# RE-CONFIGURING SOUTH AFRICAN PATENT LAWS IN SEARCH OF AN AFROCENTRIC APPROACH FOR EXPANDING ACCESS TO ESSENTIAL PATENTED MEDICINES IN THE COVID-19 ERA

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***Abstract***

*In an effort to fight the epidemiological health crisis precipitated by COVID-19, South Africa has declared a state of national disaster under the Disaster Management Act 52 of 2002 enabling the government to lawfully impose lockdowns and take other necessary measures. This article argues that for South Africa to succeed in overcoming the said crisis as well as the other pandemics facing the country, there is a need to re-configure the country's patent laws based on an Afrocentric approach to expanding access to essential medicines. It contends that South Africa's current patent laws are based on problematic theories of intellectual property law largely steeped in a Eurocentric regulatory construct which advances neo-colonial economic interests contrary to the country's desperate need to ensure access to essential medicines. The article argues for acceptance of justificatory indigenous and communalistic theories that enable the enactment of intellectual property rights anchored on the philosophy of Ubuntu as supplementary to some of the extant western individualistic notions currently underpinning patents on essential medicines. Such a humanising approach, together with other complimentary measures, has the potential to re-orient and re-engineer the concept of patents on essential medicines and the concomitant regulatory framework thereby promoting access to medicines in the COVID-19 era and beyond.*

***Keywords****: epidemiological health crisis, Afrocentric, Eurocentric, neoliberalism, neo-colonial, Ubuntu, humanising, re-orient, re-configure, communalistic, intellectual property regime.*

**JEL Classification:** K32

## 1. Introduction

South Africa is confronted with an unprecedented epidemiological health crisis emanating from the coronavirus (COVID-19) and other pandemics.[4] The Severe Acute Respiratory Syndrome (SARS-CoV-2), first reported in the Chinese city of Wuhan on 31 December 2019, is responsible for a highly contagious coronavirus disease which has infected millions of people across the world.[5] This novel COVID-19 virus constitutes one of the greatest public health threats that South Africa has faced since the dawn of the democratic order.[6] At the time of writing, more than 2, 948, 760 people in South

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[4] South African Department of Health, Update on COVID-19 2021, retrieved from, https://sacoronavirus.co.za/1, consulted on 24.11. 2021.
[5] This submission requires the application of a cautionary rules and does not in any way suggest that Covid-19 originated in China or elsewhere. While the available factual data demonstrate that the first case of Covid-19 was reported in China, it remains a matter of contestation which is veiled in obscurity as to whether indeed that was the first case. It is trite that the nature, virological composition and transmissibility of Covid-19 makes it impossible to ascertain with accuracy or even probability the precise origin of the diseases beyond the politicisation and weaponisation of the subject matter. Alexandra L. Phelan, Rebecca Katz & Lawrence O. Gostin, *The Novel Coronavirus Originating in Wuhan, China Challenges for Global Health Governance*, 8, JAMA 232 (2020); Md Saiful IslamI, Abu-Hena Mostofa Kamal, Alamgir Kabir, Dorothy L. Southern, Sazzad Hossain Khan, S. M. Murshid Hasan, Tonmoy Sarkar, Shayla Sharmin, Shiuli Das,Tuhin Roy, Md Golam Dostogir Harun, Abrar Ahmad Chughtai, Nusrat Homaira, Holly Seale, *COVID-19 vaccine rumors and conspiracy theories: The need for cognitive inoculation against misinformation to improve vaccine adherence*, 16, PLoS ONE 17 (2021).
[6] The South African democratic order was ushered in by the adoption of the Interim Constitution which allowed the country to transition from apartheid system into a non-racial legal order. The Interim Constitution was then superseded by the final Constitution. For a further general discussion on the adoption of the South African Constitution and its transformative nature see Pierre de Vos, Warren Freedman, Danie Brand, Christopher Gevers, Karthigasen Govender, Patricia Lenaghan, Douglas Mailula, Nomthandazo Ntlama, Sanele Sibanda & Lee Stone (eds.) *South African Constitutional Law in Context* Oxford University Press, 2014, p. 2.

Africa had contracted the COVID-19 and 89 635 have died from the disease and related complications.[7] The number of people who succumb to COVID-19 may increase as South Africa experiences more waves of infections from the virus.[8] This epidemiological health crisis is exacerbated by the fact that South Africa still has a high number of people living with the Human Immunodeficiency virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS), tuberculosis, cancer and other deadly diseases.[9] Combined with other interventions, increasing access to essential medicines could reduce the effect of this epidemiological health crisis in South Africa.[10]

Meanwhile, to curb and limit the transmission of COVID-19 in the country, South Africa has taken other proactive measures such as the imposition of lockdowns, conduct of contact tracing and mandatory isolation of COVID-19 infected persons, among others.[11] While these measures have proven somewhat efficacious in containing the spread of the virus, polycentric issues such as socio-economic conditions and lack of access to essential medicines, including vaccines, continue to hamper their effectiveness.[12] The ability to effectively combat the COVID-19 and other pandemics depends, *inter alia*, on ensuring access to essential medicines including appropriate vaccines.[13] From a constitutional perspective, access to essential medicines is crucial for the realisation of the entrenched human rights.[14] In particular, the enjoyment of the constitutionally protected right of access to health care services entrenched in section 27(1) as well as the right to life enshrined in section 11 of the Constitution of South Africa, 1996, is predicated on the accessibility of essential medicines.[15] When a biomedical company produces life-saving drugs it will have performed a crucial public health function.[16] Clinically tested drugs reduce suffering, improve public health outcomes and positively impact on the people's standard of living resulting in the enjoyment of the various fundamental human rights.[17] Equally, inadequate access to essential medicines infringes, *inter alia,* on the right to health care services, and the right to life.[18] It similarly inhibits South Africa's socio-economic development.[19]

The United Nations (UN) has recognised the significance of improving access to essential medicines to the disadvantaged people of the world by declaring it a Sustainable Development Goal

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[7] Notably, South Africa reported its first confirmed case on March 5, 2020. See World Health Organisation, South Africa: WHO Coronavirus Disease Dashboard (2021), 1, retrieved from, https://covid19.who.int/region/afro/country, consulted on 01.16.2021.

[8] The National Institute for Communicable Diseases, The Emergence of a Mutated Sars-Cov-2 Lineage in South Africa (2020), 2 retrieved from, https://www.nicd.ac.za/the-emergence-of-a-mutated-sars-cov-2-lineage-in-south-africa/#:~:text=Between%20March%20and%20September%202020,spreads%20and%20responds%20to%20antibodies.

[9] Katijah Khoza-Shangase, *Burden of disease: A scoping review of HIV/AIDS and TB in occupational noise-induced hearing loss*, 67, South African Journal of Communicable Disorder 669 (2020); World Health Organisation, Global tuberculosis report, (2019), 5, retrieved from, https://www.who.int/teams/global-tuberculosis-programme/tb-reports, consulted on 09.07.2021.

[10] Ismail S. Kalla, *COVID-19: The Concept of Herd Immunity – Is It A Strategy for South Africa*, 2, Wits Journal of Clinical Medicine 39 (2020).

[11] Thirusha Naidu, *The COVID-19 Pandemic in South Africa*, 12, Psychological Trauma: Theory, Research, Practice, and Policy 559 (2020); Ciara Staunton, Carmen Swanepoel, Melodie Labuschaigne, *Between a rock and a hard place: COVID-19 and South Africa's response*, 7, Journal of law and Biosciences 1 (2020).

[12] Marius Gilbert, Giulia Pullano , Francesco Pinotti, Eugenio Valdano, Chiara Poletto, Pierre-Yves Boëlle, Eric D'Ortenzio, Yazdan Yazdanpanah, Serge Paul Eholie, Mathias Altmann, Bernardo Gutierrez, Moritz U G Kraemer, *Preparedness and Vulnerability of African Countries against Importations of COVID-19: A Modelling Study*, 20, Lancet 871 (2020).

[13] Ciara Staunton, Carmen Swanepoel, & Melodie Labuschaigne, *between a rock and a hard place: COVID-19 and South Africa's response*, 7, Journal of Law and the Biosciences issue 3 (2020).

[14] The Constitution of South Africa, 1996.

[15] Ibid.

[16] The World Health Organisation, Health is a fundamental rights The right (2017), 3, Retrieved from, https://www.who.int/newsroom/commentaries/detail/healthisafundamentalhumanright#:~:text=Human%20Rights%20Day%202017&text=%E2%80%9CThe%20enjoyment%20of%20the%20highest,%2C%20economic%20or%20social%20condition%E2%80%9D.&text=Everyone%20has%20the%20right%20to,treated%20with%20respect%20and%20dignity, consulted on 16.04.2021; World Health Organisation, Background document potential Ebola therapies and vaccines (2014), 12, retrieved on https://apps.who.int/iris/handle/10665/137590, consulted on 17.04.2021.

[17] Yu-Fang Wen and Thapi Matsaneng, Patents, pharmaceuticals and competition: benefiting from an effective patent examination system (2014), 5, retrieved from, www.compcom.co.za/wpcontent/uploads/2014/09/PatentsPharmaceuticalsandCompetitionYuFangWenandThapiMatsanengAnnualCompetition-Conference-2013.pdf, consulted on 23.04.2021.

[18] Hans Hogerzeil, *Essential medicines and human rights: what can they learn from each other?*,84, Bulletin of the World Health Organization 377 (2006).

[19] Katrina Perehudoff, Brigit Toebes, and Hans Hogerzeil, *Essential medicines in national constitutions: Progress since 2008*, 18, Health and human rights 144 (2016).

and setting an ambitious target in relation thereto.[20] The World Health Organisation (WHO) which is a specialised entity of the UN responsible for global public health has described essential medicines as those that satisfy the public health care needs of countries based on the WHO standards of efficacy, relevance, cost effectiveness and safety.[21] Such essential medicines should always be accessible, and comparatively affordable for the health care systems of member states to function well.[22] In order for a particular medicine to be deemed an essential medicine, it should be part of the list published annually by the WHO called the Model Essential Medicines List.[23] Medicines contained in this list are recognised as life-saving and indispensable for tackling many diseases such as COVID-19, HIV and AIDS, respiratory infections, Malaria, and Tuberculosis.[24] The WHO enjoins member states to facilitate access to these essential medicines.[25] On a continental level, the African Union (AU) of which South Africa is a member has, in light of the continent's 2063 development agenda, adopted a number of resolutions on access to essential medicines in the COVID-19 era in addition to providing strategic public health direction for member states.[26]

Regionally, the Southern African Development Community (SADC) has adopted resolutions in response to the COVID-19 pandemic which acknowledge the importance of expanding access to medicines in the member states.[27] These resolutions recognize that the region is beleaguered with many problems which result in the inaccessibility of essential medicines.[28] Access to these medicines in SADC, including South Africa, depends on the following basic factors: (a) establishing and maintaining the necessary infrastructure including healthcare institutions; (b) combating corruption and adoption of sound procurement policies; (c) reducing the spread of disease through health literacy; (d) enhancing the quality of medicines manufacturing; (e) political commitment towards acquiring new versions of medicines; and (f) reform of the countries' intellectual property laws.[29] Nonetheless, in the context of this article, patents on essential medicines will be treated as one of the greatest obstacles to the accessibility of essential medicines.[30]

Etymologically, the term patent is derived from the Latin *patere*.[31] The term *patere* means 'to

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[20] See Sustainable Development Goal 3 (Good health and well-being), and in particular the 8th target of this goal which is to achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all. United Nations (UN), United Nations Sustainable Development Goal Target, (2020), 1, retrieved from, https://www.undp.org/sustainable-development-goals?utm_source=EN&utm_medium=GSR&utm_content=US_UNDP_PaidSearch_Brand_English&utm_campaign=CENTRAL&c_src=CENTRAL&c_src2=GSR&gclid=CjwKCAiA4veMBhAMEiwAU4XRr5g9MxJDZi7RTEwfuISwlltV8eeUJvJCQjypln_OLilF0PMLHAl8PBoCM8YQAvD_BwE, consulted on 23.05.2021.

[21] World Health Organisation, 2021 Model List of Essential Medicines, (2021), retrieved on, https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists, consulted on 25.05.2021.

[22] World Health Organisation, Access to essential medicines, (2010), 7, retrieved from, https://www.who.int/activities/strengthening-access-to-essential-medicines, consulted on 28.05.2021.

[23] Ibid, 1, 8.

[24] The WHO essential medicine list has been adopted by countries as a guiding template for their public health response efforts. See South African Department of Health, National Essential Medicines List Committee Tertiary and Quaternary Level Essential Medicines List, (2020), 1, retrieved from, http://www.kznhealth.gov.za/pharmacy/Tertiary-quaternary-level-essential-medicine-recommendations_January2020.pdf, consulted on 01.06.2021.

