TITLE: "INTELLECTUAL PROPERTY NORMS IN THE POLYCRISIS - (STILL) OMNIPRESENT, DISTRACTING, IRRELEVANT?"

BILL CORNISH MEMORIAL LECTURE, 2024

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Abstract: Twenty years since Professor Cornish asked whether IP is "omnipresent, distracting, irrelevant?" that question is more pertinent than ever. Recent years of instability have compounded the polycrisis the world is facing whilst the 2030 deadline to achieve the UN Sustainable Development Goals looms closer and closer. Intellectual Property (IP) remains one of multiple regulatory systems seeking solutions in the highly dynamic and insecure contexts of the climate emergency, uneven global development, and pandemics. Now is an opportune time to return to Prof. Cornish's question and ask whether appropriate IP norms have been set; or whether states, policymakers and legislatures have merely settled for a "more of the same" approach? If the former, then IP's relevance to combatting the polycrisis may be confirmed; but if the latter, then debates about IP may have become no more than a deadly distraction.

Please note, the text in this document will still be amended and more footnotes are to be added. The lecture, as presented, was based on this text with minor amendments in its delivery.

Introduction

Many wonderful accounts and tributes to Professor Cornish have been authored by others, so I will ride on those and will simply start when and where I met him.[1] In the latter part of his academic career Professor Cornish was the Herschel Smith Professor of Intellectual Property (IP) at Cambridge from 1995 to 2004. It is in that context that I first met him in 1999 when I took his LLM course in Intellectual Property. I have often told the story that I took the course as a wild card having not studied IP at undergraduate level and being at Cambridge intending to study Company Law, Corporate Governance and Corporate Finance. To my surprise and delight, that wildcard turned into my destiny.

Indeed, my first inclination was to entitle this lecture something that included 'Of wild-cards and destiny'. The ways in which Prof Cornish shaped my destiny are invaluable. First, he taught me IP law and policy in a comprehensive and contextual way. For him, the technicalities were always to be probed in real life contexts. To be granted a patent an invention must meet specific criteria but he challenged us to consider several other aspects, such as (1) what is the purpose patents and how should they contribute to human flourishing? (2) Who should determine patent policy and (3) how much weight should be given to stakeholder representation? Second, he ensured that we understood the significance of the international norm-setting institutions. So, he took our class on a field trip to WIPO. What an experience that was, the crummy youth hostel we stayed in, the fondue we enjoyed and of course how awed we were by the hallowed halls of WIPO in Geneva. Third, after we completed our studies, he became a considerate mentor and guide. That was the role in which I last was in his presence, at the 2013 and 2015 International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) congresses at Oxford and Cape Town, respectively. He was still the gentle and quiet person I remembered, keen to support young scholars and to ensure their inclusion in the scholarly community. I, like all who knew him, was saddened by his passing and remain grateful that his scholarship continues to inspire us today. It is a rare privilege to be asked to give the second memorial lecture in his honour, following Prof Jane Ginsburg, whose work I admire greatly.

2004: Intellectual Property: Omnipresent, Distracting, Irrelevant?

In November 2002 Professor Cornish gave three one-hour long lectures at the University of Oxford (the Clarendon Lectures) later published by Oxford University Press in 2004, with the necessary updates, as a book entitled *Intellectual Property: Omnipresent, Distracting, Irrelevant?* This important work has been reviewed several times over the years[2]. My purpose is not to construct another review, but to ask, twenty years after its publication if we have come any closer to answering the questions asked by Professor Cornish – to wit, in which instances is IP omnipresent, a distraction or irrelevant? Prof Cornish used the metaphor of an unpleasant skin condition in

[1] For example, Llewelyn, D. In Memoriam – Professor William Rodolph Cornish. *IIC* 53, 169–172 (2022). https://doi.org/10.1007/s40319-022-01157-y; see Squire Law Library, Cambridge Extended Biography https://www.squire.law.cam.ac.uk/eminent-scholars-archiveprofessor-william-rodolph-cornish/extended-biography-professor-william.

