that are vital to the health and lives of the majority of society, have not escaped appropriation as private goods.[205]

[199] UN 'Special Rapporteur on human rights defenders' available at *https://www.ohchr.org/en/special-procedures/sr-human-rights-defenders#:~:text=Ms.,of%20Business%20and%20Human%20Rights* (accessed on 19 May 2022).
[200] ICESCR, Article 15. UDHR, Article 27.
[201] ICESCR, Article 15. UDHR, Article 27.
[202] Ostergard RL 'Intellectual Property: A Universal Human Right?' (1999) 21 Human Rights Quarterly 156.
[203] Ostergard RL (1999) 157.
[204] Drahos P 'The universality of intellectual property rights: Origins and development' available at *http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf* (accessed on 23 March 2021.
[205] Drahos P 'The universality of intellectual property rights: Origins and development' available at *http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf* (accessed on 23 March 2021.

As a result, essential medicines are regularly viewed as private commodities because of various factors, including:

> 1)"reigning bioethical models with their focus on patient autonomy have emphasised individual aspects of health care, reinforced by the fact that medicines are privately consumed.
> 2) the market pre-selects consumers of highly-priced medicines, by excluding those individuals who cannot afford them." [206]

However, this research paper submits that medicines should be considered public goods as they have momentous implications for the general health of society, are also international in their development and impact, and are disposed to regulation in their development, production, distribution and use. Furthermore, the public dimensions of medicines are renowned for the part that they play in public health vaccination measures, and in the management of endemic diseases and pandemics.[207]

The public dimension correspondingly entails the social consequences emanating from decisions made in research and development of new medications, "and the profiteering surrounding lifestyle drugs which draws resources away from research into so-called neglected diseases."[208] Contrastingly, public goods are those that are essentially social in nature, although they maybe intended for private use, as with medicines.[209] Public goods also often have progressive externalities, meaning that their wide scope of accessibility benefit the general public, and is not limited to a small group of persons. [210]

This public benefit is most obvious in the instance of vaccines, in which herd immunity progresses due to wide diffusion.[211] However, the same approach can be seen in regard to the

[206] Giovanetti T & Matthews M 'Intellectual Property Rights and Human Rights' available at *http://www.ipi.org/ipi/1PIPublications.nsf/* (accessed on 24 March 2021).
[207] Giovanetti T & Matthews M 'Intellectual Property Rights and Human Rights' available at http://www.ipi.org/ipi/1PIPublications.nsf/ (accessed on 24 March 2021).
[208] Vadwa YA and Baker BK 'Achieving social justice in the human rights/intellectual property debate : realising the goal of access to medicines' available at *https://journals.co.za/doi/epdf/10.10520/EJC145309* (accessed on 19 May 2022).
[209] Harms AJ ' Tweaking Patent Law: Patent Law Policy and Pharmaceutical Benefits' (2014) 1 *IPLJ* 11.
[210] Harms AJ (2014) 11.
[211] Holland J 'The Effects of Patents on Access to Essential Medicines for HIV/AIDS in Developing countries: With Malawi a Typical Example' (2016)19 *IPLJ* 7.

prevention and treatment of infectious diseases. [212] As healthier populations have more capacity in political, cultural and economic spheres, there could be successful outcomes for treating short-term and chronic diseases.[213] Hence, medications should not be identified as private goods. [214]

As mentioned earlier, social justice involves the equal distribution of resources within society and although there is no accepted definition to this, the meaning to be advanced in the African context is that essential, life-saving medication which are often needed by the most vulnerable in society are to be accessible to these persons by it being equally distributed among society or it being affordable and therefore, being accessed by even the poorest and most vulnerable in society. Social justice discussions regarding the right to health and IP are important because the interests of achieving social justice require that a counter-narrative be presented to the prevailing narrative which promotes IP protection in practice, which occurs at the expense of the right to health and to accessing life-saving medication.[215] The human rights model enables the articulation of such a counter-narrative. [216] This research paper is of the view that when human rights are respected in theory and practice, and when the value of medicines is acknowledged as public goods, then social justice will prevail.

[212] Holland J (2016) 8.
[213] Dubois M 'The Appropriate Scope of Property Rights in Patents'(2018) 67 *IPLJ* 75.
[214] Dubois M (2018) 76.
[215] Vadwa YA and Baker BK 'Achieving social justice in the human rights/intellectual property debate : realising the goal of access to medicines' available at *https://journals.co.za/doi/epdf/10.10520/EJC145309* (accessed on 19 May 2022).
[216] Dubois M (2018) 76.

2.4 REGIONAL PATENT LAWS

2.4.1 African Regional Intellectual Property Organization

There are currently two regional patent systems, the African Regional Intellectual Property Organisation (ARIPO) and the African Intellectual Property Organization (OAPI); South Africa has not joined either system. However, it has been suggested that it will join ARIPO.[217]

ARIPO was established in 1976 and it mainly consists of countries that were previously ruled by the English.[218] In 1984, in Harare, the ARIPO Protocol on Patents and Industrial Designs was implemented (the Harare Protocol). It is important to note that parties to ARIPO do not automatically become members of the Protocol as it is only binding on member states that ratify or assent to it. The Protocol authorises the ARIPO Secretariat to process "patent, utility models and industrial design applications as well as to grant patents, utility models and industrial design on behalf of its contracting parties but contracting parties do retain the right to object to the grant of intellectual property." [219] Subsequent to a patent being issued, the right is governed by national intellectual property legislations.[220]

Most of the current ARIPO member states are Sub-Saharan countries who suffer from various non-communicable and communicable diseases, which have substantial socio-economic effects, and adversely impacts the development prospects of these states.[221] Many of these diseases are treatable, however, access to affordable medication is an enormous challenge in the region.[222] A particular hindrance to access to medication is the expensive costs of medicines which are aided by stringent patent laws.[223] Generic manufacturers have been instrumental in lowering the price of

[217] Kameni EI *Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects* (unpublished LLM thesis, University of Pretoria, 2015).
[218] Kameni EI *Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects* (unpublished LLM thesis, University of Pretoria, 2015).
[219] Agaba DK 'Tackling inequality and governance challenges: Insights from the COVID-19 pandemic' 2021 *AHRLJ* 877.
[220] Agaba DK (2021) 877.
[221] Rega J 'G20 freezes poor countries' debts to add $20B for pandemic fight' available at *ttps://www.politico.eu/article/coronavirus-g20-freezes-poor-countries-debts-to-add-20b-for-pandemic-fight/* (accessed 15 June 2021).
[222] Biryabarema E 'IMF approves $ 491,5 million loan for Uganda to limit corona virus impact' available at *https://www.reuters.com/article/us-health-coronavirus-uganda-imf/imf-approves-491-5-mln-loan-for-uganda-to-limit-coronavirus-impact-idUSKBN22I321* (accessed 15 June 2021).
[223] Igunza E 'Corona virus corruption in Kenya: Officials and business people targeted' available at *https://www.bbc.com/news/world-africa-54278417* (accessed 30 April 2021).

essential medicines and in scaling up treatment.[224] Unfortunately, such competition is only possible in an system where patents are not obstacles to accessing medicines.[225]

ARIPO's aims include the:

> "(a) [P]romotion of the harmonisation and development of industrial property laws and matters related thereto, appropriate to the needs of its members and of the region as a whole; (b) establishment of such common services or organs of harmonization and development of the industrial property activities affecting its members; (c) assisting its members in the development and acquisition of suitable technology; and, (d) evolution of a common view in industrial property matters." [226]

A challenge, however, with ARIPO is that despite some of its objectives being designed to benefit members of the region, its system does not.[227] Since the outbreak of the Covid-19 pandemic, over 90 organisations have called for the reform of ARIPO in order to ensure that citizens of member states have access to medicine as the current patent system favours patent rights as opposed to human rights such as the right to health.[228]

Timely and inexpensive medicines is essential to prevent and treat diseases that are of serious nature to public health and overall reduce the disease burden in this region.[229] Therefore, implementing a legal system that facilitates countries in this region to import and manufacture inexpensive essential medicine and safeguarding a consistent supply of such medicines is a necessity.[230] Further, academics in this region opine that in order to prevent growing pandemics, patent laws should be amended in a manner which helps the public access medication.[231] This could also be done by means of generic mediations and the granting the granting of compulsory

[224] Dos Santos F 'Levelling the Playing Field to Promote Technology Transfer and Innovation in African Least Developed Countries' (2020) 8 *IPLJ* 38.
[225] Dos Santos F (2020) 38.
[226] ARIPO 'About us' available at *https://www.aripo.org/about-us/our history/#:~:text=Objectives%20of%20ARIPO&text=The%20objectives%20of%20the%20Organization,development%20of%20the%20member%20states.* (accessed on 24 May 2022).
[227] Attaran A and Lee-Gillispie C (2001) 482.
[228] Avafia T, Berger J and Hartzenberg T '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' available at *https://www.tralac.org/publications/article/6841-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.html*(accessed on 7 June 2021).
[229] Kovac M and Rakovec L 'The COVID-19 pandemic and long-termincentives for developing vaccines: Patent law under stress' (2022) *The Journal of World Intellectual Property* 11.
[230] Kovac M and Rakovec L (2022) 11.
[231] Capling A *Intellectual Property, Trade Politics: International, domestic and regional perspectives* 56-75.

licenses, which is provided for in Article 31 of TRIPS.[232] In this respect, a particular concern is the availability of effective regional actions to deal with the issue of patent laws that could obstruct the importation and local manufacture of inexpensive essential medication.