[25] African Union, African Ministers of Health endorsed an adapted strategy to fight COVID-19 underpinned by enhanced approaches to Prevent, Monitor, and Treat, (2021), 1, retrieved from, https://au.int/en/pressreleases/20210517/african-ministers-health-endorsed-adapted-strategy-fight-covid-19-underpinned, consulted on 03.06.2021.

[26] See African Union 141 Resolution on Access to Health and Needed Medicines in Africa, November 24, 2008, retrieved from, https://www.achpr.org/sessions/resolutions?id=212, consulted on 21.11.2021.

[27] SADC Secretariat, SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study, (2013), 6, retrieved from, https://www.sadc.int/files/6614/1890/8516/SADC___Sadc_Pooled_Procurement_Of_Essential_Medicines_And_Medical_Suppli....Pdf , consulted on 23.11.2021.

[28] Ellen F. M. 't Hoen, Tapiwanashe Kujinga and Pascale Boulet, *Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region*, 31 Journal of Pharmaceutical Policy and Practice (2018), 4.

[29] WTO, Regional issues brief: Intellectual property rights and access to medicines (2017), 4, retrieved from, https://hivlawcommission.org/wp-content/uploads/2017/06/Africa-RIB-IP.pdf, consulted on 27.10.2021.

[30] Peter S. Menell, Intellectual Property: General Theories, (2003), 10, retrieved from, https://reference.findlaw.com/lawandeconomics/1600-intellectual-property-general-theories.pdf, consulted on 29.10.2021; World Health Organisation, Towards Access 2030 WHO Medicines and Health Products Programme Strategic Framework 2016 – 2030, (2017), 1, retrieved from https://apps.who.int/iris/handle/10665/258757, consumed on 28.10.2021.

[31] Colleen V. Chien, *Contextualising Patent Disclosure*, 69, Vanderbilt Law Review 849 (2017).

be open', a phrase which was commonly used to refer to an open letter of privilege granted by the sovereign or government to a particular person to practice art.[32] The first patent legislation was enacted by the Venetian Senate in Italy around 1474.[33] It allowed an inventor to have exclusive monopoly rights of use for more than ten years over his new and ingenious product.[34] As time progressed, other countries followed suit by granting limited monopoly for inventions, and later to publishers and authors of literary works as a means of spurring innovation, creativity and literature.[35] In the contemporary era, patent claims on essential medicines confer exclusive rights upon the patent holders thereby ensuring that there is a monopoly over the supply of medicines in the market.[36] In the absence of stern price regulation, the attendant monopoly created by patent claims can increase the cost of essential medicines, a problem which impedes access to them, especially in the developing and least-developed countries.[37]

This article seeks to present an Afrocentric critique of South Africa's current patent regime in light of the country's developmental needs of expanding access to essential medicines in the COVID-19 era and beyond.[38] It considers how the South African Intellectual Property regime embeds neo-colonial interests through its persistent element of patent monopoly rights.[39] The central premise of this article is that there is a need to supplement the western centric model of intellectual property protection with an Afrocentric approach underpinned by the philosophy of *Ubuntu* as a model for re-calibrating the current intellectual property regime to eliminate potential obstacles to increasing access to essential medicines.[40] This article therefore offers some critical insights on how to re-orient and re-configure South African patent laws on essential medicines as an effective response to the persisting national epidemiological health crises.[41]

There are three approaches adopted in this article to structure an Afrocentric critique of the South African patent laws in pursuit of increasing access to essential medicines.[42] The approaches are: (a) an examination of the strengths and shortfalls of the justificatory theories supporting patent claims on essential medicines in light of other potential Afrocentric rationales; (b) a scrutiny of the patent protection rules in South Africa, their status and effect on access to essential medicines; and lastly, (c) proposals for re-configuring, re-humanising and re-orienting South African patent laws in enlarging access to essential medicines. The first part of the article explores various intellectual property law theories that constitute the basis for justifying the granting of patents on essential medicines.[43] Although justificatory theories of intellectual property rights maybe many, the engagement in this part is limited to those with an immediate bearing on access to essential medicines.[44] This part establishes the nexus between the epidemiological health crises, the

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[32] F.M Scherer and J. Wata, Competition policy and intellectual property: insights from developed country experience, (2014), 21, retrieved from https://www.hks.harvard.edu/publications/competition-policy-and-intellectual-property-insights-developed-country-experience, consulted on 04.05.2021.

[33] Craig Allen Nard and Andrew P. Morriss, *Constitutionalising Patents: Patents: From Venice to Philadelphia*, 2, Review of Law and Economics 323 (2006).

[34] Ibid.

[35] G. Dutfield and U. Suthersanen, Global Intellectual Property Law (Edward Elgar, (Publishing) Edition no. 2nd, 2020 p. 576.

[36] Ibid, 9.

[37] Ibid, 10.

[38] Caroline Ncube, *Decolonising Intellectual Property Law in Pursuit of Africa's Development*, 8, The World Intellectual Property Organisation Journal 34 (2016); Andreas Rahmatian, *Neo-Colonial Aspects of Global Intellectual Property Protection*, 12, Journal of World Intellectual Property Law 42 (2009).

[39] C. Wu, *Transnational pharmaceutical corporations legal and moral responsibilities in relation to access to medicine*s, 7, *Asian Journal of WTO and International Health Law and Policy* 77 (2012); J Pfumorodze, *WTO TRIPS Agreement and access to medicines in South Africa*, 13, University of Botswana Law Journal 102 (2013).

[40] Daniel J. Gervais, 'IP Calibration' in Daniel J. Gervais (ed.), Intellectual Property, Trade and Development: Strategies to Optimise Economic Development in a TRIPS Plus Era (Oxford University Press, (Publisher) Edition no. 1st, 2014 p. 87.

[41] Caroline B. Ncube, *Harnessing Intellectual Property for Development: Some Thoughts on an Appropriate Theoretical Framework*, 16, Potchefstroom Electronic Law Journal 370 (2013).

[42] UNDP, Using competition law to promote access to health technologies a guidebook for low- and middle-income countries (2014), 13, retrieved from, https://www.hks.harvard.edu/publications/competition-policy-and-intellectual-property-insights-developed-country-experience, consulted on 06.04.2021.

[43] A. Van der Merwe 'Introduction' in Van der Merwe (ed.), H.B. Klopper, T. Pistorius, B.R. Rutherford, L. Tong and P. Van der Spuy, Law of Intellectual Property in South Africa (LexisNexis, (Publisher) Edition no. 2nd, 2011 p. 267.

[44] C. Wilson, The Proprietary Justifications for the Patenting of DNA, 11, *UCL Juris Rev* 229 (1994).

justificatory theories of patent protection and challenges of access to essential medicines in South Africa. It will demonstrate that justificatory theories which inform patents on essential medicines embed eurocentrism and negate endogenous perspectives, such as the African philosophy of *Ubuntu*, which may offer a better theoretical foundation for developing intellectual property rights amiable for expanding access to essential medicines.[45] The second part of the article examines patent protection rules in South Africa, and their effects on access to essential medicines. Ultimately, the article offers some proposals on how to re-configure and re-orient South African patent laws in search of an Afrocentric approach for increasing access to essential medicines.[46]

## 2. Orthodox justificatory basis for patenting essential medicines and the problematique

The proponents of the extant intellectual property protection regime in South Africa, with their emphasis on the desirability of patents on essential medicines, argue that the adoption of a domestic patent system and rules improves the accessibility of essential medicines to the country's population.[47] Diametrically opposing are the human rights scholars and other academic commentators who argue that the current patent rules on essential medicines exacerbate the inaccessibility of essential medicines and contribute to the increase in prices charged on patented medicines in developing countries such as South Africa.[48] Despite this divergence in viewpoints, the concern that patent rules should promote access to essential medicines is gaining momentum in the age of COVID-19.[49] The argument(s) is that theories which provide the intellectual premise for recognising patents on essential medicines mask neo-liberal and neo-colonial interests in favour of a western capitalist oriented construct which undermines the goal of increasing access to essential medicines in developing countries such as South Africa.[50] Therefore, developing countries including India and South Africa have recently tendered a proposal for the World Trade Organisation (WTO) to waive patent rights imposed on COVID-19 medicines and new technologies essential for curbing the pandemic on a global scale.[51] Against this backdrop, a critical assessment of the theories underpinning patents is necessary to determine their effectiveness and potential shortcomings in light of South Africa's desperate need to expand access to essential medicines.[52]

### 2.1. The theory of utilitarianism

The utilitarian theory is deployed to justify the social value informing the recognition of patents on essential medicines.[53] It revolves around the assumed economic benefits derived from

[45] K. Balasubramaniam, 'Access to Medicines: Patents, Prices and Public Policy: Consume Perspectives', in P. Drahos and R. Mayne (eds), Global Intellectual Property Rights, Knowledge, Access and Development (Palgrave Macmillan, (Publisher) edition 1st, 2013 p. 92.

[46] Daniel J. Gervais, 'TRIPS and Development' in Matthew David and Deborah Halbert (eds.), The Handbook of Intellectual Property (SAGE Publications Ltd (Publisher) Edition 1st, 2014 p. 16.

[47] Carolyn Deere, The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries (Oxford University Press (Publisher) Edition 1, 2009 p. 9.

[48] Caroline B. Ncube, *The Politics of National Intellectual Property Policy Design and the Provision of Health Services in South Africa*, 3, South African Intellectual Property Law Journal 15 (2015).

[49] Médecins Sans Frontières, Overcoming intellectual property monopolies in the COVID-19 pandemic (2020), 3, retrieved from, https://msfaccess.org/sites/default/files/2020-07/MSF-AC_COVID-19_IP-monopolies_briefing-doc_July2020.pdf) consulted on 12. 06.2021.

[50] SE. Crager, *Improving global access to new vaccines: intellectual property, technology transfer, and regulatory pathways*, 11, American Journal of Public Health 104 (2014).

[51] European Parliament, India and South Africa's call for the WTO to suspend or waive intellectual property rights for COVID-19 related technologies (2021), 2, retrieved from, https://www.europarl.europa.eu/doceo/document/E-9-2021000464_EN.html, consulted on 13.06.2021.

[52] Amanda Barratt, *The Curious Absence of Human Rights: Can the WIPO Development Agenda Transform Intellectual Property Negotiation*, 14, Law Democracy and Development 17 (2010).

[53] Kahsay Debesa Gebray, Justifications for Claiming Intellectual Property in traditional herbal medicines and biodiversity conservation: Prospects and Challenges (2013) 12, retrieved from, www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2013/chapter_4_2013_e.pdf), consulted on 15.06.2021.

establishing an intellectual property regime offering strong patent-related rights.[54] The argument is that patent rights are necessary practical incentives for encouraging pharmaceutical companies to invest their limited resources in the uncertain and highly demanding project of developing new medicines or improving the current ones.[55] The central premise is utilitarianism as it focuses on the perceived outcomes emanating from the temporary exclusionary rights conferred upon pharmaceutical companies under the applicable intellectual property regime.[56] Whilst this theory maybe sound, it should be viewed in light of the consequences of the well renowned patent monopoly including higher pricing of medicines which typically excludes the poor people in society from accessing new essential medicines available on the market.[57]

Further, utilitarianism maintains that in a capitalist based economy, ordinary commercial entities barely develop new innovative ideas when their competitors can easily replicate their new products without incurring the research and development (R and D) costs associated with the original invention.[58] Pharmaceutical manufactures need to recover the costs of developing medicines, but may be unable to do so when faced with stiff competition from competitors who copy their goods and sell them below the actual cost of production.[59] The natural response to this unbridled risk of copying is that inventors may stop investing in R and D which will ultimately undermine future innovation activities in society.[60]

### 2.2. The fundamental justice theory

The fundamental justice theorists generally endorse the view that inventors have an inalienable natural right with regard to their inventions as fruits of their labour.[61] For them, justice places an obligation upon society to establish a legal framework which recognises the inventors' right to have control over their products including essential medicines.[62] The theory prioritises the owner's property right in his or her invention. It is largely credited to John Locke, an English philosopher, who maintained that people own themselves, and by extension, their invention which are and should be regarded as the fruits of their labour.[63] For John Locke, the relationship between the inventor's labour and an abstract product emanating from that labour creates strong property interest for the inventor.[64] It follows that a legal system should be adopted which gives inventors a monopoly by prohibiting their competition from using their invention without consent through patent laws.[65] Not surprisingly, this theory protects intellectual property rights of inventors with respect to essential medicines.[66] However, the non-exclusive nature of the inventive idea, the item created by the inventor's labour, poses significant challenges to the recognition of patents on essential medicines.[67]

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[54] S.J. Graham, A.C. Marco, and A.F Myers, *Patent transactions in the marketplace: Lessons from the USPTO patent assignment dataset*, 27, Journal of Economics and Management Strategy 345 (2018).
[55] Emma Perot, *Maximising utility: applying utilitarian theory to international patents*, 9, The King's College Student Law Review 475 (2014).
[56] Stanford, Encyclopedia of Philosophy, the history of utilitarianism (2009), 1, retrieved from, https://plato.stanford.edu/entries/utilitarianism-history/, consulted on 18.06.2021.
[57] Ibid, 2.
[58] G Zaharia, *Review of intellectual property and human development: current trends and future*, 31, Berkeley Journal of International Law 510 (2014).
[59] Mark A Lemley, *Property, intellectual property, and free riding*, 83, Texas Law Review 1031 (2005); Sachiko Ozawa, Raja Shankar, Christine Leopold, Samuel Orubu, *Access to medicines through health systems in low- and middle-income countries*, 34, Health Policy and Planning iii l (2019).
[60] Ibid.
[61] Justin Hughes, *The Philosophy of Intellectual Property*, 77, Georgia Law Journal 287 (1988).
[62] Hannah Brennan, Rebecca Distler, Miriam Hinman, Alix Rogers, A human rights approach to intellectual property and access to medicines, (2013), 54, retrieved from, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2323144, consulted on 19.06.2021.
[63] D Liu, Patent, *but where is home and global justice? A Rawlsian and Senian inquiry*, 14, Chicago-Kent Journal of intellectual Property 174 (2015).
[64] Ibid, 174.
[65] Ibid, 175.
[66] Ibid, 175.
[67] M Du Bois, *Justificatory Theories for Intellectual Property Viewed through the Constitutional Pri*sm, 21, Potchefstroom Electronic Law Journal 4 (2018).