[2] .Ong, B. (2004). [Review of *Intellectual Property: Omnipresent, Distracting, Irrelevant?*, by W. Cornish]. *Singapore Journal of Legal Studies*, 595–597. http://www.jstor.org/stable/24869500; Adebambo Adewopo "INTELLECTUAL PROPERTY Omnipresent, Distracting, Irrelevant? William Cornish Clarendon Law Lectures. Oxford University Press. London. 2004. ISBN 0199263078, £35' 2004) 1:2 SCRIPT-ed 351

elucidating his theme. Under the descriptor of omnipresence, he was addressing IPRs that were "spreading like a rash, particularly across new technologies and threatening to leave few patches of unblemished, open skin".[3] In the category of "distracting" IPRs he discussed rights that "achieve little of their essential purpose but cause persistent itching" and "irrelevant" IPRs are those that appear to be rendered nugatory by technology.[4]

In his lectures and book Professor Cornish arranged his thoughts under three topics, namely – Inventing, Creating and Branding. Each section had 10 -12 subheadings and covered extensive ground. For instance, the the first lecture and chapter on 'Inventing' have subheadings ranging from Intellectual Property; Inventing; Patents: Basic Elements; Medical Patents; Biotechnology and Genetics; Genetics and Patent Theory; Contributions to Advances in Genetic Medicine; Towards Medical Applications; Compulsory Licensing and Crown Use; Rules of Competition; Patent policy to Second-tier Protection: Petty Patents and Database Rights.

As can be seen, in his thorough fashion, under each category he addressed: (1) the technical requirements for protection, (2) the means by which the obtained rights are typically commercialised, (3) the theories relevant to our understanding of those IP rights (4) infringement and permissible uses (5) policy questions and (6) the impact of technology. He discussed the challenges posed by advances in technology to the normative framework, such as his exploration of Napster as an example of 'instilling copyright discipline' in chapter 2 on creating. He also considered whether technology may provide solutions or answers to copyright infringement, in the section entitled 'Technology as Answer.' This question has also been addressed in other landmark works, such Lawrence Lessig's *Code and Other Laws of Cyberspace* (1999). He also asked whether technology may render copyright irrelevant as a result of its disruption of modes of creation and distribution of creative works.

The passage of time has shown us that copyright and other IPRs remain relevant even in current highly digitized contexts. In industrial sectors experiencing rapid technological development IP law is challenged and stretched regarding the scope of protection and coverage. For instance, foreshadowed by Prof Cornish's early work on computer programs, advances in computing technology have engrossed the IP scholarly community and IP stakeholders in debates for years. For example, WIPO set up the Conversations on IP and AI series, the ninth session of which was held in March 2024. These sessions grapple with a gamut of questions including the appropriate forms of protection for AI generated work. On the output side, questions about authorship and inventorship of AI generated works and inventions remain the subject of much scholarship and litigation. On the input side, questions about infringement and the proper way to attribute training materials and remunerate the right holders of training materials are very topical.[5]

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[3] Cornish (2004) 1.
[4] Cornish (2004) 1.
[5] Rens, A., Hlomani, H, & Msipa, S. (2023). *Clarifying copyright to enable AI research in Africa.* Generative AI and Intellectual Property Brief no. 1. Research ICT Africa. https://researchictafrica.net/publication/ai-and-intellectual-property-brief-1/

Another example of technological advancement where IP looms large is in relation to prosthetics a topic discussed by where there is increased reliance on patents industrial designs, copyright and trade marks.[6]

Prof Cornish's 2004 text was informed by decades of work on these issues through his research, writing, teaching and conference participation. For example, prior to the Clarendon Lectures, in 2001 Prof Cornish, was part of an organising team that put together a conference on Collaboration and Ownership in the Digital Economy (CODE). He worked on this team with computer scientists, social and political science scholars such as Prof Alan Blackwell and Dr David Good, both of whom I met this March following which Prof Blackwell kindly sent me links to the conference website. I mention the disciplines of others involved in organising that conference to make the point that Prof Cornish's scholarly engagement went beyond law and legal scholars. Of course, many of us are aware that he was also an historian.[7] These attributes made for a well-rounded and thorough scholar whose sterling work continued beyond his retirement. Everything he wrote contained profound insights but this evening I have chosen to focus on the 2004 text as a launch pad for my following interventions.

This evening, I have elected to focus on the subject matter addressed in the first part of Prof Cornish's 2004 text, namely medical and health contexts. In discussing this topic Prof Cornish had much to say about developing countries and their experience of IP. He returned to this theme in later work, including his co-authored chapter, with Prof Kathline Liddel, on the origins and structure of the TRIPS Agreement.[8] In that work, they noted that "patenting is blamed for imposing impossible prices on developing countries desperate for ant-AIDS drugs and other medical supplies which would give practical expression to the right to life and health."[9]