Hence, various regional and sub- regional instruments and initiatives have highlighted the importance of TRIPS flexibilities to enable access to affordable medication, as ARIPO's current laws do not include all of the flexibilities which are aimed at benefiting all citizens of developing nations by enabling them to have access to medicines, even the most vulnerable in society in order to ensure fairness in the distribution of essential medicines so that social justice may be achieved.[233] Currently, Article 8 of the Harare Protocol stipulates that compulsory licenses are subject to what member states' legislation provides. [234] Hence, it does not adopt a position or expressly permit compulsory licenses.[235] The Protocol further does not make provision for parallel importation or generics for the purposes of public interest.

However, in 2008, the WHO Health Assembly adopted a Global Strategy and Plan of Action (GSPOA) on Public Health, Innovation and Intellectual Property and member states of ARIPO, such as Kenya, played an instrumental role in the negotiations leading to the final GSPOA.[236] The GSPOA recognises that "the price of medicines is one of the factors that can impede access to treatment and that TRIPS flexibilities could facilitate increased access to pharmaceutical products by developing states"[237]

The GSPOA needs governments and other relevant parties, including ARIPO, to embolden and support the application and management of IP in a way in which health-related innovation is maximised and promotes access to essential medicines; and further, to endorse and support

[232] TRIPS, Article 31.
[233] Avafia T, Berger J and Hartzenberg T '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' available at *https://www.tralac.org/publications/article/6841-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.html*(accessed on 7 June 2021).
[234] Harare Protocol, Article 8.
[235] The Harare Protocol, Article 8
[236] WHO Health Assembly adopted a Global Strategy and Plan of Action on Public Health, 2008.
[237] WHO Health Assembly adopted a Global Strategy and Plan of Action on Public Health, 2008, 31.

national and regional institutions in their efforts to strengthen their capacity to apply patent laws in a way oriented towards public health needs and reconising human rights. [238]

Furthermore, The 2011 UN declaration on HIV and AIDS commits governments to optimise the "use, to the full of existing flexibilities" available under the TRIPS Agreement with the aim to remove, where feasible, obstacles that limit the capacity of low-and middle income countries to provide affordable and effective HIV prevention and treatment products, diagnostics, medicines and commodities and other pharmaceutical products, as well as treatment for opportunistic infections and co-infections, and to reduce costs associated with life-long chronic care." [239]

This was followed with the World Health Assembly endorsing the WHO Global Action Plan for the Prevention and Control of NCDs in 2013, which required members of the WHO to promote increased access to cheap medication and health care by utilising the TRIPS flexibilities completely and global pharmaceutical companies to contribute to such efforts.[240]

At a regional level, similar ingenuities have developed with the aim to improve accessibility of essential medication in the region. Hence, in 2012 certain presidents of ARIPO member states adopted a Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Malaria and Tuberculous Response in the region.[241] This treats the commonness of AIDS, TB, malaria and other infectious diseases as a crisis for the ARIPO region, and increases concern that national responses to communicable an con-communicable disease are largely dependent on foreign produced medication and that this is a great risk to the ARIPO region and African continent as a whole.[242]

An important feature of the Roadmap is Pillar 2, under which a suite of high priority actions are listed in order to guarantee enhanced access to quality but cheap medication.[243] It embraces

[238] WHO Health Assembly adopted a Global Strategy and Plan of Action on Public Health, 2008.
[239] The United Nations General Assembly Declaration on Commitment on HIV/AIDS, GA Res S-26/2.
[240] WHO Global Action Plan for the Prevention and Control of NCDs, 2013.
[241] Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Malaria and Tuberculous Response, 2012.
[242] Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Malaria and Tuberculous Response, 2012.
[243] Roadmap on Shared Responsibility remove these extra gaps between your work and in the footnotesand Global Solidarity for the AIDS, Malaria and Tuberculous Response, 2012, Pillar 2.

investing in regional pharmaceutical manufacturing plants, more efforts to guarantee that information is introduced into the region and the all-out use of TRIPS flexibilities.[244]

Furthermore, in 2013 the East African Community (EAC) also established an East African Community Regional Pharmaceutical Manufacturing Plan of Action for purposes of guiding the EAC towards developing an effective regional pharmaceutical manufacturing industry that will supply national, regional and international markets with the essential medications.[245] An important objective of this plan is to make complete use of the flexibilities provided for in TRIPS for more local production of pharmaceuticals. [246] Furthermore, the EAC Secretariat published the EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation, and given that ARIPO Members are part of the abovementioned initiatives, they have the same objectives and purpose.[247] However academics opine that the realisation of these outcomes to the degree that it relates to ARIPO members states, hinges greatly on the patent granting system of ARIPO.[248]

This research paper agrees with the above view as based on a review from a public health perspective of ARIPO's Harare Protocol, specifically relating to regulations and administrative instructions and the type of patents that have been granted reveals that the application of patentability standards is lax.[249] For instance, Rule 22 allows for an extension of a patent by means of secondary patents, whereby minor changes including new formulations, combinations, dosages and uses are enabled by ARIPO's current patent law.[250] This practice has been termed "evergreening" and are mainly used by multinational pharmaceutical companies who attempt to prevent competitors from entering the market with affordable generic medication which is the

[244] Roadmap on Shared Responsibility and Global Solidarity for the AIDS, Malaria and Tuberculous Response, 2012, Pillar 2.
[245] Deere C *TRIPS Implementation in Francophone Africa: The implementation game: The TRIPS Agreement and the global Politics of Intellectual Property Reform in Developing Countries* 18-34.
[246] WTO 'Responding to Least Developed Countries' Special Needs in Intellectual Property' available at https://www.wto.org/english/tratop-e/trips-e/ldc-e.htm (accessed on 10 June 2021).
[247] Stone L and Gostin LO 'Using Human Rights to Combat the HIV/AIDS Pandemic' (2004) 31 Human Rights 22.
[248] Stone L and Gostin LO (2004) 23.
[249] Harare Protocol, Article 22.
[250] Engelbred A 'South Africa: Patents: ARIPO Or OAPI…What Is The Difference?' available at *https://www.mondaq.com/southafrica/patent/819886/patents-aripo-or-oapiwhat-is-the-difference* (accessed on 7 June 2021).

main way in which the majority of people in these regions access essential medication.[251] Hence, this research paper is of the view that this constitutes a significant obstacle towards achieving social justice and towards the realisation of the right to health.

A case of point is the life-saving medication for treating HIV, called "Kaletra". This medication is an amalgamation of two ARVS.[252] The patent for the core compound had to come to an end in 2014 and 2016 respectively, which meant that generic manufacturers could have applied to supply such medication at the start of 2016.[253] Unfortunately, the multinational pharmaceutical company, Abbott, filed various frivolous and secondary patents which threatened to prevent generics from being manufactured in certain markets until around 2028.[254] During the extended exclusivity period, Abbott will be able to set prices extremely high in which the majority of people will not be able to afford.[255] This prevents the right to health from being realised as well as social justice being achieved. Hence, it is essential for the realisation of health that patent laws become more stringent and human rights be respected more in practice and trump IP rights as only the minority benefit from the rights which flow from IP.

2.4.2 The African Intellectual Property Organization (OAPI)

OAPI was established by African states previously under French colonial rule.[256] This was done in partnership with France's National Institute of Industrial Property for registration and granting of industrial property rights.[257] It was then assented to and implemented in March 1977.[258] This system establishes common administrative procedures by centralising applications and

[251] Engelbred A 'South Africa: Patents: ARIPO Or OAPI…What Is The Difference?' available at *https://www.mondaq.com/southafrica/patent/819886/patents-aripo-or-oapiwhat-is-the-difference* (accessed on 7 June 2021).
[252] Kameni EI Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects (unpublished LLM thesis, University of Pretoria, 2015).
[253] Kovac M and Rakovec L (2022) 18.
[254] Kameni EI Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects (unpublished LLM thesis, University of Pretoria, 2015).
[255] Deere C *TRIPS Implementation in Francophone Africa: The implementation game: The TRIPS Agreement and the global Politics of Intellectual Property Reform in Developing Countries* 18-34.
[256] Deere C *TRIPS Implementation in Francophone Africa: The implementation game: The TRIPS Agreement and the global Politics of Intellectual Property Reform in Developing Countries* 18-34.
[257] Kongolo T 'The new oapi agreement as revised in february 1999: Complying with trips.' (2000) 3 *Journal of World Intellectual Property* 718.
[258] Kongolo T (2000) 720.

registrations of all types of IP. OAPI sets out a standardised system of laws that is relevant to all signatories.[259]