### 2.3. Economic justifications

The economic justification theory recognises patents as instruments of public good. It states that patents are given when a sovereign entity, such as the government, acts on behalf of the public interest.[68] This means patent rights should only be given when the public can potentially gain from the transaction.[69] When it appears as if the public will not benefit as a result of granting monopoly rights the patent application should be denied.[70] The economic theory views the patent system as a means for promoting economic development and improving the society's overall welfare.[71] Societal welfare is quantified and viewed in material and economic terms, the objective being to increase society's wealth. This theory is the brain child of the Greeks,[72] who subscribed to the idea of establishing an incentive based regulatory system that encouraged inventors to disclose new ideas to society.[73]

The patent incentive is understood as an exclusive reward given to inventors for their scientific contribution.[74] The patent system is therefore designed to promote scientific breakthroughs for the betterment of society. In terms of this theory, a patent incentive spurs innovation which ultimately benefits the society that grants the patent.[75] Currently, this theory is also supported by the view that patents increase Foreign Direct Investment (FDI), industrialisation and economic prosperity in developing countries.[76] However, some academic commentators maintain that FDI decisions are not entirely pre-conditioned on the adoption of an intellectual property rights regulatory framework, but on other capricious grounds such as (a) geo-political interest; (b) infrastructural development; and (c) human capital.[77]

### 2.4. The theory of protecting incorporeal property rights

An argument deployed in support of protecting incorporeal property is anchored on the view that patents should be protected because they are an important expression of the innovators mind.[78] In other words, the basic rationale for establishing a patent based regulation derives from the view that the invented item is the product of the inventor's mind rather than just looking at vague personal or public interests and other extraneous considerations.[79] The theory maintains that as long as the invented product exists as an intrinsic idea in the creator's mind, it is owned by the inventor.[80] Therefore, the theory seeks to promote and protect patents as the incorporeal property of an inventor capable of being exchanged for economic value.[81] The theory's pontification of the creator's mind and the created product oversimplifies the complexity of this relationship.[82] It takes for granted that the inventor and his invented item are intertwined and inter-dependent with the inventor being a

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[68] Anna Ramalho, Intellectual property and social justice (2009), 6, retrieved from, http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=446A1E7E383CFABC9E3624E0AADED9B9?doi=10.1.1.423.1945&rep=rep1&type=pdf, consulted on 24.06.2021.

[69] Adam Karbowskia *and Jacek Prokopb, Controversy over the economic justifications for patent protection, 5, Procedia* Economics and Finance 394 (2013).

[70] Ibid, 395.

[71] Ibid, 395.

[72] Michael Witty, Athenaeus describes the most ancient intellectual property, 35, Prometheus Critical Studies in Innovation 139 (2018).

[73] Ibid, 140.

[74] Ibid, 141.

[75] Rochelle Cooper Dreyfuss; César A Rodríguez Garavito (eds.), *Law and global governance series: balancing wealth and health: battle over intellectual property and access to medicines in Latin America*, 16, (Oxford University Press (Publisher) Edition 1st, 2014 p.17.

[76] Ibid, 17.

[77] Ibid, 20.

[78] Howard Brody and Donald W. *Light, Efforts to undermine public health – the inverse benefits law: how drug marketing undermines patient safety and public health*, 6 American Journal of Public Health 399 (2011).

[79] Ibid, 399.

[80] Ibid, 400.

[81] Karen Walsh, Andrea Wallace, Mathilde Pavis, Natalie Olszowy, James Griffin and Naomi Hawkins, *Intellectual Property Rights and Access in Crisis*, 52, IIC-International Review of Intellectual Property and Competition Law 379 (2021).

[82] Dorine Eva Van Norren, *The nexus between Ubuntu and Global Public Goods: its relevance for the post 2015 development Agenda*, 1, Development Studies Research (2014), 255.

natural bearer of real rights including ownership rights over the invention.[83] Such a reading does not properly identify the social location of the inventor and his invented products.[84] Arguably, the invented product has dual characteristics. While it can be reduced and nested to an item of intangible private property rights, it is also a matter of public good(s).[85]

### 2.5. Objections and shortcomings of the justificatory theories

The central justification propagated by the aforementioned intellectual property theories is that inventors of essential medicines should be economically incentivised on the assumption that this will stimulate and sustain great scientific innovation in the pharmaceuticals sector.[86] It is accepted, in terms of these theories that innovation only occurs when patents are extended or imposed on essential medicines as a way of protecting such intellectual property from exploitation by copiers.[87] This view narrowly reduces the meaning of incentives to monetary gain as the major stimulus of innovation in the market place.[88] Such an understanding of incentives is capitalist in nature as it suggests that persons who are incentivised in monetary terms are the drivers of innovation, giving impetus to the current intellectual property regimes.[89] Given that innovation in South Africa pre-dates the patent era, it would be unsustainable and illogical to consider economic incentives as the only means by which society can spur scientific innovation and development.[90]

Another compelling criticism of the foregoing justificatory theories of intellectual property law is that the underlying regulatory model creates innovation based monopolies as a result of the patent based exclusionary rights conferred upon pharmaceutical companies.[91] Du Bois[92] has observed that, in some instances, the concomitant patent monopoly renders essential medicines inaccessible without necessarily encouraging innovation.[93] The resulting state of affairs is both undesirable and unsustainable as it allows few innovative pharmaceutical companies to possess the monopoly of charging high prices for their medicines, which undermines access to essential medicines for the poor.[94]

Theories of intellectual property law are also mute on the negative impact that patent linkage has on the accessibility of medicines in developing and least developing countries.[95] Patent linkage is a phenomenon whereby patent holders are given data exclusivity rights by which they are able to prevent or at least delay the introduction of generic drugs through ensuring that generic drugs manufacturers do not have the clinical data necessary to produce cheap drugs.[96]Another criticism of

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[83] Mzukisi Njotini, *Examining the objects of property rights- lessons from the Roman, Germanic and Dutch legal history*, 50, De jure 154 (2017).
[84] Ibid, 155.
[85] Ibid, 156.
[86] H.E. Kettle, *Using intellectual property regimes to meet global health R&D needs*, 5, Journal of World Intellectual Property (2003) 657; L. Diependaele, J. Cockbain, S. Sterckx, *Raising the barriers to access to medicines in the developing world—the relentless push for data exclusivity*, 17, Dev World Bioeth 11 (2017).
[87] F.M Scherer, Pharmaceutical industry and world intellectual property standard, 53, Vanderbilt Law Review 2246 (2003).
[88] Adam Karbowskia and Jacek Prokopb, *Controversy over the economic justifications for patent p*rotection, 5, Procedia Economics and Finance 396 (2013).
[89] Ibid, 396.
[90] Olga Gurgula and Wen H Lee, *COVID-19, IP and access: Will the current system of medical innovation and access to medicines meet global expectations?*, 17, Journal of Generic Medicines 66 (2021).
[91] Aidan Hollis, Me-too drugs: is there a problem (2005), retrieved from, https://www.semanticscholar.org/paper/Me-too-drugs-%3A-is-there-a-problem-Hollis/f1f6eb533bcb664a2c020bf200825cd1631ed8d3, consulted 26.06.2021.
[92] Mikhalien *Du Bois, State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid-19 Crisis and Beyond*, 23, Potchefstroom Electronic Law Journal 2 (2020).
[93] Ibid, 3.
[94] Muhammad Zaheer Abbas, *The issue of undeserving patent monopolies in innovation-based businesses and implications thereof for underprivileged consumers*, 9, The Business and Management Review (2017) 441; PM Danzon, AW Mulcahy, AK Towse, *Pharmaceutical pricing in emerging markets: effects of income, competition, and procurement, 24, Health Economics* 239 (2015).
[95] C. Butler, *Human rights and the trade organisation: the right to essential medicines and the TRIPS Agreemen*t, V, Journal of international law and policy 5 (2007); Hilde Stevens and Isabelle, *Improving approaches to increase access to medicines in developing countries*, 4, Frontiers in Medicine 3 (2017).
[96] Ibid, 4.

patent claims on essential medicines is that they result in the problem of evergreening.[97] Advocates of strong intellectual property rights have done little to dispel such concerns.[98]

Evergreening is a means by which pharmaceutical manufacturers keep essential medicines updated, with the intent of maintaining patent protection for longer periods of time beyond what is permissible under the applicable intellectual property law.[99] Pharmaceutical manufacturers also modify their products in order to circumvent the legislated patentability required standards.[100] Evergreening has the consequence of extending the life span of a patent monopoly beyond 20 years thereby enabling the patent holder to maximise profits and benefits for a prolonged period.[101]

Another objection mounted against the imposition of patents on essential medicines is that they can be used as instruments for the appropriation and monopolisation of indigenous traditional knowledge (TK) without permission from the indigenous communities.[102] Empirical studies have shown that many pharmaceutical manufacturers have relied on indigenous traditional knowledge in developing their own patented medicines.[103] Patenting of medicines developed from components and elements sourced from indigenous knowledge effectively result in a transfer of knowledge from the community into a commodity inaccessible to such community.[104]

### 2.6. Current patent regime in South Africa

The main legal instrument governing intellectual property in South Africa, including patents on essential medicines, is the Patents Act.[105] This Act operates in tandem with other legislation, including the Medicines and Related Substances Control Amendment Act,[106] which permits the government to import generic drugs or grant third parties licences to import medicines in limited circumstances with a view to improving access to essential medicines.[107] The Patents Act incorporates international standards sourced from the Trade Related Intellectual Property Rights Agreement (TRIPS) of the World Trade Organisation (WTO).[108] TRIPS is a global agreement which established minimum standards of intellectual property protection required to be incorporated into all WTO members' national legislation, including that of South Africa.[109]

It can be strongly argued that the enforceable minimum standards for intellectual property protection in TRIPS safeguard and support pharmaceuticals companies' economic penetration, monopoly and control.[110] Many scholars now accept that the embedding of these standards of

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[97] Say-yed Hesameddin Tafreshi, *Anti-Pharmaceutical Patent Ever-greening Law: Global Need in Support of Public Health*, 24, Journal of Intellectual Property Rights 108 (2019).
[98] Ibid, 108.
[99] Ibid, 109.
[100] C. Tomlinson, C Waterhouse, Yuan Qiong and Hu S Meyer, *How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies*, 6, South African Journal of Medicine (2019), 397.
[101] R. Bala, S. Kunnumkal, and M.G, Sohoni, *Evergreening and operational risk under price competition, 63, Naval Research Logistics* (2016) 74.
[102] Grenier provides a succinct definition of indigenous knowledge as "the unique, traditional knowledge existing within and developed around specific conditions of women and men indigenous to a particular geographic area." In other words, what makes the knowledge indigenous is its inalienable link to the native people. See Gaëlle Krikorian and Amy Kapczynski, Access to knowledge in the age of intellectual Property, retrieved from, https://tigerprints.clemson.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1179&context=cheer(2010), 63, consulted on 19.07.2021.
[103] E.P Amechi, *Leveraging traditional knowledge on the medicinal uses of plants within the patent system: the digitisation and disclosure of knowledge in South Africa*, 1, Potchefstroom Electronic Law Journal 1727 (2015).
[104] Ibid, 1728.
[105] Act 57 of 1978.
[106] Act 90 of 1997.
[107] Generally, a non-voluntary license holder is not exempt from paying royalties to the patent holder, but is allowed for a specified period to manufacture the product in question. See Carlos M. Correa, Pharmeceutical innovation, incremental patenting and compulsory licencing< (2011), 37, retrieved from, http://www.thaidrugwatch.org/download/rp_41_pharm_complice_ccorrea.pdf, consulted on 24. 07.2021.
[108] Andrew L. Gray and Yousuf A. Vawda TRIPS, Access to Medicines and Local Production in South Africa (SpringerLink (Publisher) Edition 1, 2013 p. 2.
[109] Dhar, Biswajit; Gopakumar, K. M, Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS (2020), 3, retrieved from, https://www.econstor.eu/handle/10419/226692, consulted from consulted on 27.07.2021.
[110] Ibid, 50.

Intellectual Property (IP) protection in the domestic legislative framework of developing countries was mainly informed by the external capitalist interests of developed countries, especially the United States (US), Germany, Britain, France and others at the expense of developing countries' public health needs such as access to essential medicines.[111] These western countries favoured the imposition of international IP standards as they contended that the obligations generated by the Berne and Paris Conventions had shortcomings and inadequately protected their interest at the international level and were often not being enforced by many developing countries.[112] It is therefore surprising that South Africa and other developing countries, being largely net importers of IP rights, agreed to be bound by an international instrument which is clearly against their economic and developmental interests.[113] However, the answer is easily found in the unbalanced power relations at play in the negotiations between developed and developing countries at the WTO.[114] Most of the developing countries were not properly represented in the technical drafting of the TRIPS.[115] They lacked the necessary technical expertise and were overwhelmed by the US economic, political and military dominance, including the potential threat of economic sanctions.[116]

Notwithstanding the above, there are existing regional and sub-regional Intellectual Property (IP) frameworks such as the African Regional Intellectual Property Organisation (ARIPO), Regional Economic Communities (RECs) and the Organisation *Africaine de la Propriete Intellectuelle* (OAPI) which have a bearing on South Africa.[117] In terms of these sub regional intellectual property frameworks and the New Partnership for Africa's Development (NEPAD), members of the African Union are required to domesticate minimum intellectual property standards including granting appropriate of patent rights in their national legislation.[118] On this score, the South Africa Patents Act authorises the Registrar of Patents to receive, accept, grant, publish and register patent applications in the country.[119] The Patents Act provides that the Companies and Intellectual Property Commission (CIPC) is the custodian of all patent applications submitted in South Africa.[120] While the Patents Act allows individuals to lodge their patent application, only a patent attorney is allowed to draft the patent specifications and make a non-provisional patent application.[121]

### 3. Substantive examination and the non-substantive system

South Africa has a depository patent regime which is non-examination based.[122] This means

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[111] This view is mainly projected by historical revisionist who contest the mainstream idea that free trade amounts to fair trade. These scholars posit that free trade as espoused in the current WTO agreement is laden with capitalist interest in favour of developed countries. For a further reading see Karen Walsh, Andrea Wallace, Mathilde Pavis, Natalie Olszowy, James Griffin and Naomi Hawkins, *Intellectual Property Rights and Access in Crisis*, 52, ICC-International Review of Intellectual Property and Competitition Law 388 (2021); Brian Vincent Ikejiaka, *International Law is Western made Global Law : The Peception of third world category*, 6, African Journal of Legal Studies 373 (2013).

[112] Martin de Beukelaer and Martin Fredriksson, *The Political Economy of Intellectual Property Rights: the Paradox of Article 27 Exemplified in Ghana*, 46, Review of African Political Economy 460 (2019).

[113] Ikechi Mgbeoji, The Comprador Complex: Africa's IPRs Elite, Neo-colonialism and the Enduring Control of African IPRs Agenda by External Interest (2014), 7, retrieved from, https://digitalcommons.osgoode.yorku.ca/cgi/viewcontent.cgi?article=1042&context=olsrps, consulted on 29.07.2021.

[114] Catherine Field, Negotiating for the United States (2015), 129, retrieved from, https://www.wto-ilibrary.org/the-wto/the-making-of-the-trips-agreement_6a0429b6-en, consulted on 28.07.2021.

[115] Jayashree Watal and Antony Taubman, The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations (2015) 2, retrieved from, https://www.wto.org/english/res_e/publications_e/trips_agree_e.htm, consulted on 29.07.2021.

[116] Ibid, 2.

[117] ARIPO African Regional Intellectual Property Organisation (2020),1, retrieved from, www.google.com/search?q=African+Regional+Intellectual+Property+Organisation&rlz=1C1GCEV_enZA857ZA862&oq=African+Regional+Intellectual+Property+Organisation+&aqs=chrome..69i57.1748j0j15&sourceid=chrome&ie=UTF-8, consulted on 01.08.2021.

[118] Companies and Intellectual Property Commission, Patent application process (2021), consulted on http://www.cipc.co.za/za/, consulted on 01.08.2021.

[119] Ibid, 1.

[120] Ibid, 1.

[121] Ibid, 1.

[122] Lonias Ndlovu, Why should South Africa introduce Patent Searches and Examination to improve access to essential medicines (2015), 3, retrieved from, https://www.wto.org/english/tratop_e/trips_e/colloquium_papers_e/2015/chapter_9_2015_e.pdf, consulted on 03.08.2021.

patent applications are merely assessed for compliance with the requisite procedural requirements deemed necessary for granting patents, including whether the correct official forms were used and prescribed fees paid.[123] This is notwithstanding that the patentability requirements for novelty, inventiveness and industrial applicability are codified in the Patents Act.[124] The South African depository system does not have a substantive search and examination mechanism to ensure that a patent application meets patentability requirements prior to the granting of the patent.[125] This means that patent claims on essential medicines could be granted without complying with the criteria for patentability.[126] Challenges to patentability can only be made subsequent to the grant of a patent via the court system.[127] Objections have been made that this process is costly and often protracted, which makes it inadequate and unsuitable for addressing patentability challenges in respect of essential medicines.[128]

It is noteworthy that due to lack of substantive patent examination, South Africa has been granting more sub-standard patent claims on essential medicines than other developed and developing countries such as China, India, Germany, Denmark and the US.[129] Many of these patents have a negative impact on the accessibility of essential medicines.[130] This shortcoming is acknowledged by the Government in the 2017 Draft Intellectual Property Policy (DIPP) of South Africa.[131] It is tantamount to an admission that South Africa's patent laws have fallen short in improving access to essential medicines and by extension, in enabling realisation of the right of access to health care services. The need for re-calibration of South Africa's patent laws with a view to expanding access to essential medicines is therefore compelling and urgent.

### 3.1. Compulsory licencing in South Africa: is it an effective device for increasing access to essential medicines?

Notwithstanding the above, some academic commentators maintain that compulsory licencing is an important mechanism which allows the state to expand access to essential medicines by circumventing and overcoming the barriers presented by the patent monopoly.[132] On that score, Article 6 of TRIPS establishes the right of WTO member states to have their own patent regime.[133] Articles 30 and 31 of the TRIPS and the Doha Declaration allow member states to employ compulsory licencing as a means of expanding access to essential medicines for domestic use in exceptional circumstances.[134] Section 4 of the Patents Act states that: "A patent shall in all respects have the like effect against the State as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in

[123] Stefanie Busch, Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening, 4 South African Intellectual Property Law Journal (2016), 103.
[124] Medecines Sans Frontiers, Benefits of substantive examination for pharmaceutical patent claims in IP forum, South Africa (2019), 19, retrieved from, https://www.thedti.gov.za/business_regulation/presentations/pharmaceutical_patent_claims.pdf, consulted on 04. 08.2021.
[125] C. Tomlinson, *Reforming South Africa's procedures for granting patents to improve medicine access*, 105, South African Medical Journal 741 (2015).
[126] Ibid, 742.
[127] Yousuf A Vawda, Compulsory Licensing Jurisprudence In South Africa: Do We Have Our Priorities Right? (2018),12, retrieved from https://www.southcentre.int/wp-content/uploads/2018/12/RP90_Compulsory-Licensing-Jurisprudence-in-South-Africa-Do-We-Have-Our-Priorities-Right_EN-1.pdf, consulted on 08.08.2021.
[128] Erika G, The human right to health and HIV/AIDS: South Africa and south-south cooperation to reframe global intellectual property principles and promote access to essential medicines, 18, Indiana Journal of Global Legal Studies 167 (2011).
[129] Ibid, 14.
[130] J De Beer, C Armstrong, C Oguamanam, T Schonwetter, T, Innovation and Intellectual Property – Collaborative Dynamics in Africa (2014), 39, retrieved on, http://www.openair.org.za/images/9781775821427.pdf, consulted on 10.08.2021.
[131] South African Government, 2017 Draft Intellectual Property (IP) Policy of South Africa (2017), 8, retrieved from, https://www.gov.za/sites/default/files/gcis_document/201708/draftintellectual-property-policy.pdf, consulted on 12.08.2021.
[132] Sri Wartini, *The Legal Implication Of Compulsory Licence Pharmaceutical Products in the TRIPS Agreement To The Protection Of The Right To Health In Developing Countries*, 18, Jurnal Dinamika Hakum 3 (2018); Mansi Sood, Natco *Pharma Limited v. Bayer Corporation and the Compulsory Licensing Regime in India*, 6, NUJS Law Review 110 (2013).
[133] Ibid.
[134] Article 30 of the TRIPS allows WTO members to make an exception for patents and Article 31 fleshes out Article 30 by providing a comprehensive exception which allows member states to make exceptions for patent rights.

default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee."[135]

Further, section 56 of the Patents Act empowers the Commissioner of Patents to grant a compulsory licence to an "interested party", including a government body, without the consent of the patent holder, in instances where the patentee has abused the patent claim.[136] There are procedural requirements that must be followed before issuing a compulsory licence.[137] An interested party is required to make an attempt at negotiating the issuing of voluntary licencing with the patentee.[138] However, the process of voluntary licencing can be circumvented in an epidemiological health crisis or in an extreme public health crisis such as the current COVID-19 conditions.[139] The effect of the compulsory licencing dispensation is that it authorises the government to grant licenses to third parties enabling them to produce generic medicines without the consent of the patent claim holder which has the potential to boost access to essential medicines.[140] Diametrically opposing are critics who argue that the benefits of access to medicines derived from compulsory licencing are very limited.[141] The argument is that compulsory licencing is a short term measure which brings temporal relief to the problem of access to essential medicines in exceptional circumstances and that it is not far reaching enough and will not sufficiently settle the problems of patent exclusivity.[142]

Although there may not be much legally recognised opposition to the acceptability of using compulsory licencing in situations of public health emergency, it should not be treated as a permanent solution.[143] Any use of the mechanism beyond the permissible legislated parameters in terms of the current law may constitute expropriation, and a blatant limitation of property rights.[144] In this light, any such expropriation must comply with sections 25 and 36 of the Constitution. Such compulsory licencing will be open to challenge as demonstrated in *Pharmaceutical Manufacturers' Association v President of the Republic of South Africa*[145] where the court invalidated legislative amendments permitting the issue of parallel import or compulsory licensing based on the finding that the Minister had not complied with the procedure prescribed for adopting such amendment.[146] It can be strongly argued that the subsistence of compulsory licencing beyond the period of a particular public health crisis will be inconsistent with the section 56 of the Patents Act and *ultra vires*.[147]

### 3.2. Re-configuring the patent regime through principled humanisation of the theoretical underpinnings

As mentioned, South Africa's capacity to tackle the current epidemiological health crisis including COVID-19 and other pandemics largely depends on expanding access to essential medicines including efficacious vaccines.[148] However, many essential medicines and other medical