The most relevant agreement that regulates the OAPI system is the Revised Bangui Agreement of 1999.[260] This agreement has been revised from its previous version in an attempt to be on par with the TRIPS agreement.[261] Hence, the revised agreement makes provision for some, but not all, of the flexibilities provided for in Article 31 TRIPS.[262] For instance, parallel importation is allowed under Article 8 of the agreement.[263] However, under this provision, only regional parallel importation is allowed.[264] This means that member states may only import from each other, provided that they have the consent of the patent right holder.[265] Hence, this agreement does not maximise TRIPS' flexibility which allows for international parallel importation.[266]

A case of note which displays the impact of this provision on access to medicine is the ARV saga in Togo.[267] In 2002, the cheapest ARVS in the OAPI region were from Senegal which were priced at R13.70; and in Togo ARVs were priced at R28.57.[268] However, India's ARVs were priced at R9.47, which were the cheapest ARVs on the market at the time.[269] Since the Revised Bangui Agreement has a regional exhaustion regime, Togolese citizens could only purchase ARVs from Senegal and not from India as the OAPI system does not adopt an international exhaustion regime.[270] As a result, Togo had to purchase more expensive vaccines from Senegal, as opposed to those available from India at the cheapest price on the market. The effect of this was that, once imported, these Senegalese manufactured ARVs were not affordable to a significant part of the

[259] Botoy I 'Potential and substantial benefits of the trips agreement to the member countries of the african intellectual property organization in the patent field: An african's perspective' (2001) 4 *Journal of World Intellectual Property* 94.
[260] Botoy I (2004) 93.
[261] Bowers SA 'Location, location, location: The case against extending geographical indication protection under the trips agreement' (2003) 31 *AIPLA Quarterly Journal* 129.
[262] Martin AO and Devades SK 'Patents with an = patients' (2009) 18 *Annals of Health Law* 264.
[263] Bowers SA (2003) 135.
[264] Vandoren P and Van Eeckhaute JC 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making It Work' (2003) 6 *Journal of World Intellectual Property* 779.
[265] Vandoren P and Van Eeckhaute JC (2003) 781.
[266] TRIPS Agreement, Article 31.
[267] Kameni EI *Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects* (unpublished LLM thesis, University of Pretoria, 2015.
[268] Kameni EI *Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects* (unpublished LLM thesis, University of Pretoria, 2015.
[269] Love JP 'Recent examples of the use of compulsory licensing on patents. knowledge ecology international' available at *http://www.keionline.org/misc_docs/recent_cls_8mar07.pdf* (accessed on 15 June 2021).
[270] Attaran A and Lee-Gillispie C (2001) 485.

Togolese population.[271] This accordingly made these vaccines inaccessible as the TRIPS flexibility of an international exhaustion regime was not adopted in the revised Bangui Agreement.[272]

Another TRIPS flexibility that is provided for in the revised agreement is that of compulsory licensing under Article 46.[273] TRIPS also makes provision for non-working licenses.[274] However, Articles 8(1) and (2) have been used as a justification for granting compulsory licenses on the basis of "failing to work the patent locally as well."[275] This is due to Article 8(1) which enables signatory states to implement measures which protect technological advancements as well as socio-economic developments.[276] Academics opine that discontinuing compulsory licenses due to failure of them working locally "has seriously undermined industrial policies in the region."[277]

Another shortfall of the Revised Agreement is that it omits the incorporation of transition regulations for lesser developed countries (LDCs).[278] The Doha Declaration on TRIPS provides that LDCs are exempt from granting pharmaceutical patents until the year 2023.[279] The exclusion of the transition period disadvantages OAPI member states as only four of them are not LDCs.[280] Hence, LDCs in the OAPI region do not benefit from the exclusion set out in the declaration attempts to benefit LDCs and this could contribute to making medicines more accessible to people in LDCs who need it most.[281]

[271] Kameni EI *Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects* (unpublished LLM thesis, University of Pretoria, 2015.
[272] Love JP 'Recent examples of the use of compulsory licensing on patents. knowledge ecology international' available at *http://www.keionline.org/misc_docs/recent_cls_8mar07.pdf* (accessed on 15 June 2021).
[273] TRIPS Agreement, Article 46.
[274] TRIPS Agreement, Article 46.
[275] TRIPS Agreement, Article 8.
[276] Abbott FM and Rudolf VVP 'Compulsory licensing for public health: a guide and model documents for the implementation of the Doha declaration paragraph 6 decision' available at *http//www..dep.mo/ud/engelsk/p2500832* (accessed on 20 June 2021).
[277] Yosick JA 'Compulosry Patent licensing for effiecient use of inventions' 2001 *University of Illinois Law Review* 1275.
[278] Yosick JA (2001) 1276.
[279] Council for TRIPS, Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, WTO Doc. IP/C/73 (Nov. 6, 2015).
[280] Vandoren P and Van Eeckhaute J 'The WTO decision on paragraph of the doha declaration on the trips agreement and public health: Making it work' (2003) 6 *Journal of World Intellectual Property* 783.
[281] Tomlinson C 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies' (2019) 109 South African Medical Journal 387.

The accessibility of medication is further affected by the omission of competition-based flexibilities.[282] Academics view this as outlandish as it plays an important role in facilitating access to medicines.[283] Furthermore, it is peculiar as TRIPS makes provision for competition-based flexibilities.[284] Hence, it is recommended that such a provision should be included, along with thorough implementation of it as most LDCs and developing countries fail at implementation of laws.[285]

This research paper is therefore of the view that the Revised Bangui Agreement should make full use of all of the exceptions provided for in TRIPS as well as all of the TRIPS flexibilities such as compulsory licensing, anti-competitive contractual licenses, the 'bolar' exception, as well as parallel importation which all would contribute to the increased access to essential medicine and the realisation of the right to health. It would also contribute to achieving social justice as more people would be able to access these essential medicines as they'd be priced at what is affordable to the majority of people.

2.4.3 AFRICAN CONTINENTAL FREE TRADE AREA (AfCFT) AND PROPOSED PROTOCOL ON INTELLECTUAL PROPERTY RIGHTS (IPR)

The AfCFTA intends to establish an exclusive continental market in which services, products and people can move which will expand intra-African trade across the Africa, which will increase competition as well as support economic transformation within the continent.[286] As discussed above, there are two regional IP organisations on the continent ARIPO and OAPI, the AfCFTA Agreement recognises the preservation of *acquis* as one of the governing principles of the Agreement.[287] The principle means building on what has been achieved and in regard to IPRs, this

[282] Vandoren P and Van Eeckhaute J (2003) 784.
[283] Kongolo T 'The new oapi agreement as revised in February 1999: Complying with trips.' (2000)3 *Journal of World Intellectual Propert* 726.
[284] Botoy I 'Potential and substantial benefits of the trips agreement to the member countries of the african intellectual property organization in the patent field: An African's perspective' (2001) 4 *Journal of World Intellectual Property* 97.
[285] Mzungu W '90 Organisations demand reform to ARIPO to improve access to medicines' 24 November 2019.
[286] Moeti M ' African Traditional Medicine Day 2022' available at *https://www.afro.who.int/regional-director/speeches-messages/african-traditional-medicine-day-2022* (accessed on 14 December 2022).
[287] Alvez A 'The Protection Of Traditional Knowledge In Africa' Available at *https://www.mondaq.com/southafrica/trademark/841656/the-protection-of-traditional-knowledge-in-africa* (accessed on 13 December 2022).

could mean building on what has been achieved in ARIPO and OAPI.[288] The establishment of AfCTFA does, however, pose the question of what is the place, role and provisions of IP in the agreement as rights associated with IP are generally jurisdictional, and whether it would require member states to harmonise their various IP policies to suit the single continental market envisaged under the AfCFTA.[289] As mentioned, the legal systems of ARIPO and OAPI are different but under the AfCFTA, right holders are afforded a single regional title of protection valid in each country.[290]

Further, one of the main benefits of having an optimised AfCFTA IP Protocol is that it would attract more foreign investors and provide the conditions needed for the technology transfer relating to the health sector.[291] The importance of technology globally and in the continent's, economy was highlighted by the Covid-19 pandemic which increased the need and use of technological products. Therefore, in these circumstances, "IP is also set to assume greater importance and the IPR Protocol can serve as a catalyst for things such as transfer of knowledge regarding medicine and technology, technology diffusion as well as the economic transformation of the continent's economy from one that is primary resource-based, to one that is driven by knowledge, information and ideas."[292]

Further, it is evident that IP protection has an important role in inspiring development within the continent. Hence, the effective commercialisation of IP is a remarkable stimulus to the economic growth of the AfCFTA single continental market as well as the continent if properly managed and adequately protected. Some of the ways in which more protection could be afforded to IP within the continent would be to not limit protection to a very narrow subject area or provide protection

[288] Hardy A 'The Integration of Traditional and Western Medicine' available at *https://digitalcollections.sit.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1568&context=isp_collection* (accessed on 13 December 2022).
[289] Mokgobi M 'Towards integration of traditional healing and western healing: Is this a remote possibility?' available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4652795/* (accessed on 14 December 2021).
[289] Hardy A 'The Integration of Traditional and Western Medicine' available at *https://digitalcollections.sit.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1568&context=isp_collection* (accessed on 13 December 2022).
[290] Du Plesis A 'The proposed AfCFTA Protocol on Intellectual Property Rights - tralac trade law centre' available at *https://www.tralac.org/blog/article/14066-the-proposed-afcfta-protocol-on-intellectual-property-rights.html* (accessed on 14 December 2022).
[291] Moeti M ' African Traditional Medicine Day 2022' available at *https://www.afro.who.int/regional-director/speeches-messages/african-traditional-medicine-day-2022* (accessed on 14 December 2022).
[292]

for only a short period of time or lack strict enforcement of laws. Further, protection should extend to indigenous knowledge and traditional medicine which is prevalent in Africa.