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[135] Ibid.
[136] Ibid.
[137] Ibid.
[138] Ibid.
[139] Eduardo Urias and Shyama V. Ramani, *Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence*, 3, Journal of International Business Policy 367 (2020).
[140] Yousuf A Vawda and Bonginkosi Shozi, Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa (2020) 16, retrieved from, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3559478, consulted on 12.08.2021.
[141] Hans Morten Haugen, *Does TRIPS prevent treatment of COVID-19 vaccines as a global public good*? 24 Journal of World Intellectual Property 4 (2020).
[142] C Stavropoulou, T Valletti, *Compulsory licensing and access to drugs*, 16, European Journal of Health Economics 85 (2014).
[143] Khor M., The Need to Avoid 'TRIPS—Plus' Patent Clauses in Trade Agreements (2017), 3, retrived from, https://www.twn.my/title2/health.info/2017/hi170301.htm, consulted on 13.08.2021.
[144] Rudolf Dolzer and Felix Bloch, *Indirect Expropriation: Conceptual Realignments*?, 5, International Law Forum du droit international (2003), 133.
[145] TPD 4183/98 (March 2001).
[146] Ibid, 57.
[147] The Constitution of the Republic of South Africa, 1996 protects the right to property in section 25 whether incorporeal or corporeal. Section 16 protects the right to freedom of expression which includes artistic creation and lastly section 22 protects the right to freedom of trade and occupation.
[148] Access to medicines Foundation, Access to Medicine Index 2021 Methodology (2021),1, retrieved from, https://accesstomedicinefoundation.org/, consulted on 19.08.2021.

technologies required to combat the epidemiological health crisis are patented, which may hinder their accessibility and delay access to medical treatment for many South Africans.[149] The current South African 'western-centric' patent rights or claims on essential medicines are largely designed to benefit pharmaceutical companies. In practice, the theoretical underpinnings justifying the extant patent regime entrench unequal access to essential medicines, medical technologies and give rise to power asymmetries.[150] The patent monopoly is, therefore, one of the critical impediments of access to essential medicines.[151]

It can be strongly argued that a crucial device for enabling neo-colonialism via economic means is an IP regime which provides legally enforceable exclusionary rights that protect the economic hegemony and penetration of global pharmaceutical companies to the detriment of developmental needs such as access to essential medicines.[152] As is typical of colonial economic architecture, this consists of the legally enforceable guarantee that pharmaceutical companies, largely originating from the west, are given creating the leeway to reap huge profits from the commodification of essential medicines in developing regions of the world such as South Africa.[153] At present, the South African patent regime with its emphasis on patenting essential medicines, consistent with the model prescribed by the TRIPS agreement, fulfils this economic penetration and hegemonic role.[154] It follows that there is a need to supplement South Africa's western centric model of IP rights protection with an Afrocentric approach underpinned by the philosophy of Ubuntu as the basis for re-calibrating the current IP regime to eliminate potential obstacles to increasing access to essential medicines.[155]

### 3.3. Developing a post-colonial Afrocentric intellectual property rights regime

It can be strongly argued that the development of a comprehensive humanised Intellectual Property regime informed by the values and principles of Ubuntu is crucial for ameliorating the problem of patent-induced inaccessibility of essential medicines in South Africa.[156] The concept of Ubuntu is an acclaimed African philosophical construct and value system subscribed to mainly by indigenous communities throughout sub-Saharan Africa.[157] The meaning of this construct is captured in the isiZulu phrase, "*umuntu ngumuntu ngabantu*" translated as a person is a person through other people.[158] Ubuntu as a philosophical concept dates back to precolonial days and constitutes part of a long African oral tradition of how communities should be ordered.[159] According to South African guidelines for good corporate governance, King Code IV, Ubuntu encapsulates mutual support, respect, unity, interdependence, collectivism and social responsibility.[160] Ubuntu as an indigenised teleological and ontological value has the potential to influence the development of an IP regime that

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[149] C. Tomlinson, C. Waterhouse, Y Q Hu, S. Meyer, H. Moyo, *How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies*, 109, The South African Medical Journal 387 (2019).
[150] Anand Grover, 'Politics of access to medicines and human rights from' in Richard Parker, Jonathan García Routledge Handbook on the Politics of Global Health (Routledge (Publisher) Edition 1st, 2018 p. 307.
[151] Ibid, 309.
[152] Ibid, 310.
[153] Cindy Bors, Andrew Christie, Daniel Gervais, Ellen Wright Clayton, *Improving access to medicines in low-income countries: a review of mechanisms*, 18, The Journal of World Intellectual Property 3 (2015).
[154] V. Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and A Few Other Things*, 21, Michigan Journal of International Law 333 (2000).
[155] Sarah McKeith, *Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion, 6, African Journal of Legal Studies* 287 (2013).
[156] C Himonga, M Taylor and A Pope, *Reflections on Judicial Views of Ubuntu*, 16, Potchefstroom Electronic Law Journal 67 (2013).
[157] Hanri Magdalena Du Plessis, *Legal Pluralism, uBuntu and the Use of Open Norms in the South African Common Law of Contract*, 22, Potchefstroom Electronic Law Journal 16 (2019).
[158] K Gyekye, Tradition and Modernity: Philosophical Reflections on the African Experience Countries (Oxford University Press (Publisher) Edition 1, 1997 p. 9.
[159] Lovemore Mbigi and Jenny Maree, Ubuntu: The Spirit of African Transformation Management (Randburg (Publisher) Edition 1, 1995 p. 7.
[160] Institute of Directors Southern Africa, King IV Report on corporate governance for Southern Africa (2016), 24, retrieved from, https://cdn.ymaws.com/www.iodsa.co.za/resource/collection/684B68A7-B768-465C-8214-E3A007F15A5A/IoDSA_King_IV_Report_-_WebVersion.pdf, consulted on 18.08.2021.

is more responsive to the communitarian needs of access to essential medicines in order to combat the COVID-19 and other pandemics.[161]

The process of re-engineering the South African IP regime requires the infusion of the values of Ubuntu into the country's patent laws.[162] It entails the adoption of a regime that mandates substantive search and examination of patents with a view to promoting social justice and the collective good, and not simply calibrated to favour a particular interest group such as the pharmaceutical companies.[163] The adoption of a substantive search and examination (SSE) of patents should replace the extant depository system, and strengthen the patentability requirements so that patents are not simply approved based on compliance with procedural formalities.[164] Such an approach, which eliminates the granting of weak patents, is consistent with the social values of Ubuntu which require the enactment of IP laws that assign collective responsibility to all persons (either juristic or natural) to contribute towards the acceptable, common good of society.[165] In this context, the common good would be the expansion and promotion of access to essential medicines.[166]

Foregrounding the South African IP regime on Ubuntu, through the prescription of a strong substantive search and examination of patents, requires appropriate capacity building for the patent regime to work.[167] Substantive examination of a patent application needs the examiner to have technical expertise in the field to which the invention applies.[168] In tackling the problem of lack of expertise to carry out substantive search and examination of patents, the South African government should capacitate the CIPC with the necessary financial and human resources to enable it recruit technical experts who will routinely conduct such examination of patents.[169] Meanwhile, the CIPC's IP office has conducted some training for its 18 member technical staff in preparation for substantive patent examination.[170] Whilst this is commendable, the number of patent examiners who have been trained is still very negligible compared to the number of patent applications which have been received by the CIPC.[171]

### 3.4. Increasing access to essential medicines through an open source System

In an effort to re-configure the IP regime in pursuit of improving access to essential medicines, South Africa should adopt an open source system predicated on the values of Ubuntu.[172] Such a system primarily consists of a public voluntary initiative where scientists donate their expertise, time and energy towards developing new medicines.[173] In return for their medical innovations, participants will receive noble recognition in the form of certificates of excellence and national honours instead

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[161] C Himonga , *The Right to Health in an African Cultural Context: the Role of Ubuntu in the Realisation of the Right to Health with Special Reference to South Africa*, 57, Journal of African Law 167 (2013).
[162] P Adusei, *The right to health and constitutional imperatives for regulating the exercise of pharmaceutical patent rights in Sub-Saharan Africa*, 21, African Journal of International and Comparative Law 250 (2013).
[163] Ibid, 251.
[164] Forman L and Kohler JC, Access to essential medicines as a human right: Implications for pharmaceutical Industry Responsibility (University of Toronto Press (Publisher), 2018 p. 4.
[165] Perehudoff, Katrina, Nikita V. Alexandrov, and Hans V. Hogerzeil, *Access to essential medicines in 195 countries: A human rights approach to sustainable development*, 14 Global public health 434 (2019).
[166] Ibid, 435.
[167] Innovative Pharmaceutical Association of South Africa. Proposed Legislative Amendment: Substantive Search and Examination of Patent Applications (2015), 2, retrieved on, http://ipasa.co.za/wp-content/uploads/2017/12/Revised-Draft-IP-Policy-IPASA-Narrative-Submission-171117.pdf, consulted on 19.08.2021.
[168] Ibid, 2.
[169] Lutz Mailänder, Challenges and Options in Substantive Patent Examination (2016), 1, retrieved from, https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=33375, consulted on 24.08.2021.
[170] Bheki Zulu, Maanda Phosiwa, Mehluli Ncube "CIPC to introduce Substantive Search and Examination (2018), 1, retrivived from, https://www.derebus.org.za/cipc-introduce-substantive-search-examination/, consulted on 26.08.2021.
[171] Companies and Intellectual Property Commission, Notice To Service Providers For A Capacity Building Program For Substantive Search And Examination of Patent Applications And The Provision Of A Search Tool For Patent Searches (2021), 2, http://www.cipc.co.za/files/7916/1155/8734/ANNEXURE_A-RFI_001-2020-2021-_Patent_Examination_Search_tool.pdf, consulted on 28.08.2021.
[172] A Alessandro, *Biotechnology in Brazil: promoting open innovation*, 10, Technology forecasting and Social Change 136 (2020).
[173] TB Kepler, MA Marti-Renom, SM Maurer, *Open source research-the power of US*, 59, Australian Journal of Chemistry 291 (2006).

of being granted patent rights for their inventions.[174] The invention-related data stored in an open source database are made available to all scientist and can be examined, challenged, and modified by the wider members of the public and scientific society.[175] An open source model has been successfully used in software development.[176] It has been instrumental in the invention of a decentralised operating system dubbed Linux.[177] Linux is a result of the combined efforts of a number of software scientists who organised themselves via the internet using a software code made available to them free of costs, enabling anyone to view, modify, improve and share the innovative development openly throughout the word.[178]

It is also noteworthy that an open source system is currently being used in the specialised field of bioinformatics where scientists use superhuman computers to carryout research.[179] In this field the public is invited to deposit their data in a software vault which is accessible through an open software code.[180] While the open source system has been used successfully in the foregoing field, it remains unclear whether it will achieve the same desirable results in downstream supply chain where patents are used to incentivise pharmaceutical companies to invest huge sums of money in the development of new medicines.[181] Although many pharmaceutical manufacturers may refuse to participate in open source projects involving the discovery of highly profitable medicines, this system may prove effective in two areas.[182] First it can be a stimulus to the development of non-patentable essential medicines. Given that the development of such essential medicines will be non-patentable nor garner high profits, inventors will probably be unwilling to pursue research in such areas.[183] Second, an open source system may be instrumental in areas involving the so called neglected diseases where the market is not large enough for pharmaceutical companies to recoup their R&D expenses incurred in developing such essential medicines.[184] Given that many pharmaceutical companies' innovation projects are profit driven, they may find it unprofitable to participate in open source projects involving such diseases.[185] In order to encourage other developers of medicines to venture into these areas, South Africa should consider offering tax cuts for those who engage in open sources initiatives. Such R&D strategy will be in sync with the perspective of the WTO which encourages member states to develop a sustainable, diverse research portfolio for the discovery of new medicines and other medical technologies.[186]

Further, there currently exist precedents which support the adoption of an open source system in developing and least developing countries.[187] For example, India which is termed the 'pharmacy of the world,' through the Council of Scientific and Industrial Research (CSIR), has established an open source system called Open Source Drug Discovery (OSDD).[188] OSDD is a ground breaking web-based vault which offers experiment coordination opportunities for scientists to develop new

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[174] This approach largely based on the idea of conferring medal of hour which is prevalent in many countries but often underutilised or forgotten. It allows the head of state to award a medal to a nominee as an expression of the people's gratitude for particular distinctive work or civilian contribution. See Lisa M. Mandrusiak, *Balancing Open Sour Balancing Open Source Paradigms and Padigms and Traditional Intellectual Property Models to Optimise Innovation*, 63, Maine Law Review 305 (2010).
[175] Weilbaecher, *Diseases endemic in developing countries: how to incentivise innovation*, 18 Annals of Health Law 281 (2009).
[176] Ibid, 282.
[177] Ibid, 282.
[178] Ibid, 283.
[179] L. Petherbridge, *Road map to revolution? Patent-based open science*, 59, Maine Law Review (2007), 333.
[180] Ibid, 334.
[181] Ibid, 334.
[182] B Munos "Can Open-Source R and D reinvigorate drug research (2006), 1, retrieved on, http://www.nature.com/nrd/journaU/v5/n9/pdf/nrd2131.pdf, consulted on 04.09.2021.
[183] Ibid, 1.
[184] World Health Organisation, Neglected tropical diseases (2021),1, retrieved from, http://www.who.int/neglected_diseases/diseases/en/, consulted on 05.09.2021.
[185] Ibid, 1.
[186] WHO, Global strategy and plan of action on public health, innovation and intellectual property (2018) 1, retrieved from, http://pps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, consulted on 07.09.2021.
[187] VN Vasudeva VN, *A Relook at Sui Generis Software Protection through the Prism of Multi-Licens*ing, 16, Journal of World Intellectual Property 87 (2013).
[188] Seema Singh, *India takes an open source approach to drug discovery*, 18, Cell 133 (2009).

affordable essential medicines.[189] This project has been able to draw together scientific researchers ranging from senior lecturers and college students. It is noteworthy that this project received one third of its funding from the government, and the remainder of their budget support comes from well-wishers and philanthropic organisations.[190]

### 3.5. Increasing access to essential medicines through patent waivers

As stated earlier, India and South Africa have tabled a proposal before the TRIPS Council requesting a suspension or temporary cessation of the implementation, application and enforcement of patents rights on essential medicines and other medical technologies necessary for combating COVID-19.[191] The adoption of an intellectual property rights waiver would accord with the values and principles of Ubuntu.[192] This request is now being supported by more than 150 countries including the US.[193] The waiver has the potential to promote the production of affordable ventilators, and medical technologies including vaccines, to prevent, contain or treat COVID-19.[194] While a WTO driven temporal suspension of patent rights might be desirable in the fight against COVID-19, this cannot be a permanent solution to the problem of access to essential medicines as the waiver will have an expiry date.[195]

### 3.6. Adopting innovative provisions for strengthening patentability criteria: lessons from Indian and Chinese experiences

The COVID-19 and other pandemics oblige South Africa to re-configure its patent laws in the same way that India and China have done over the years.[196] India has amended its Patent Rules 2003 by introducing 2017 Patent (Amendment) Rules aimed at encouraging innovation and creating a conducive environment for technology transfer.[197] In terms of section 3(d) of the 2017 Patent (Amendment) Rules, in addition to complying with the other patentability criteria of novelty, the invented essential medicines in India must pass the eligibility test in the form of efficacy before a patent claim is approved.[198] This additional requirement of efficacy is not found in the South African Patents Act.[199] Whilst the Indian may not considered to be TRIPS compliant because it introduces stringent efficacy requirement for pharmaceutical companies to prove therapeutic efficacy, it is crucial for tackles the problem of patent ever greening.[200] South Africa should consider adopting a similar provision in order to combat the problem of evergreening consistent with the obligation to provide access to essential medicines.[201]

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[189] Ibid, 134.
[190] WIPO, *Copyright Protection of Computer Software* (2021), 1, https://www.wipo.int/copyright/en/activities/software.html, consulted on 08.09.2021.
[191] Patsy Widakuswara, Biden Agrees to Waive COVID-19 Vaccine Patents, but It's Still Complicated (2021), 1, retrieved from, https://www.voanews.com/covid-19-pandemic/biden-agrees-waive-covid-19-vaccine-patents-its-still-complicated, consulted on 15.09.2021.
[192] Gerhard Erasmus, The proposed TRIPS Waiver to respond to the COVID-19 pandemic (2021), 1, retrieved from, https://www.tralac.org/blog/article/15235-the-proposed-trips-waiver-to-respond-to-the-covid-19-pandemic.html, consulted on 18.09.2021.
[193] Third World Network, TRIPS Waiver poposals: A Compilation of statements and reports (2021), 1, retrieved from, https://www.twn.my/title2/intellectual_property/trips_waiver_proposal.htm, consulted on 21.09.2021.
[194] European Parliament, Parliament calls for temporary COVID-19 vaccine patent waiver (2021), 1, retrieved from, https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-callsfortemporary-covid-19-vaccine-patent-waiver, consulted on 24.09.2021.
[195] Human Rights Watch, Urgently Waive Intellectual Property Rules for Vaccine (2020) 3, retrieved from, https://www.hrw.org/news/2020/12/10/urgently-waive-intellectual-property-rules-vaccine, consulted on 27.09.2021.
[196] Ravinder Gabble and Jillian Clare Kohler, *To patent or not to patent? the case of Novartis' cancer drug Glivec in India*, 14, Globalisation and Health 5 (2013).
[197] Department of Industrial Policy and Promotion, Patent Amendment Rules (2017), 2, retrieved from, https://www.egazette.nic.in/WriteReadData/2017/180577.pdf, consulted on 01.10.2021.
[198] Ibid, 1.
[199] Act 57 of 1978.
[200] N Bhaven,Kenneth C. Shadlen, Indian pharmaceutical patent prosecution: The changing role of Section 3(d) (2018), 1, retrieved from, journals.plos.org/plosone/article?id=10.1371/journal.pone.0194714, consulted on 02.10.2021.
[201] Ibid, 1.

Further, on the 17th of October 2020 China implemented the decision of the 'Standing Committee of the National People's Congress' to amend the country's Patent Law.[202] A brief overview of the new provisions shows that China strengthened its intellectual property protection framework taking into account the interest of the pharmaceutical companies, patent holders, patent litigants and the need to meet public interest goals such as access to essential medicines.[203] Prior to these changes, in 2019 the Chinese National Intellectual Property Administration had adopted the new guidelines for patent examination.[204] The most significant aspect of the changes to the patent examination in china relates to the introduction of a collective examination system.[205] This innovative approach allows for pharmaceutical companies, among others, to apply for collective patent examination.[206] The date for carrying out such a substantive collective examination may not exceed one year after the authorities receive the patent application.[207] South Africa could adopt a similar approach which allows pharmaceutical companies to lodge their patent application as a collective and expedite the patent approval process through substantive examination of such patents consistent with the normative obligations of increasing access to essential medicines.[208]

## 4. Conclusion

This article has argued that there is a need for South Africa to re-configure its patent laws in pursuit of an Afrocentric approach to expanding access to essential medicines in the COVID-19 era and beyond.[209] It has demonstrated that South African patent laws are based on problematic theories of intellectual property law largely steeped in a Eurocentric regulatory construct which advances neo-colonial interests without due regard for the country's desperate need for access to essential medicines.[210] The article has also argued that there is a need for South Africa to adopt more indigenous and communalistic theories of intellectual property rights anchored on the philosophy of Ubuntu as supplementary to some of the extant western individualistic notions underpinning the granting of patents on essential medicines.[211] Such a humanising approach, coupled with other complimentary measures, would be amiable to the quest for improved access to essential medicines.[212] The possible complimentary measures include the use of open source systems, compulsory licencing and import licencing, adoption of the WTO TRIPS waiver on patent rights, establishment of vaccines technological hubs for easy transferring of vaccine technology, amendment of the Patents Acts and the adoption of a substantive patent examination system in South Africa.[213]

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[202] The full text of China's Amended Patent Law (2020), retrieved from, https://www.natlawreview.com/article/text-china-samended-patent-law>, consulted on 06.10.2021.

[203] Meyer Dulheur, Changes in patent examination in China (2019), 1, retrieved from, https://legal-patent.com/patent-law/patent-examination-changes-in-china/, consulted on 08.10.2021; Lanying Shen, New Patent Examination Guidelines For China (2019), 1, retrieved from, ficpi.org/ip-news/new-patent-examination-guidelines-china, consulted on 09.10.2021.

[204] Chinese National Intellectual Property Administration, Rules for the Implementation of the Patent Law of the People's Republic of China (2021), 1, retrived from, https://lenglish.cnipa.gov.cn/, consulted on 15.10.2021.

[205] Jones Day, China Promulgates Fourth Amendment to Patent Law' (2020),1, retrieved from, https://www.jonesday.com/en/insights/2020/11/chinapromulgatesfourth-amendment-to-patentlaw> a, consulted on 17.10.2021.

[206] Richard Stockton, Leveraging Amended Patent Law to protect design in China' Law (2020), 360, retrieved from, https://www.law360.com/ articles/1322985>, consulted on 16.10.2021.

[207] Ibid.

[208] Section 27, Fix the Patent Laws supports proposal to facilitate access to COVID-19 vaccine (2020), 5, retrieved from, https://section27.org.za/tag/fix-the-patent-laws/, consulted on 21.05.2021.

[209] Luara Páez, *A Continental Free Trade Area: Imperatives for Realizing a Pan-African Market*, 50, Journal of World Trade 533 (2016).

[210] Pugatch, *Meir Perez, Patent Pools and Collaborative Initiatives: Assessing the Efficacy of Alternatives to IP in the Development of New Pharmaceutical Drugs, Especially for Neglected Diseases – An Empirical Analysis*, 2, European Journal of Risk Regulation 566 (2011).

[211] J. R. Rudolph and PM Ricolfi *TRIPS and Developing Countries: Towards a New Intellectual Property World Order*? 31, The International Trade Journal 479 (2017).

[212] T. D. Leong, S M McGee, A. L. Gray, R de Waal, T. Kredo, K. Cohen, G. Reubenson, M. Blockman, J. Nel, G. Maartens, H. Rees, R. Wiseman, K. Jamaloodien, A. G. Parrish, *Essential medicine selection during the COVID-19 pandemic: Enabling access in uncharted territory*, 110, The South African Medical Journal 1077 (2020).

[213] M. Du Bois, *State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid-19 Crisis and Beyond*, 23, Potchefstroom Electronic Law Journal 16 (2020).

These measures, among others, have the potential to re-orient, re-engineer and re-configure the South African patent laws towards the promotion of access to essential medicines in the COVID-19 era and beyond.

## Bibliography


1. A. Alessandro, *Biotechnology in Brazil: promoting open innovation*, 10, Technology forecasting and Social Change 136 (2020).
2. A. Barratt, *The Curious Absence of Human Rights: Can the WIPO Development Agenda Transform Intellectual Property Negotiation*, 14, Law Democracy and Development 17 (2010).
3. A. Grover, 'Politics of access to medicines and human rights from' in Richard Parker, Jonathan García Routledge Handbook on the Politics of Global Health (Routledge (Publisher) Edition 1st, 2018.
4. A. Karbowskia and J. Prokopb, *Controversy over the economic justifications for patent protection, 5, Procedia* Economics and Finance 394 (2013).
5. A. L. Gray and Y. A. Vawda, *TRIPS, Access to Medicines and Local Production in South Africa* (SpringerLink (Publisher) Edition 1, 2013.
6. A. Ramalho, *Intellectual property and social justice* (2009), 6, retrieved from, http://citeseerx.ist.psu.edu/viewdoc/download;jsessionid=446A1E7E383CFABC9E3624E0AADED9B9?doi=10.1.1.423.1945&rep=rep1&type=pdf, consulted on 24.06.2021.
7. African Union 141 Resolution on Access to Health and Needed Medicines in Africa, November 24, 2008, retrieved from, https://www.achpr.org/sessions/resolutions?id=212, consulted on 21.11.2021.
8. African Union, African Ministers of Health endorsed an adapted strategy to fight COVID-19 underpinned by enhanced approaches to Prevent, Monitor, and Treat, (2021), 1, retrieved from, https://au.int/en/pressreleases/20210517/african-ministers-health-endorsed-adapted-strategy-fight-covid-19-underpinned, consulted on 03.06. 2021.
9. B. Zulu, M. Phosiwa, M. Ncube "CIPC to introduce Substantive Search and Examination (2018), 1, retrivived from, https://www.derebus.org.za/cipc-introduce-substantive-search-examination/, consulted on 26.08.2021.
10. B. Munos, "Can Open-Source R and D reinvigorate drug research (2006), 1, retrieved on http://www.nature.com/nrd/journaU/v5/n9/pdf/nrd2131.pdf, consulted on 04.09.2021.
11. C. B. Ncube, *The Politics of National Intellectual Property Policy Design and the Provision of Health Services in South Africa*, 3, South African Intellectual Property Law Journal 15 (2015).
12. C. Allen Nard and Andrew P. Morriss, *Constitutionalising Patents: Patents: From Venice to Philadelphia*, 2, Review of Law and Economics 323 (2006).
13. C. B. Ncube, *Harnessing Intellectual Property for Development: Some Thoughts on an Appropriate Theoretical Framework*, 16, Potchefstroom Electronic Law Journal 370 (2013).
14. C. Bors, Andrew Christie, D. Gervais, E. W. Clayton, *Improving access to medicines in low-income countries: a review of mechanisms*, 18, The Journal of World Intellectual Property 3 (2015).
15. C. Butler, *Human rights and the trade organisation: the right to essential medicines and the TRIPS Agreemen*t, V, Journal of international law and policy 5 (2007); Hilde Stevens and Isabelle, *Improving approaches to increase access to medicines in developing countries*, 4, Frontiers in Medicine 3 (2017).
16. C. Deere, *The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries* (Oxford University Press (Publisher) Edition 1, 2009 p. 9.
17. C. Field, Negotiating for the United States (2015), 129, retrieved from, https://www.wto-ilibrary.org/the-wto/the-making-of-the-trips-agreement_6a0429b6-en, consulted on 28.07.2021.
18. C. Himonga, M.Taylor and A. Pope, *Reflections on Judicial Views of Ubuntu*, 16, Potchefstroom Electronic Law Journal 67 (2013).
19. C. Himonga, *The Right to Health in an African Cultural Context: the Role of Ubuntu in the Realisation of the Right to Health with Special Reference to South Africa*, 57, Journal of African Law 167 (2013).
20. C. M. Correa, *Pharmaceutical innovation, incremental patenting and compulsory licencing* (2011), 37, retrieved from, http://www.thaidrugwatch.org/download/rp_41_pharm_complice_ccorrea.pdf, consulted on 24.07.2021.
21. C. Ncube, *Decolonising Intellectual Property Law in Pursuit of Africa's Development*, 8, The World Intellectual Property Organisation Journal 34 (2016); Andreas Rahmatian, *Neo-Colonial Aspects of Global Intellectual Property Protection*, 12, Journal of World Intellectual Property Law 42 (2009).
22. C. Staunton, C. Swanepoel, M. Labuschaigne, *Between a rock and a hard place: COVID-19 and South Africa's response*, 7, Journal of law and Biosciences 1 (2020).
23. C. Tomlinson, C. Waterhouse, Yuan Qiong and Hu S Meyer, *How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies*, 6, South African Journal of Medicine (2019), 397.
24. C. Tomlinson, *Reforming South Africa's procedures for granting patents to improve medicine access*, 105, South African Medical Journal 741 (2015).
25. C. Wilson, *The Proprietary Justifications for the Patenting of DNA*, 11, *UCL Juris Rev* 229 (1994).