2.5 CONCLUSION

This chapter discussed the evolution of patents and the intersection of human rights and patent law. It considered the nature of IP rights against human rights such as the right to health. It was argued that the right to health should take preference over IP rights as human rights are indivisible whereas IP rights flow from legislation. There were competing arguments which advocated that rights which stem from IP are also human rights. A fair position resolved in this chapter was that human rights, such as the right to health should take preference as they are interrelated to other rights such as the right to life. This is because, for instance, if one cannot access life-saving medication, this could result in the infringement of this right.

Further, it was demonstrated that most of the current ARIPO member states and OAPI member states suffer from various non-communicable and communicable diseases, which has substantial socio-economic effects, and adversely impacts the development prospects of these states. Many of these diseases are treatable, but access to affordable medication is a big problem for them due to the expensive costs of medicines which could be resolved if patent laws in the region were not lax. This chapter also demonstrates how human rights, such as the right to health takes preference in theory but not practically whereas it should in order for the right to be realised and for social justice to be achieved. If patent laws made complete use of the TRIPS flexibilities, essential medications would be accessible to the majority of society and especially to the most vulnerable who need these life-saving medication the most.

CHAPTER 3

SOUTH AFRICAN PATENT LAW

3.1 INTRODUCTION

This chapter discusses the South African Patents Act (the Act) and analyses the requirements for a valid patent and intends to show the need to reform South Africa's patent laws. It further seeks to illustrate the need for change from a right to health perspective. This chapter further discusses ways that patent laws can be reformed in manner that realises the right to health. It begins by reviewing the current patent laws of South Africa by showing how it either contributes to the right to health being recognised or social justice being achieved or it demonstrates how the Act does the contrary and possible ways to address this in a transformative manner which could realise the right to health.

3.2 THE SOUTH AFRICAN PATENTS ACT

The South African Patents Act came into effect in 1978.[293] It has not been amended since the time of its inception and therefore, has many shortcomings.[294] According to the Act, in order for an invention to become patented, it has to meet the requirements of novelty, inventive step or industrial application.[295] Novelty as defined in the Patents Act requires that an invention must 'not form part of the state of the art immediately before the priority date of that invention with the state of the art "comprising all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way and including matter contained in an application, open to public inspection, for a patent".[296]

Novelty is a requirement as the purport of the South African patent system is to provide a monopoly to an inventor for creating a new invention and introducing it to the general public, and

[293] The South African Patents Act 57 of 1978.
[294] Baker BK (2015) 309.
[295] The South African Patents Act 57 of 1978, s25.
[296] The South African Patents Act 57 of 1978, s25.

where an invention is already in the intellectual commons then there is no longer a reason to provide any monopoly to the inventor. [297]

An inventive step only features once the patent has survived the novelty inquiry. Section 25(10) states that 'an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art by virtue only of subsection (6)'.[298] This means that the state of the art comprises 'all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way'.[299]

This requirement prevents an obvious invention from gaining patent protection, because an obvious invention would provide no benefit to the public and society at large and as such does not deserve a monopoly. The question then becomes what is obvious? Currently, obviousness serves as a ground to challenge a patent for revocation in court. This is therefore a post-grant challenge to a patent. [300] To date there has only been once case regarding the validity of a patent, which is the matter of *Ascendis Animal Health (Pty) Limited v Merck Sharpe Dohme Corporation*. [301]

The judgment potentially has far-reaching implications for patent litigation in South Africa. At issue was the question of whether a court's finding of patent validity on one ground in a revocation hearing ought to have a bearing on a subsequent infringement hearing on the same patent, to the extent that the alleged infringer is barred from raising a different ground to attack the validity of a patent. In essence, did the attempt to do so offend the principle of *res judicata*. This was a direct

[297] Naidoo M 'Clearing the CRISPR patent landscape: Towards a solution for South Africa' 2022 *SALJ* 365.

[298] South African Patents Act 57 of 1978, s25(10).
[299] Haywood M 'Seize Power! The Role of The Constitution in Uniting a Struggle for Social Justice in Sout Africia ' available at *https://library.oapen.org/bitstream/handle/20.500.12657/41794/9781776147069_WEB.pdf?sequence=1#page=260* (accessed on 17 May 2022).
[300] Du Bois M 'State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid19 Crisis and Beyond' available at *http://dx.doi.org/10.17159/1727-3781/2020/v23i0a8150* (accessed on 26 May 2022).
[301] Ascendis Animal Health (Pty) Limited v Merck Sharpe Dohme Corporation 2020 1 SA 327 (CC).

appeal to the Constitutional Court after the High Court ruled that it did so offend, and the Supreme Court of Appeal refused leave to appeal.

The Constitutional Court was deadlocked on this issue, with the result that the decision of the High Court refusing Ascendis' application to amend to introduce a new ground of attack stood, and the *res judicata* objection was upheld. The decision raises important questions about the application of the principle of *res judicata* in such cases where the Patents Act allows dual proceedings for revocation and infringement actions, the meaning of provisions of the Act as they relate to the certification of patent claims, and the broader public interest considerations implicated in patent law adjudication.[302]

This observes that while the outcome sends a strong signal about the courts' displeasure at attempts to prosecute "repeat litigation", an unsatisfactory outcome is that patents can apparently be validated on the basis of merely one of the mandatory requirements for patent validity as required by the Act. [303] It argues that such an outcome is undesirable and does not serve the public interest. This is because it closes the door to further challenges while potentially thousands of patents, which would not have passed the validity test had they been subjected to substantive examination, remain on the patent register.[304]

In addition to novelty and inventiveness, the invention must also be capable of being used or applied in trade, industry or agriculture.[305] At the moment, the South African patent system is a depository system which means that inventions are checked for formal compliance only and not for substantive validity, which is one of the main shortfalls of the Act as it does not ensure that patent applications are examined, nor does it provide for mechanisms to be put in place to ensure satisfaction of the Act's requirements, instead it permits a depository regime.[306] In simple terms,

[302] Du Bois M 'State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid19 Crisis and Beyond' available at *http://dx.doi.org/10.17159/1727-3781/2020/v23i0a8150* (accessed on 26 May 2022).
[303] Haywood M 'Seize Power! The Role of The Constitution in Uniting a Struggle for Social Justice in Sout Africia ' available at *https://library.oapen.org/bitstream/handle/20.500.12657/41794/9781776147069_WEB.pdf?sequence=1#page=260* (accessed on 17 May 2022).
[304]
[305] 'For South Africa during the Covid19 Crisis and Beyond' available at *http://dx.doi.org/10.17159/1727-3781/2020/v23i0a8150* (accessed on 26 May 2022).
[306] Pechacek JT 'The Past, Present, and Future of South Africa's Patent System' (2012) 3 *Cybaris: An Intellectual Property Law Review* 188.

The Companies and Intellectual Property Commission (CIPC) merely collects applications but it does not ensure that the requirements specified in the Act are satisfied.[307] CIPC only determines whether the appropriate application forms are completed.[308] Once this is established, the patent application is approved by CIPC without the form being reviewed in order to determine if the said requirements have been satisfied.[309]

A possible way to reform patent law and allow for medicine to be more accessible is that the law should only grant patents for applications that meet patentability criteria, South Africa can adopt substantive search and examination systems that can be used for assessing patent applications.[310] Under a substantive search and examination system, all patent applications should be examined prior to being approved, to ensure that patentability criteria has been met.[311] Therefore, legislation should include a provision that states patent applications should be examined by competent persons because if there was a system in place which examined patents then "evergreening" which will be discussed later, could be prevented or subdued.

Further, this could be achieved by AfCFTA, which as mentioned, amongst other things, aims to introduce more stringent patent laws within the African region. Hence, if there was an optimised AfCFTA IP Protocol in place that provides more stringent requirements for persons to obtain IP rights, less frivolous patents would be granted that hinder access medicine. [312] Further, the IPR Protocol can serve as a catalyst for things such as transfer of knowledge regarding medicine and technology, technology diffusion as well as the economic transformation of the South African economy from one that is primary resource-based, to one that is driven by knowledge, information and ideas.[313]

[307] Pechacek JT (2012) 190.
[308] Varella M 'The wto, intellectual property and aids: Case studies from brazil and south africa' (2014) 7 *Journal of World Intellectual Property* 523.
[309] Varella M (2014) 523.
[310] Naidoo M (2022) 366.
[311] Du Bois M 'State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid19 Crisis and Beyond' available at *http://dx.doi.org/10.17159/1727-3781/2020/v23i0a8150* (accessed on 26 May 2022).
[312] Moeti M ' African Traditional Medicine Day 2022' available at *https://www.afro.who.int/regional-director/speeches-messages/african-traditional-medicine-day-2022* (accessed on 14 December 2022).
[313] Moeti M ' African Traditional Medicine Day 2022' available at *https://www.afro.who.int/regional-director/speeches-messages/african-traditional-medicine-day-2022* (accessed on 14 December 2022).