26. C. Wu, *Transnational pharmaceutical corporations legal and moral responsibilities in relation to access to medicine*s, 7, *Asian Journal of WTO and International Health Law and Policy* 77 (2012).
27. C.V. Chien, *Contextualising Patent Disclosure*, 69, Vanderbilt Law Review 849 (2017).
28. Chinese National Intellectual Property Administration, Rules for the Implementation of the Patent Law of the People's Republic of China (2021), 1, retrived from, https://lenglish.cnipa.gov.cn/, consulted on 15.10.2021.
29. Companies and Intellectual Property Commission, Patent application process (2021), consulted on http://www.cipc.co.za/za/, consulted on 01.08.2021.
30. Cooper Dreyfuss; C. A Rodríguez Garavito (eds.), *Law and global governance series: balancing wealth and health: battle over intellectual property and access to medicines in Latin America*, 16, (Oxford University Press (Publisher) Edition 1st, 2014 p.17.
31. D. Biswajit, K.M, Gopakumar, *Towards more affordable medicine: A proposal to waive certain obligations from the Agreement on TRIPS* (2020), 3, retrieved from https://www.econstor.eu/handle/10419/226692, consulted from consulted on 27.07.2021.
32. D. C. Armstrong, C Oguamanam, T Schonwetter, T, *Innovation and Intellectual Property – Collaborative Dynamics in Africa* (2014), 39, retrieved on, http://www.openair.org.za/images/9781775821427.pdf, consulted on 10.08.2021.
33. D. Eva Van Norren, *The nexus between Ubuntu and Global Public Goods: its relevance for the post 2015 development Agenda*, 1, Development Studies Research (2014), 255.
34. D.J. Gervais, 'IP Calibration' in Daniel J. Gervais (ed.), *Intellectual Property, Trade and Development: Strategies to Optimise Economic Development in a TRIPS Plus Era* (Oxford University Press, (Publisher) Edition no. 1st, 2014.
35. D.J. Gervais, 'TRIPS and Development' in Matthew David and Deborah Halbert (eds.), *The Handbook of Intellectual Property* (SAGE Publications Ltd (Publisher) Edition 1st, 2014.
36. E. P. Amechi, *Leveraging traditional knowledge on the medicinal uses of plants within the patent system: the digitisation and disclosure of knowledge in South Africa*, 1, Potchefstroom Electronic Law Journal 1727 (2015).
37. E. Perot, *Maximising utility: applying utilitarian theory to international patents*, 9, The King's College Student Law Review 475 (2014).
38. E. Urias and S.V. Ramani, *Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence*, 3, Journal of International Business Policy 367 (2020).
39. Erasmus, The proposed TRIPS Waiver to respond to the COVID-19 pandemic (2021), 1, retrieved from https://www.tralac.org/blog/article/15235-the-proposed-trips-waiver-to-respond-to-the-covid-19-pandemic.html, consulted on 18.09.2021.
40. European Parliament, *India and South Africa's call for the WTO to suspend or waive intellectual property rights for COVID-19 related technologies* (2021), 2, retrieved from https://www.europarl.europa.eu/doceo/document/E-9-2021000464_EN.html, consulted on 13.06.2021.
41. European Parliament, Parliament calls for temporary COVID-19 vaccine patent waiver (2021), 1, retrieved from, https://www.europarl.europa.eu/news/en/press-room/20210604IPR05514/parliament-callsfortemporary-covid-19-vaccine-patent-waiver, consulted on 24.09.2021.
42. F.L and J.C Kohler, *Access to essential medicines as a human right: Implications for pharmaceutical Industry Responsibility* (University of Toronto Press (Publisher), 2018.
43. F.M Scherer and J. Wata, *Competition policy and intellectual property: insights from developed country experience*, (2014), 21, retrieved from, https://www.hks.harvard.edu/publications/competition-policy-and-intellectual-property-insights-developed-country-experience, consulted on 04.05.2021.
44. F.M Scherer, *Pharmaceutical industry and world intellectual property standard*, 53, Vanderbilt Law Review 2246 (2003).
45. F.M. Ellen , T. Kujinga and P. Boulet, *Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region*, 31 Journal of Pharmaceutical Policy and Practice (2018), 4.
46. G. Dutfield and U. Suthersanen, *Global Intellectual Property Law* (Edward Elgar, (Publishing) Edition no. 2nd, 2020.
47. G. Erika, *The human right to health and HIV/AIDS: South Africa and south-south cooperation to reframe global intellectual property principles and promote access to essential medicines*, 18, Indiana Journal of Global Legal Studies 167 (2011).
48. G. Krikorian and A. Kapczynski, *Access to knowledge in the age of intellectual property*, retrieved from, https://tigerprints.clemson.edu/cgi/viewcontent.cgi?referer=https://www.google.com/&httpsredir=1&article=1179&context=cheer(2010), 63, consulted on 19.07.2021.
49. G. Zaharia, *Review of intellectual property and human development: current trends and future*, 31, Berkeley Journal of International Law 510 (2014).
50. H. Brennan, R. Distler, M. Hinman, A. Rogers, *A human rights approach to intellectual property and access to medicines*, (2013), 54, retrieved from, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2323144, consulted on 19.06.2021.
51. H. Brody and D.W. *Light, Efforts to undermine public health – the inverse benefits law: how drug marketing*

*undermines patient safety and public health*, 6 American Journal of Public Health 399 (2011).
52. H. Hogerzeil, *Essential medicines and human rights: what can they learn from each other?*,84, Bulletin of the World Health Organization 377 (2006).
53. H. M. Haugen, *Does TRIPS prevent treatment of COVID-19 vaccines as a global public good*? 24 Journal of World Intellectual Property 4 (2020).
54. H.E. Kettle, *Using intellectual property regimes to meet global health R&D needs*, 5, Journal of World Intellectual Property 657 (2003).
55. Hesameddin Tafreshi, *Anti-Pharmaceutical Patent Ever-greening Law: Global Need in Support of Public Health*, 24, Journal of Intellectual Property Rights 108 (2019).
56. Human Rights Watch, *Urgently Waive Intellectual Property Rules for Vaccine* (2020) 3, retrieved from, https:// www.hrw.org/news/2020/12/10/urgently-waive-intellectual-property-rules-vaccine, consulted on 27.09. 2021.
57. I. Mgbeoji, *The Comprador Complex: Africa's IPRs Elite, Neo-colonialism and the Enduring Control of African IPRs Agenda by External Interest* (2014), 7, retrieved from, https://digitalcommons.osgoode.yorku.ca/cgi/view content.cgi?article=1042&context=olsrps, consulted on 29.07.2021.
58. I.S. Kalla, *COVID-19: The Concept of Herd Immunity – Is It A Strategy for South Africa*, 2, Wits Journal of Clinical Medicine 39 (2020).
59. Innovative Pharmaceutical Association of South Africa. Proposed Legislative Amendment: Substantive Search and Examination of Patent Applications (2015), 2, retrieved on, http://ipasa.co.za/wp-content/uploads/2017/ 12/Revised-Draft-IP-Policy-IPASA-Narrative-Submission-171117.pdf, consulted on 19.08.2021.
60. Institute of Directors Southern Africa, King IV Report on corporate governance for Southern Africa (2016), 24, retrieved from https://cdn.ymaws.com/www.iodsa.co.za/resource/collection/684B68A7-B768-465C-8214-E3A 007F15A5A/IoDSA_King_IV_Report_-_WebVersion.pdf, consulted on 18.08.2021.
61. J. Hughes, *The Philosophy of Intellectual Property*, 77, Georgia Law Journal 287 (1988).
62. J. Pfumorodze, *WTO TRIPS Agreement and access to medicines in South Africa*, 13, University of Botswana Law Journal 102 (2013).
63. K. Balasubramaniam, 'Access to Medicines: Patents, Prices and Public Policy: Consume Perspectives', in P. Drahos and R. Mayne (eds), *Global Intellectual Property Rights, Knowledge, Access and Development* (Palgrave Macmillan, (Publisher) Edition 1st, 2013 p. 92.
64. K. D. Gebray, *Justifications for Claiming Intellectual Property in traditional herbal medicines and biodiversity conservation: Prospects and Challenges* (2013) 12, retrieved from www.wto.org/english/tratop_e/trips_e/collo quium_papers_e/2013/chapter_4_2013_e.pdf), consulted on 15.06.2021.
65. K. Gyekye, *Tradition and Modernity: Philosophical Reflections on the African Experience Countries* (Oxford University Press (Publisher) Edition 1, 1997 p. 9.
66. K. Khoza-Shangase, *Burden of disease: A scoping review of HIV/AIDS and TB in occupational noise-induced hearing loss*, 67, South African Journal of Communicable Disorder 669 (2020); World Health Organisation, Global tuberculosis report, (2019), 5, retrieved from, https://www.who.int/teams/global-tuberculosis-pro gramme/tb-reports, consulted on 09.07.2021.
67. K. Perehudoff, B. Toebes, and H. Hogerzeil, *Essential medicines in national constitutions: Progress since 2008*, 18, Health and human rights 144 (2016).
68. K. Walsh, A. Wallace, M. Pavis, N. Olszowy, J. Griffin and N. Hawkins, *Intellectual Property Rights and Access in Crisis*, 52, IIC-International Review of Intellectual Property and Competition Law 379 (2021).
69. L. Diependaele, J. Cockbain, S. Sterckx, *Raising the barriers to access to medicines in the developing world—the relentless push for data exclusivity*, 17, Dev World Bioeth 11 (2017).
70. L. Mailänder, *Challenges and Options in Substantive Patent Examination* (2016), 1, retrieved from, https://www. wipo.int/meetings/en/doc_details.jsp?doc_id=33375, consulted on 24.08.2021.
71. L. Mbigi and J. Maree, Ubuntu: *The Spirit of African Transformation Management* (Randburg (Publisher) Edition 1, 1995.
72. L. Ndlovu, *Why should South Africa introduce Patent Searches and Examination to improve access to essential medicines* (2015), 3, retrieved from, https://www.wto.org/english/tratop_e/trips_e/colloquium_ papers_e/2015/ chapter_9_2015_e.pdf, consulted on 03.08.2021.
73. L. Páez, *A Continental Free Trade Area: Imperatives for Realizing a Pan-African Market*, 50, Journal of World Trade 533 (2016).
74. L. Petherbridge, *Road map to revolution? Patent-based open science*, 59, Maine Law Review (2007), 333.
75. L. Shen, New Patent Examination Guidelines For China (2019), 1, retrieved from, ficpi.org/ip-news/new-patent-examination-guidelines-china, consulted on 09.10.2021.
76. Lisa, Mandrusiak, *Balancing Open Sour Balancing Open Source Paradigms and Padigms and Traditional Intellectual Property Models to Optimise Innovation*, 63, Maine Law Review 305 (2010).
77. Liu, Patent, *but where is home and global justice? A Rawlsian and Senian inquiry*, 14, Chicago-Kent Journal of intellectual Property 174 (2015).
78. M. A Lemley, *Property, intellectual property, and free riding*, 83, Texas Law Review 1031 (2005).
79. M. de Beukelaer and M. Fredriksson, *The Political Economy of Intellectual Property Rights: the Paradox of Article 27 Exemplified in Ghana*, 46, Review of African Political Economy 460 (2019).