Another manner in which AfCTFA could assist in improving South African patent laws is more protection could be afforded to IP within the continent as many pharmaceutical companies apply for patent rights in South Africa due to it being lax, having a depository system and allowing for 'evergreening" but if there is a single African patent system in place, South Africa would not be an easy way out for companies seeking to get patents as the IP Protocol would apply to all member states. Currently, South Africa grants some of the most patents in the world which could be combatted with a uniform African market.[314]

Another way to improve access to medicine could also be achieved by utilising artificial intelligence with the use of automated processes of establishing the applicability of the patentability criteria.[315] This can be done as the internet of things allows for valuable data to be retrieved and collected for use in predicting future scenarios, such as the likelihood of patent growth in specific fields of technology and as everything will be connected through the Internet of things, it will be easier to retrieve the most vital information about patent specifications, especially regarding claims that define the essential integers of an invention.[316] Hence, all of the above would prevent South Africa from having a deposit system.

Unfortunately, as current South African law enables a depository patent system.[317] The Patents Act does not provide any procedure for persons wanting to oppose the registering of a patent.[318] Currently, the only way to challenge patents in South Africa is to file for revocation after a patent has been granted. [319] Revocation procedures are lengthy and expensive as one must apply to court

[314] Beall RF and Attaran A 'Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines' Available at *http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_qc_ip_ge_16/wipo_qc_ip_ge_16_www_334437.pdf* (accessed on 21 June 2021).
[315] Vadwa YA and Shozi B 'Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa' available at *https://www.southcentre.int/wp-content/uploads/2020/02/RP103_Eighteen-Years-After-Doha-An-Analysis-of-the-Use-of-Public-HealthTRIPS-Flexibilities-in-Africa_EN.pdf* (accessed on 27 May 2022).
[316] Du Bois M 'State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid19 Crisis and Beyond' available at *http://dx.doi.org/10.17159/1727-3781/2020/v23i0a8150* (accessed on 26 May 2022).
[317] Hacohen, UY 'Evergreening at Risk' (2020) 33 *Harvard Journal of Law & Technology* 479.
[318] Hacohen, UY (2020) 479.
[319] South African Patents Act 57 of 1978, s60.

for the revocation of a patent and this will normally be against wealthy multinational corporations who can afford lengthy litigation.[320]

Due to the lack of affordable and expedited procedures or opposing patents, this disincentivises persons wanting to challenge a patent and as a result, many low-quality patents remain unchallenged.[321] South African patent law should provide for a procedure to challenge and oppose patents apart from only allowing for the revocation of a patent by court procedures. Hence, South Africa should adopt affordable and efficient administrative procedures for opposing patents and the patents office should also ensure transparency regarding pending applications and patents granted. [322]

If this option is made open to competitors, it would raise the standards of patents as it could cause "revelation of information and argumentation about prior art" as currently, the Act allows limited information on a product to be available to competitors. [323] Hence, if these shortcomings in the Act were to be rectified, it would lead to higher standards of patentability which in turn increases access to medicine and contributes to realising the right to health as there are less patents being granted on medications which opens the market to generic manufacturers and more competitors.[324]

Another shortcoming that ties in with the lack of substantive examination of patent applications is "evergreening".[325] Unfortunately, in terms of the Act, generics are not permitted to be manufactured for a period of 20 years. [326] This contributes to the inaccessibility of medication and further prevents generics from entering the market. This is a tactic used by pharmaceutical companies to prolong their periods of patent protection beyond 20 years and keep the prices of

[320] Vadwa YA and Shozi B 'Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa' available at *https://www.southcentre.int/wp-content/uploads/2020/02/RP103_Eighteen-Years-After-Doha-An-Analysis-of-the-Use-of-Public-HealthTRIPS-Flexibilities-in-Africa_EN.pdf* (accessed on 27 May 2022).
[321] Lanoszka A 'The global politics of intellectual property rights and pharmaceutical drug policies in developing countries' (2003) 24.2 *International Political Science Review* 182.
[322] Lanoszka (2003) 182.
[323] The South African Patents Act 57 of 1978, s68.
[324] Saurombe A 'The protection of indigenous traditional knowledge through the intellectual property system and the 2008 south african intellectual property law amendment bill' (2009) 4 *Journal of International Commercial Law and Technology* 196.
[325] Lietzan E 'The Evergreening Myth' (2020) 43 *Regulation* 24.
[326] The South African Patents Act 57 of 1978, s.68.

medicines artificially high. [327] This is the practice of applying for patents on existing medication, with minor modifications. "Evergreening" is common in South Africa and statistics show that 40% more patents are granted in South Africa compared to the US and certain European states.[328]

In order to circumvent this practice, South African can introduce strict patentability criteria. This would limit the granting of new patents for minor modifications to existing medication.[329]

As mentioned, it is South Africa's current patent system which contributes to "evergreening", if it had a system in place which examined patents then evergreening could be prevented or subdued.[330] For instance, in India, its Supreme Court refused to grant Swiss pharmaceutical company Novartis a patent for a new version of its cancer drug Gleevec.[331] Novartis claimed that the drug was more easily absorbed into the blood and, considering it is used to fight leukemia, that was enough of an improvement to warrant patent protection.[332] At its core, this case has been about the interpretation of section 3 of India's patent law, which explains what does not constitute an invention under its patent law.[333] Section 3(d) in particular states that:

> "[T]he mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance

[327] Moore R 'Opinion: Patent Evergreening – A Valid Concern in South Africa?' available at *http://www.moorepatent.co.za/opinion-patent-evergreening-a-valid-concern-in-south-africa* (accessed on 21 June 2021).

[328] Moore R 'Opinion: Patent Evergreening – A Valid Concern in South Africa?' available at *http://www.moorepatent.co.za/opinion-patent-evergreening-a-valid-concern-in-south-africa* (accessed on 21 June 2021).

[329] Genetic Resources Action International (GRAIN) 'TRIPs-plus Through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO' available at *http://www.grain.org/docs/trips-plus-en.pdf* (accessed on 20 June 2021).

[330] Beall RF and Attaran A 'Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines' Available at *http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_www_334437.pdf* (accessed on 21 June 2021).

[331] Amin T and Kesselheim AS 'Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades' available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0107* (accessed on 20 June 2021).

[332] Beall RF and Attaran A 'Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines' Available at *http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_www_334437.pdf* (accessed on 21 June 2021).

[333] Baker BK 'International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) 60 *New York Law School Law Review* 307.

or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."[334]

This provision is one of the patent law's public interest safeguards and is most likely to play a vital role in the ongoing battle between Big Pharma and India's generic drug manufacturers. [335]

Another shortfall of the South African Patents Act is that it does utilise all of the TRIPS flexibilities as provided for in the international agreement.[336] A point of note is Article 6 of the agreement which allows countries the option to implement an exhaustion rule.[337] This rule allows for medicines to be legally imported from other states.[338] However, the "regulations for implementing section 15C's allowance of parallel importation are overly complex, rendering it essentially unusable."[339] However, South Africa has secured an agreement with the WTO in regard to vaccinations in which international patent laws would be relaxed in order to provide more equitable access to Covid-19 vaccines. Therefore, concessions have been made to stringent international patent laws.[340]

An international flexibility that has been allowed and which South Africa makes use of is the TRIPs flexibility of compulsory licensing which is incorporated into the Patents act but is unfortunately incomplete.[341] For instance, the Act permits compulsory licenses on the grounds of:

"(1) failure to work within a specified period of time;

[334] Beall RF and Attaran A 'Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines' Available at http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_www_334437.pdf (accessed on 21 June 2021).
[335] Amin T and Kesselheim AS Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades' available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0107 (accessed on 20 June 2021).
[336] Genetic Resources Action International (GRAIN) 'TRIPs-plus Through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO' available at http://www.grain.org/docs/trips-plus-en.pdf (accessed on 20 June 2021)
[337] TRIPS, Article 6.
[338] TRIPS, Article 6.
[339] Pouris A 'Patents and economic development in South Africa: Managing intellectual property rights' (2011) 107 *South African Journal of Science* 7.
[340] Du Plesis A 'The proposed AfCFTA Protocol on Intellectual Property Rights - tralac trade law centre' available at https://www.tralac.org/blog/article/14066-the-proposed-afcfta-protocol-on-intellectual-property-rights.html (accessed on 14 December 2022).
[341] Saha S 'Patent law and trips: Compulsory licensing of patents and pharmaceuticals' (2009) 91 *Journal of the Patent and Trademark Office Society* 364.

(2) failure to meet demand for the patented article to an adequate extent and on reasonable terms; (3) detrimental refusal to grant a license on reasonable terms, 43; and

(4) excessive prices for imported goods in relation to prices charged in countries where those goods are manufactured."[342]

The South African Patents Act does not make provision for exceptions in terms of public interest or public health, exceptions for unreasonably priced products, competition-based exceptions or exceptions based on the necessity to produce fixed-dose medicines which combine products from multiple patent holders .[343] Unfortunately, the procedure that one has to follow in order to obtain a compulsory license is expensive as one has to make an application to the court which is lengthy and costly.[344]

To date, South Africa has never issued a compulsory license on a medication in order to address access barriers, in part due to burdensome court procedures that are required to secure a compulsory license. [345] This research paper therefore submits that in regard to current patent laws on compulsory licensing, the legislature should include expedited, administrative procedures to facilitate the granting of the compulsory licenses instead of judicial procedures which are costly.[346] The United Nations Development Programme estimates that, given burdensome procedures required, issuing a compulsory license in South Africa would take more than three years.[347]

In regard to the above, it is important to note that although the court process might be expensive and costly, an advantage of litigating would be that courts would potentially get to determine whether the granting of compulsory licenses or even pharmaceutical patents are lawful, reasonable and procedurally fair as set out in the noteworthy case of *Bato Star* in which it was stated that a courts powers to review administrative action no longer flow directly from the common law, but

[342] South African Patents Act 57 of 1978, s56.
[343] Gold RE 'Patents and human rights: heterodox analysis (2013) 41 *Journal of Law, Medicine and Ethics* 187.
[344] Gold RE (2013) 189.
[345] Pouris A (2011) 9.
[346] *Bato Star Fishing (Pty) Ltd v The Minister of Environmental Affairs and Tourism and Others* BCLR 687 (CC), para 67.
[347] *Bato Star Fishing (Pty) Ltd v The Minister of Environmental Affairs and Tourism and Others* BCLR 687 (CC), para 68

from the Promotion of Administrative Justice Act (PAJA) and the Constitution itself.[348] Further, the court also stated that the achievement of equality is one of the fundamental goals that the Constitution sets and this commits us to the transformation of society.[349] It was acknowledged that there are profound difficulties that will be confronted in giving effect to the constitutional commitment of achieving equality and that measures that bring about transformation will inevitably affect some members of the society adversely, but these other considerations may have to yield in favour of achieving the constitutional goal of equality.[350] Taking this into consideration, if persons challenge the validity of a patent, courts will be take the Constitutional values into account and be aware of achieving equality and social justice by making medication that would be generally inaccessible, accessible and distributed to the most vulnerable of society who often require these medications the most.

In addition to the above, the Patent Act does, to an extent, enable social justice to be achieved in the context of the right to health and access to medicine, as the Act stipulates that the state and ministers may acquire patents for reasons concerning the general public.[351] Unfortunately, the Act does not provide for exclusions where there are national emergencies, even though this might be included by the public purpose language of the Ac.[352] However, this is not clear from the Act.

3.3 CONCLUSION

This chapter discussed South African patent laws. It specifically considered the South African Patents Act. It was argued that South African patent laws are lax. However, there were competing arguments that South African paten laws try to achieve or contribute to achieving social justice. This research paper submits that South African patent laws need to be reformed in order to realise the right to health as envisaged in the Constitution as well as for social justice to be achieved as current laws do not allow for this.

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[348] *Bato Star Fishing (Pty) Ltd v The Minister of Environmental Affairs and Tourism and Others* BCLR 687 (CC), para 70.
[349] De Ville JR 'Deference as respect and deference as sacrifice : a reading of Bato Star Fishing v Minister of Environmental Affairs' (2004) 4 *SAJHR* 14.
[350] De Ville JR (2004) 14.
[351] Baker BK 'International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) 60 *New York Law School Law Review* 307.
[352] Pouris A (2011) 3.

CHAPTER 4

CONCLUSION AND RECOMMENDATIONS

4.1 SUMMARY

This research paper was carried out using a purely desktop-based doctrinal approach. The primary objective was to illustrate the intersection between human rights and IP and that human rights should trump rights which flow from IP in order to realise the right to health and achieve social justice.

The first chapter of this research paper set out the background of the study, the research questions, the methodology of the research, and key concepts relevant to the research and the outline of the research paper.

In chapter two, the history of patents was explored as well international law and the intersection of human rights and IP. Relevant recommendations were made in this chapter on how to achieve social justice could be achieved. It also provided a brief overview of regional patent laws and how inaccessible medicine is due to the ineffective use of TRIPS flexibilities, which ultimately results in the majority of people in the region not being able to access life-saving medicine. Hence, the right to health is not recognised. Further, social justice cannot be achieved. The relevant recommendations were made in this chapter.

Chapter three studied the South African Patents Act and how it is ineffective in realising the right to health and achieving social justice. It further discussing arguments advocating for the reform of patent law based from a human rights perspective and how international flexibilities, AI, AfCTFA and other means can be utilised to achieve this.

This final chapter strives to draws conclusions and makes recommendations on the findings made in the previous chapters as mentioned.

4.2 CONCLUSION OF MAIN ARGUMENT AND RECOMMENDATIONS

In chapter 2, the preamble of the Constitution of the WHO states that the enjoyment of the right to health is one of the indiscriminative fundamental rights of every human being. Hence, the right to

health is a right afforded to everyone and it is more than just a political or civil right. This is also recognised in the South African Constitution. Further, as mentioned in *Minister of Health and Others v Treatment Action Campaign and Others* (1) 2002 (10) BCLR 1033 (CC), there exists a hierarchy of laws and a hierarchy of rights, and that the conduct of restricting the distribution of ARVS was a violation of the right to health. This therefore means that if indeed the right to IP was to be deemed a human right (as in the context of the UDHR) then the right to health would trump the right to IP for a number of reasons as discussed in this paper, ie access to medicine would take preference over patents of Big Pharma.

Furthermore, having considered the flexibilities made available in the TRIPS Agreement and comparing them to what is stipulated in South Africa's Patent Act, this research paper submits that it is crucial that South African patent laws be reformed in a manner in which it makes compete use of all of the relevant flexibilities of the TRIPS agreement as this would promote the increased access to medicine and in turn, the realisation of the right to health would be realised. These would include incorporating provisions on government-use licensing, exhaustion of rights/parallel importation, exceptions to rights conferred by a patent and exemptions from patentability. Furthermore, if medicines are more accessible to the majority of South Africans then social justice would be achieved as there would be fair distribution of resources within the South African society, and would include the most vulnerable persons. Further, this could be achieved by AfCFTA, which as mentioned, amongst other things, aims to introduce more stringent patent laws within the African region. As stated, an optimised AfCFTA IP Protocol would assist in achieving this. [353] Further, the IPR Protocol can serve as a catalyst for things such as transfer of knowledge regarding medicine and technology, technology diffusion as well as the economic transformation of within the African economy from one that is primary resource-based, to one that is driven by knowledge, information and ideas.[354]

[353] Nkumo M 'The African Continental Free Trade Area: a significant role for IP' available at *https://www.wipo.int/wipo_magazine/en/2020/04/article_0005.html* (accessed on 14 December 2022).
[354] 'How the African Continental Free Trade Area could revolutionise IP' available at *https://www.ipstars.com/NewsAndAnalysis/How-the-African-Continental-Free-Trade-Area-could-revolutionise-IP-in-Africa/Index/8038* (accessed on 14 December 2022).

As mentioned, in South Africa the only exceptions to patent laws that may practically assist in realising the right to health and achieving social justice is compulsory licensing, the 'bolar exception'. This research paper recommends that the 'bolar exception' as stated in section 69(1), should be amended to introduce a provision allowing experimental use. In regard to compulsory licenses, the provision in the Act is incomplete and should either be reformed to include expedited, administrative procedures to facilitate the granting of the compulsory licenses instead of judicial procedures which are costly or sections 55 and 56 of the Patents Act should be repealed and they should draft a provision which is dedicated to both compulsory licences for abuse of patents and dependent patents.

Another possible way to reform patent law and allow for medicine to be more accessible, as mentioned in chapter 3, is that the law should only grant patents for applications that meet patentability criteria, South Africa can therefore adopt substantive search and examination systems that can be used for assessing patent applications. Therefore, legislation should include a provision that states patent applications should be examined by competent persons.

Studies have shown that 80% of African communities prefer traditional medicine.[355] South Africa has taken cognisance of this and has implemented the Traditional Health Practitioners Act 2007 which has been designed to regulate the registration, training and practices of traditional health practitioners, and serve and protect the interests of members of the public who utilise their services.[356] If this is Act is developed and utilised effectively it could address the inaccessibility of western medicine as most people do make use of traditional medicine in South Africa.

This research paper further recommends that medicines should be considered public goods as they have enormous implications for the general health of society and due to the fact that public goods in general have progressive externalities, which means that their wide scope of accessibility benefit the general public, and is not limited to a minute group only.

Lastly, South Africa could use India as a model as to how it dealt with becoming a member of TRIPS while continuing to ensure the accessibility of medicines to the majority of people, which was mainly by fully utilising the flexibilities as provided for in TRIPS.

[355] Moeti M ' African Traditional Medicine Day 2022' available at *https://www.afro.who.int/regional-director/speeches-messages/african-traditional-medicine-day-2022* (accessed on 14 December 2022).
[356] Traditional Health Practitioners Act 22 of 2007.

BIBLIOGRAPHY

CONSTITUTION

Constitution of the Republic of South Africa, 1996.

TREATIES AND CONVENTIONS

International Covenant on Economic, Social and Cultural Rights, 1996.

Universal Declaration of Human Rights, 1948.