80. M. Du Bois, *Justificatory Theories for Intellectual Property Viewed through the Constitutional Pri*sm, 21, Potchefstroom Electronic Law Journal 4 (2018).
81. M. Du Bois, *State Use Provisions for Patent Law, and Expropriations: Some Comparative Law Guidelines for South Africa during the Covid-19 Crisis and Beyond*, 23, Potchefstroom Electronic Law Journal 16 (2020).
82. M. Du Plessis, *Legal Pluralism, uBuntu and the Use of Open Norms in the South African Common Law of Contract*, 22, Potchefstroom Electronic Law Journal 16 (2019).
83. M. Dulheur, *Changes in patent examination in China* (2019), 1, retrieved from, https://legal-patent.com/patent-law/patent-examination-changes-in-china/, consulted on 08.10.2021.
84. M. Gilbert, G. Pullano , F. Pinotti, E. Valdano, C. Poletto, P. Boëlle, E. D'Ortenzio, Y. Yazdanpanah, S. P. Eholie, M. Altmann, B. Gutierrez, M. U. G. Kraemer, *Preparedness and Vulnerability of African Countries against Importations of COVID-19: A Modelling Study*, 20, Lancet 871 (2020).
85. M. Khor, *The Need to Avoid 'TRIPS—Plus' Patent Clauses in Trade Agreements* (2017), 3, retrived from, https:// www.twn.my/title2/health.info/2017/hi170301.htm, consulted on 13.08.2021.
86. M. Njotini, *Examining the objects of property rights- lessons from the Roman, Germanic and Dutch legal history*, 50, De jure 154 (2017).
87. M. Perez, *Patent Pools and Collaborative Initiatives: Assessing the Efficacy of Alternatives to IP in the Development of New Pharmaceutical Drugs, Especially for Neglected Diseases – An Empirical Analysis*, 2, European Journal of Risk Regulation 566 (2011).
88. M. Sood, *Natco Pharma Limited v. Bayer Corporation and the Compulsory Licensing Regime in India*, 6, NUJS Law Review 110 (2013).
89. M. Witty, *Athenaeus describes the most ancient intellectual property*, 35, Prometheus Critical Studies in Innovation 139 (2018).
90. M. Z. Abbas, *The issue of undeserving patent monopolies in innovation-based businesses and implications thereof for underprivileged consumers*, 9, The Business and Management Review (2017) 441;
91. Médecins Sans Frontières, Overcoming intellectual property monopolies in the COVID-19 pandemic (2020), 3, retrieved from, https://msfaccess.org/sites/default/files/2020-07/MSF-AC_COVID-19_IP-monopolies_briefing -doc_July2020.pdf) consulted on 12.06.2021.
92. N. Bhaven, C. K. Shadlen, Indian pharmaceutical patent prosecution: The changing role of Section 3(d) (2018), 1, retrieved from, journals.plos.org/plosone/article?id=10.1371/journal.pone.0194714, consulted on 02.10.2021.
93. O. Gurgula and W. H Lee, *COVID-19, IP and access: Will the current system of medical innovation and access to medicines meet global expectations?*, 17, Journal of Generic Medicines 66 (2021).
94. P. Adusei, *The right to health and constitutional imperatives for regulating the exercise of pharmaceutical patent rights in Sub-Saharan Africa*, 21, African Journal of International and Comparative Law 250 (2013).
95. P. de Vos, W. Freedman, D. Brand, C. Gevers, K. Govender, P. Lenaghan, D. Mailula, N. Ntlama, S. Sibanda & L Stone (eds.) *South African Constitutional Law in Context* Oxford University Press, 2014.
96. Patsy Widakuswara, *Biden Agrees to Waive COVID-19 Vaccine Patents, but It's Still Complicated* (2021), 1, retrieved from https://www.voanews.com/covid-19-pandemic/biden-agrees-waive-covid-19-vaccine-patents-its -still-complicated, consulted on 15.09.2021.
97. Peter S. Menell, *Intellectual Property: General Theories*, (2003), 10, retrieved from, https://reference.findlaw. com/lawandeconomics/1600-intellectual-property-general-theories.pdf, consulted on 29.10.2021.
98. PM Danzon, AW Mulcahy, AK Towse, *Pharmaceutical pricing in emerging markets: effects of income, competition, and procurement, 24, Health Economics* 239 (2015).
99. R. Bala, S. Kunnumkal, and M.G, Sohoni, *Evergreening and operational risk under price competition, 63, Naval Research Logistics* (2016) 74.
100. R. Dolzer and F. Bloch, *Indirect Expropriation: Conceptual Realignments*?, 5, International Law Forum du droit international (2003), 133.
101. R. Gabble and J. Clare Kohler, *To patent or not to patent? the case of Novartis' cancer drug Glivec in India*, 14, Globalisation and Health 5 (2013).
102. R. Rudolph and P.M Ricolfi *TRIPS and Developing Countries: Towards a New Intellectual Property World Order*? 31, The International Trade Journal 479 (2017).
103. Richard Stockton, *Leveraging Amended Patent Law to protect design in China' Law* (2020), 360, retrieved from, https://www.law360.com/ articles/1322985>, consulted on 16.10.2021.
104. S. Ozawa, R. Shankar, C. Leopold, S. Orubu, *Access to medicines through health systems in low- and middle-income countries*, 34, Health Policy and Planning iii l (2019).
105. S. Sharmin, S. Das,T. Roy, Md G. D. Harun, A. A. Chughtai, N. Homaira, H. Seale, *COVID-19 vaccine rumors and conspiracy theories: The need for cognitive inoculation against misinformation to improve vaccine adherence*, 16, PLoS ONE 17 (2021).
106. S. Singh, *India takes an open source approach to drug discovery*, 18, Cell 133 (2009). South African Department of Health, Update on COVOD-19 2021, retrieved from, https://sacoronavirus.co.za/1, consulted on 24.11.2021.
107. S. Wartini, *The Legal Implication Of Compulsory Licence Pharmaceutical Products in the TRIPS Agreement To The Protection Of The Right To Health In Developing Countries*, 18, Jurnal Dinamika Hakum 3 (2018).

108. S.E. Crager, *Improving global access to new vaccines: intellectual property, technology transfer, and regulatory pathways*, 11, American Journal of Public Health 104 (2014).
109. S.J. Graham, A.C. Marco, and A.F Myers, *Patent transactions in the marketplace: Lessons from the USPTO patent assignment dataset*, 27, Journal of Economics and Management Strategy 345 (2018).
110. Sarah McKeith, *Pharmaceutical Patents in Developing Nations: Parallel Importation and the Doctrine of Exhaustion, 6, African Journal of Legal Studies* 287 (2013).
111. South African Department of Health, National Essential Medicines List Committee Tertiary and Quaternary Level Essential Medicines List, (2020), 1, retrieved from, http://www.kznhealth.gov.za/pharmacy/Tertiary-quaternary-level-essential-medicine-recommendations_January2020.pdf, consulted on 01.06.2021.
112. Stavropoulou, T. Valletti, *Compulsory licensing and access to drugs*, 16, European Journal of Health Economics 85 (2014).
113. Stefanie Busch, *Promoting access to affordable generics: reforming South Africa's patent law to prevent evergreening*, 4 South African Intellectual Property Law Journal (2016), 103.
114. T. Naidu, *The COVID-19 Pandemic in South Africa*, 12, Psychological Trauma: Theory, Research, Practice, and Policy 559 (2020).
115. T.B. Kepler, M.A. Marti-Renom, S.M. Maurer, *Open source research-the power of US*, 59, Australian Journal of Chemistry 291 (2006).
116. T.D Leong, S.M McGee, A.L Gray, R. de Waal, T. Kredo, K. Cohen, G. Reubenson, M. Blockman, J. Nel, G. Maartens, H. Rees, R. Wiseman, K. Jamaloodien, A.G. Parrish, *Essential medicine selection during the COVID-19 pandemic: Enabling access in uncharted territory*, 110, The South African Medical Journal 1077 (2020).
117. Third World Network, TRIPS Waiver poposals: A Compilation of statements and reports (2021), 1, retrieved from, https:// ww.twn.my/title2/intellectual_property/trips_waiver_proposal.htm, consulted on 21.09.2021.
118. Tomlinson, C. Waterhouse, Y. Q. Hu, S. Meyer, H. Moyo, *How patent law reform can improve affordability and accessibility of medicines in South Africa: Four medicine case studies*, 109, The South African Medical Journal 387 (2019).
119. UNDP, Using competition law to promote access to health technologies a guidebook for low- and middle-income countries (2014), 13, retrieved from, https://www.hks.harvard.edu/publications/competition-policy-and-intel lectual-property-insights-developed-country-experience, consulted on 06.04.2021.
120. V. Chiappetta, *The Desirability of Agreeing to Disagree: The WTO, TRIPS, International IPR Exhaustion and A Few Other Things*, 21, Michigan Journal of International Law 333 (2000).
121. V.N. Vasudeva VN, *A Relook at Sui Generis Software Protection through the Prism of Multi-Licens*ing, 16, Journal of World Intellectual Property 87 (2013).
122. Van der Merwe, 'Introduction' in Van der Merwe (ed.), H.B. Klopper, T. Pistorius, B.R. Rutherford, L. Tong and P. Van der Spuy, *Law of Intellectual Property in South Africa* (LexisNexis, (Publisher) Edition no. 2nd, 2011.
123. Vincent Ikejiaka, *International Law is Western made Global Law: The Peception of third world category*, 6, African Journal of Legal Studies 373 (2013).
124. Watal and A. Taubman, The Making of the TRIPS Agreement Personal insights from the Uruguay Round negotiations (2015) 2, retrieved from, https://www.wto.org/english/res_e/publications_e/trips_agree_e.htm, consulted on 29.07.2021.
125. Weilbaecher, *Diseases endemic in developing countries: how to incentivise innovation*, 18 Annals of Health Law 281 (2009).
126. WHO, Global strategy and plan of action on public health, innovation and intellectual property (2018) 1, retrieved from, http://pps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf, consulted on 07.09.2021.
127. WIPO, *Copyright Protection of Computer Software* (2021), 1, https://www.wipo.int/copyright/en/activities/ software.html, consulted on 08.09.2021.
128. World Health Organisation, 2021 Model List of Essential Medicines, (2021), retrieved on, https://www.who.int/ groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists, consulted on 25.05.2021.
129. World Health Organisation, Access to essential medicines, (2010), 7, retrieved from, https://www.who.int/ activities/strengthening-access-to-essential-medicines, consulted on 28.05.2021.
130. World Health Organisation, Background document potential Ebola therapies and vaccines (2014), 12, retrieved on https://apps.who.int/iris/handle/10665/137590, consulted on 17.04.2021.
131. World Health Organisation, Neglected tropical diseases (2021),1, retrieved from, http://www.who.int/neglected _diseases/diseases/en/, consulted on 05.09.2021.
132. World Health Organisation, South Africa: WHO Coronavirus Disease Dashboard (2021), 1, retrieved from, https://covid19.who.int/region/afro/country, consulted on 01.16.2021.
133. World Health Organisation, Towards Access 2030 WHO Medicines and Health Products Programme Strategic Framework 2016 – 2030, (2017), 1, retrieved from https://apps.who.int/iris/handle/10665/258757, consumed on 28.10.2021.
134. WTO, Regional issues brief: Intellectual property rights and access to medicines (2017), 4, retrieved from, https://hivlawcommission.org/wp-content/uploads/2017/06/Africa-RIB-IP.pdf, consulted on 27.10.2021.

135. Y. A. Vawda, *Compulsory Licensing Jurisprudence In South Africa: Do We Have Our Priorities Right?* (2018),12, retrieved from https://www.southcentre.int/wp-content/uploads/2018/12/RP90_Compulsory-Licensing-Jurisprudence-in-South-Africa-Do-We-Have-Our-Priorities-Right_EN-1.pdf, consulted on 08.08.2021.
136. Y. F. Wen and T. Matsaneng, *Patents, pharmaceuticals and competition: benefiting from an effective patent examination system* (2014), 5, retrieved from www.compcom.co.za/wpcontent/uploads/2014/09/PatentsPharmaceuticalsandCompetitionYuFangWenandThapiMatsanengAnnualCompetition-Conference-2013.pdf, consulted on 23.04.2021.
137. Y.A. Vawda and B. Shozi, *Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa* (2020) 16, retrieved from, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3559478, consulted on 12.08.2021.