Vienna Convention on the Law of Treaties, 1969.

Agreement of Trade-Related Aspects of Intellectual Property Rights, 1994.

Treaties, International Agreements, Statutes and Regulations

Doha Declaration on the TRIPS Agreement and Public Health 14 November 2001

CASES

Government of the Republic of South Africa v Grootboom 2001 (1) SA 46 (CC).

Minister of Health & Others v Treatment Action Campaign (2002) 5 SA 721 (CC).

The Pharmaceutical Manufacturers' Association of South Africa v The President of South Africa unreported case no 4183/98 (March 2001).

LEGISLATION

The South African Patents Act 57 of 1978.

Traditional Health Practitioners Act 22 of 2007.

BOOKS

Baker JH *An Introduction to English Legal History* (1990) London: Butterworths.

Deere C *TRIPS Implementation in Francophone Africa: The implementation game: The TRIPS Agreement and the global Politics of Intellectual Property Reform in Developing Countries* (2008) Oxford: Oxford University Press**.**

Fox HG *Monopolies & Patents A Study of the History and Future of the Patent Monopoly (1947)*

Toronto: University of Toronto Press.

Holdsworth SW *A History of English Law* 3 ed (1938) London: Methuen.

Pocock JG *The Ancient Constitution and the Feudal Law: A Study of English Historical Thought in the Seventeenth Century: A Reissue with a Retrospect* (1987) Cambridge: Cambridge University Press.

NEWSPAPER

Mzungu W '90 Organisations demand reform to ARIPO to improve access to medicines' *Nyasa Times* 24 November 2019.

JOURNALS

Abbott FM 'The Doha Declaration on the TRIPS Agreement and public health: lighting a dark corner at the WTO' (2002) 5 *Journal of International Economic Law* 469-475.

Armitage RA 'The Conundrum Confronting Congress: The Patent System Must Be Left Untouched While Being Radically Reformed'(2006) 3 *John Marshall Review of Intellectual Property Law* 274-281.

Attaran A 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, under WTO Law' (2002) 12 *Fordhum Intellectual Property, Media and Entertainment Law Journal* 859-890.

Attaran A and Lee-Gillispie C 'Do patents for anti-retroviral drugs constrain access to treatment drugs in Africa?' (2001) 286 *Journal of American Medical Association* 482.

Azam M 'The experience of TRIPS-compliant patent law reforms in India, Brazil and South Africa and lessons for Bangladesh' (2015) 2 *Akron Intellectual Property Journal* 61-100

Baker BK 'International Collaboration on IP/Access to Medicines: Birth of South Africa's Fix the Patent Law Campaign' (2015) 60 *New York Law School Law Review* 307.

Barnes S (2002) 'Pharmaceutical patents and trips: comparison of India and South Africa' (2002) 4 *Kentucky Law Journal* 911-934.

Berman HJ 'The Origins of Historical Jurisprudence: Coke, Seiden, Hale' (1994) 103 *Yale Law Journal* 1651–1738.

Bessen J and Meurer MJ 'Lessons for patent policy from empirical research on patent litigation' (2005) 9 *Lewis & Clark Law Review* 1-28.

Blackstock R 'Patent law reform' 1946 *Tydskrif vir Hedendaagse Romeins-Hollandse Reg* 89-92.

Boldrin M and Levine DK 'Against Intellectual Monopoly' (2009) 21 *Syracuse Science and Technology Law Reporter* 130-145.

Bond P 'Globalization, Pharmaceutical Pricing, and South African Health Policy: Managing Confrontation with US Firms and Politicians' (1999) 9 *International Journal of Health Services* 766-790.

Botoy I 'Potential and substantial benefits of the trips agreement to the member countries of the african intellectual property organization in the patent field: An african's perspective' (2001) 4 *Journal of World Intellectual Property* 97-115.

Bravo G 'From Paris Convention to TRIPs: A Brief History'(2001) 1 *Journal of Contemporary Legal Issues* 445-449.

Castree S 'The Universal Destination of Pharmaceutical Patents: Reflecting on TRIPS through the Lens of Aquinas (2014) 53 *Journal of Catholic Legal Studies* 1-23.

Cohen S 'To Innovate or Not to Innovate, That Is the Question: The Functions, Failures, and Foibles of the Reward Function Theory of Patent Law in Relation to Computer Software Platforms' (1999) 4 *Michigan Telecommunications and Technology Law Review* 1-34.

Coke E *The third part of the Institutes of the laws of England : concerning high treason, and other pleas of the crown, and criminal causes* 15-18.

Cullet P ‘Patents and medicines: the relationship between TRIPS and the human right to health’ (2003) 79 *International Affairs* 139-160.

Fox HG *Monopolies & Patents A Study of the History and Future of the Patent Monopoly* 350-388.

Gathii J ‘Rights, patents, markets and the global aids pandemic’ (2002) 14 *Florida Journal of International Law* 261-352.

George J & van Staden J ‘Intellectual property rights: plants and phyto-medicinals - past history, present scenario and future prospects in South Africa’ (2000) 96 *South African Journal of Science* 433-445.

Gerhart PM ‘The tragedy of trips (2007) 1 *Michigan State Law Review* 143-184.

Gold RE ‘Patents and human rights: heterodox analysis (2013) 41 *Journal of Law, Medicine and Ethics* 185-198.

Hacohen, UY 'Evergreening at Risk' (2020) 33 Harvard Journal of Law & Technology 479-496.

Hanauer L and Ramaphal I ‘IP Regulation in South Africa Evolution, Current Status, and Comparison with SADC Region Countries’ (2020) 30 *Revista la Propiedad Inmaterial* 5-48.

Helfer LR ‘Pharmaceutical Patents and the Human Right to Health The Contested Evolution of the Transnational Legal Order on Access to Medicines’ 2015 *Duke Law School Public Law and Legal Theory Series* 311-337.

Herren JB ‘Trips and pharmaceutical patents: The pharmaceutical industry vs. the world’ (2009) 14 *Intellectual Property Law Bulletin* 43-66.

Judd PL ‘Retooling TRIPS’ (2014) 1 *Virginia Journal of International Law* 117-162.

Kiehl, J ‘Trips article 31(b) and the hiv/aids epidemic’ (2002) 10 *Journal of Intellectual Property Law* 143-172.

Klug H ‘Access to Medicines and the Transformation of the South African State: Exploring the Interactions of Legal and Policy Changes in Health, Intellectual Property, Trade, and Competition Law in the Context of South Africa's HIV/AIDS Pandemic’ (2012) 37 *Law & Social Inquiry* 297-329.

Kongolo T 'The new OAPI agreement as revised in february 1999: Complying with trips.' (2000)3 *Journal of World Intellectual Property* 726.-734

Law A 'An analysis of the TRIPS Agreement. In Patents and Public Health: Legalising the Policy Thoughts in the Doha TRIPS Declaration of 14 November 2001' (2008) *Nomos Verlagsgesellschaft mbH* 42-155.

Mandich G 'Venetian Origin of Inventors' Rights' (1960) *Journal of the Patent Office Society* 166-224.

Mariko S and Branstetter L 'Do Stronger Patents Reduce More Innovation? Evidence from the 1998 Japanese Patent Law Reforms' (2001) 32 *Rand Journal of Economics* 98-103.

Martin AO and Devades SK 'Patents with an = patients' (2009) 18 *Annals of Health Law* 261-280.

Mossoff A 'Rethinking the Development of Patents: An Intellectual History, 1550-1800' (2006) 52 *Hastings Law Journal* 1255-1324.

Narula S 'The rights-based approach to intellectual property and access to medicines: Parameters and pitfalls' 2011 *New York University Public Law and Legal Theory Research Paper Series, Working Paper* 11-60.

Ncube C 'Equitable intellectual property protection of computer programs in South Africa: Some proposals for reform' (2012) 3 *Stellenbosch Law Review* 438-461.

Nordic J 'The Justifiability of Indivisible Rights' (2003) *Nordic Journal of International Law* 31-39.

Ostergard RL 'Intellectual Property: A Universal Human Right?' (1999) 21 *Human Rights Quarterly* 156-178.

Pavone I 'The hiv/aids pandemic and international human rights law.' (2009) (1) *LAWASIA Journal* 99-111

Pechacek JT 'The Past, Present, and Future of South Africa's Patent System' (2012) 3 Cybaris: *An Intellectual Property Law Review* 188-215.

Price P 'Natural Law and Birthright Citizenship in Calvin's Case (1608)' (1997) 9 *Yale Journal of Law and the Humanities* 76.

Saha S 'Patent law and trips: Compulsory licensing of patents and pharmaceuticals' (2009) 91 *Journal of the Patent and Trademark Office Society* 364.

Sandor J 'Rebalancing Human Rights at the Time of Covid-19 Pandemic.' (2020) 11 *Union University Law School Review* 386-412.

Sarnoff JD 'Negative Emission Technologies and Patent Rights after Covid-19' (2020) 10 *Climate Law* 225-265.

Saurombe A 'The protection of indigenous traditional knowledge through the intellectual property system and the 2008 south african intellectual property law amendment bill' (2009) 4 *Journal of International Commercial Law and Technology* 196-211.

Schermers HG 'The international protection of the right of property' (1988) 16 *International Journal of Legal Information* 565-580.

Shanker D 'India, the Pharmaceutical Industry and the Validity of TRIPS' (2002) 5 *World Intellectual Property Journal* 316-331.

Singh JA 'Do human rights matter to health?' (2007) 370 *The Lancet* 521-530.

Stone L and Gostin LO 'Using Human Rights to Combat the HIV/AIDS Pandemic' (2004) 31 *Human Rights* 2-22.

Sutherland D 'Conquest and Law' (1972) 15 *Studia Gratiana* 33–51.

Thomas R 'Debugging software patents: Increasing innovation and reducing uncertainty in the judicial reform of software patent law' (2008) 25 *Santa Clara Computer & High Technology Law Journal* 191-242.

Tomlinson C 'How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies' (2019) 109 *South African Medical Journal* 387-391.

Vadwa Y A and Baker B K 'Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines' (2013) 13 *African Human Rights Law Journal* 55-81.

Vandoren P and Van Eeckhaute J 'The WTO decision on paragraph of the doha declaration on the trips agreement and public health: Making it work' (2003) *6 Journal of World Intellectual Property* 783-801.

Varella M 'The WTO, intellectual property and aids: Case studies from brazil and South Africa' (2014) 7 *Journal of World Intellectual Property* 523-548.

Yosick JA 'Compulosry Patent licensing for effiecient use of inventions' 2001 *University of Illinois Law Review* 1275-1311.

Yu PK 'Reconceptualising intellectual property interest in a human rights framework' (2007) 40 *University of California Davis Law Review* 1039-1054.

THESIS

Kameni EI *Implementation of trips public health flexibilities in the African Intellectual Property Organisation (OAPI) region: problems and prospects* (unpublished LLM thesis, University of Pretoria, 2015.

INTERNET SOURCES

Abbott FM and Rudolf VVP 'Compulsory licensing for public health: a guide and model documents for the implementation of the Doha declaration paragraph 6 decision' available at *http//www..dep.mo/ud/engelsk/p2500832* (accessed on 20 June 2021). .

Amin T and Kesselheim AS 'Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades' available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2012.0107* (accessed on 20 June 2021).

Avafia T, Berger J and Hartzenberg T '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' available at *https://www.tralac.org/publications/article/6841-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.html*(accessed on 7 June 2021).

Beall RF and Attaran A 'Patent-based Analysis of the World Health Organization's 2013 Model List of Essential Medicines' Available at *http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_ip_ge_16/wipo_gc_ip_ge_16_www_334437.pdf* (accessed on 21 June 2021).

Berold R 'Review of 14 February March, Treatment Action Campaign' available at *http:/l www.tac.org.za/newsletter/2003/nsl00 3 2003.html* (accessed on 5 June 2021).

Bugos C 'A Timeline of COVID-19 Vaccine Side Effects' available at *https://www.verywellhealth.com/when-to-expect-covid-19-vaccination-side-effects-5176621* (accessed on 10 June 2021).

Companies and Intellectual Property Commission 'Patents' available at *http://www.cipc.co.za/index.php/trade-marks-patents-designs-copyright/patents* (accessed on 1 September 2020).

Dey S 'Drug Patents on the Rise: 3,488 in 5 Years' available at *http://www. business-standard.com/article/companies/drug-patents-on-the-rise-3-488-in-5-years-112092400024-1.Html* (accessed on 30 Jun2 2021).

Drahos P 'The universality of intellectual property rights: Origins and development' available at http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf (accessed on 23 March 2021).

Engelbred A 'South Africa: Patents: ARIPO Or OAPI…What Is The Difference?' available at *https://www.mondaq.com/southafrica/patent/819886/patents-aripo-or-oapiwhat-is-the-difference* (accessed on 7 June 2021).

Fix The Patent Laws Organisation 'Researchers and teachers call on Ramaphosa to fix the patent laws'available at *https://www.fixthepatentlaws.org/more-than-80-academics-researchers-and-teachers-call-on-president-ramaphosa-to-fix-the-patent-laws/* (accessed on 17 September 2020).

Fix The Patent Laws Organisation 'South Africa's Patent Laws Threaten Access to Future Covid-19 Medicines' available at *https://www.fixthepatentlaws.org/south-africas-patent-laws-threaten-access-to-future-covid-19-medicines/*(accessed on 18 September 2020).

Fix The Patent Laws Organisation 'Why we need to fix patent laws in South Africa' available at *https://www.cansa.org.za/files/2015/06/Fix-Patent-Laws-Briefer.pdf* (accessed on 22 September 2020).

Gakpo JO 'Africa launches its first human trial for COVID-19 vaccine' available at *https://alliance-forscience.cornell.edu/blog/2020/07/africa-launch* (accessed on 6 June 2021).

Genetic Resources Action International (GRAIN) 'TRIPs-plus Through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO' available at *http://www.grain.org/docs/trips-plus-en.pdf* (accessed on 20 June 2021)

Giovanetti T & Matthews M 'Intellectual Property Rights and Human Rights' available at *http://www.ipi.org/ipi/1PIPublications.nsf/* (accessed on 24 March 2021).

Guardia AB and Hirsch C 'Coronavirus vaccination in Europe — by the numbers' available at *https://www.politico.eu/article/coronavirus-vaccination-europe-by-the-numbers/*. (accessed on 27 March 2021).

Hardy A 'The Integration of Traditional and Western Medicine' available at *https://digitalcollections.sit.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1568&context=isp_collection* (accessed on 13 December 2022).

Hlomani H 'Patents Kill Patients: A case for the future of Covid-19 treatment' available at *https://www.mandelarhodes.org/ideas/patents-kill-patients-a-case-for-the-future-of-covid-19-treatment/* (accessed on 17 September 2020).

Hogson TF and De Falco R 'Human Rights and Universal Access to COVID-19 Vaccines: Does the Human Rights Council Resolution go far enough?' available *at http://opiniojuris.org/2021/03/23/human-rights-and-universal-access-to-covid-19-vaccines-does-the-human-rights-council-resolution-go-far-enough/* (accessed on 29 March 2021).

Hulsebosch DJ 'The Ancient Constitution and the Expanding Empire: Sir Edward Coke's British Jurisprudence'. Available at *https://doi.org/10.1057/9780230501584_12* (accessed on 4 June 2021).

Kashyap A 'Whoever finds the vaccine must share it' available at *https://www.hrw.org/report/2020/10/29/whoever-finds-vaccine-must-share-it/strengthening-human-rights-and-transparency* (accessed on 30 March 2021).

Komesaroff P, Kerridge, I and Gilbert L 'The US is fast-tracking a coronavirus vaccine, but bypassing safety standards may not be worth the cost' available at *https://theconversation.com/the-us-is-fast-tracking-a-coronavirus* (accessed on 10 June 2021).

Love JP 'Recent examples of the use of compulsory licensing on patents. knowledge ecology international' available at *http://www.keionline.org/misc_docs/recent_cls_8mar07.pdf* (accessed on 15 June 2021).

Moore R 'Opinion: Patent Evergreening – A Valid Concern in South Africa?' available at *http://www.moorepatent.co.za/opinion-patent-evergreening-a-valid-concern-in-south-africa* (accessed on 21 June 2021).

Nhemachena A 'COVID-19 and the Eternal Return of Empire? Fast-Tracking Nothing Else But Vaccines?' available at *https://www.researchgate.net/publication/351637531_Artwell_Nhemachena_2021_COVID-* (accessed on 21 June 2021).

Olowolagba F 'Covid-19: Terrible consequences await African countries without vaccine – AU, CDC' available at*https://dailypost.ng/2020/12/10/covid-19-terrible-consequences-await-african-countries-without-vaccine-au-cdc/* (accessed on 30 March 2021)

Pouris A ' Patents and economic development in South Africa: Managing intellectual property rights' available at *http:// dx.doi.org/10.4102/sajs.v107i11/12.355* (accessed on 23 March 2021).

SAHO 'HIV/Aids in South Africa' available at *https://www.sahistory.org.za/article/hivaids-southafrica#:~:text=HIV%2FAids%20is%20becoming%20the%20most%20devastating%20disease%20humankind,died%20from%20AIDS%20in%20South%20Africa%20in%202007* (accessed on 10 June 2021).

Secer HE 'Pharmaceutical Patents and Right to Health' (2019) available at*https://www.researchgate.net/publication/335689217_Pharmaceutical_Patents_And_Right_to_Health* (accessed on 23 March 2021).

Sheridan R 'Does Madagascar's herbal remedy, COVID-Organics work' available at *https://www.researchgate.net/publication/342654901* (accessed on 10 June 2021).

TAC 'Dying for Treatment. TAC Briefing Document on the Civil Disobedience Campaign' available at *http://www.tac.org.za/Documents/CivilDisobedience/briefingdocument.html*. (accessed on 10 June 2021).

WHO 'South Africa WHO Coronavirus Disease Dashboard' available at *https://covid19.who.int/region/afro/country/za* (accessed on 5 June 2021).

WIPO 'WIPO-Administered Treaties' available at *https://www,wipo,int/treaties/en/ip/plt/index.html* (accessed on 9 June 2021).