I could not resist borrowing from one of my favourite books, Nervous Conditions, by Tsitsi Dangaremba, to add my own touch to the themes presented by Prof Cornish. Carrying forward the idea of the experience of IP being a condition, I characterise it as a Nervous Condition. As emphasised by Prof Cornish, IP the experience of IP depends on one's positionality – specifically whether it is a developed or resource-rich environment as opposed to a developing or resource-poor environment. As we saw most recently access to COVID-19 vaccines corelated directly with the income status of a state. My take, borrowing from both Dangaremba and Cornish, is that **when confronted with IP, the condition of less resourced contexts is a nervous condition because IP remains omnipresent and relevant yet fails to deliver health equity, preventing the primary goal of saving lives, making it a deadly distraction.**

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[6] Rimmer, M. (2024). "Chapter 14: Open prosthetics: intellectual property, 3D printing, medical innovation, and sustainable development" in Bita Amani, Caroline B Ncube and Matthew Rimmer ed.s *The Elgar Companion to Intellectual Property and the Sustainable Development Goals*. Cheltenham, UK: Edward Elgar Publishing.

[7] Cornish, William, Michael Lobban, and Keith Smith, 'Empire's Law', *The Oxford History of the Laws of England: Volume XI: 1820–1914 English Legal System*, The Oxford History of the Laws of England (Oxford, 2010; online edn, Oxford Academic, 1 May 2010), https://doi.org/10.1093/acprof:oso/9780199258819.003.0007, accessed 23 Mar. 2024.

[8] William R Cornish and Kathleen Liddell "The Origins and Structure of the TRIPS Agreement" in Hanns Ullrich, Reto M. Hilty, Matthias Lamping, Josef Drexl ed.s *TRIPS plus 20: From Trade Rules to Market Principles* (Springer, 2016), pp. 3-51.

[9] at p.6.

2024: The more things change, the more they stay the same

The world 20 years ago was very different from what it is today. Today, still reeling from the COVID19 pandemic, the world is pummelled by the ravages of health emergencies, climate change and armed conflict, with a polycrisis looming in the future.[10] Humanity faces more and deeper challenges than before in relation to all aspects of life. Intellectual property remains centre stage because it is a knowledge governance system which regulates innovations that are required in every aspect of life. For instance, IP is right in the centre of debates and conversations about COVID-19 vaccine development, or R&D in personal protective equipment, therapeutics and diagnostics. Pandemic prevention and preparedness is critically important, considering the very real possibility of other large scale health emergencies, endemics and pandemics which will be accelerated and amplified by the climate crisis and conflict.

IP remains relevant into the foreseeable future and, in a bid to spark new approaches, contemporary debates locate it within the framing of SDGs (specifically SDG 3 on health). I recently had the privilege of co-editing a volume of intellectual property and the SDGs published last month in which more than 30 authors canvass the intersection between intellectual property and the SDGs, making a call for revised or new regulatory approaches. It remains a very live matter in the WHO Pandemic Accord negotiations, a topic to which I will remain later. In debates and negotiations IP has been allowed to take unjustified prominence over human rights and SDGs.[11] In that sense, IP presents as a distraction.

There is a lengthy and ongoing debate on the relevance of, and impact of IP on, access to critical medical technologies and products during the COVID-19 pandemic. [12] As rightly noted by Gold

> "intellectual property (IP) was not a significant driver of innovation; instead, it contributed to limiting and then delaying global access to vaccines and drugs. Although companies played a critical role in vaccine and antiviral development, they financed their work through the prospect of large procurement contracts rather than the prospect of IP. Procurement, together with early stage funding, came largely from government."[13]

The prevailing IP normative framework, as configured, could not deliver the required equitable access and distribution of medical technologies.[14] Like was the case in the late 1990s – to early 2000s, reforms were mooted. The TRIPS waiver proposal sponsored by India and South Africa, with significant global support, was premised on the appreciation of the significance of IP, not just

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[10] WEF, 2023 Global Risk Report https://www.weforum.org/publications/global-risks-report-2023/digest/

[11] Caroline B Ncube 'Moving from Mirages to Miracles: Intellectual Property, Human Rights and the Global Partnership for Sustainable Development' (2023) 72(7) *GRUR International*, 629–630

[12] Gold, E.R. What the COVID-19 pandemic revealed about intellectual property. Nat Biotechnol 40, 1428–1430 (2022). https://doi.org/10.1038/s41587-022-01485-x; Amin T, Kesselheim AS. A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness. Inquiry. 2022 Jan-Dec;59:469580221124821. doi: 10.1177/00469580221124821. PMID: 36124939; PMCID: PMC9500257; Rob J Aerts, COVID-19 vaccines, patents and an IP waiver, Journal of Intellectual Property Law & Practice, Volume 17, Issue 11, November 2022, Pages 940–945, https://doi.org/10.1093/jiplp/jpac097, Sekalala S, Forman L, Hodgson T, et al Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccineBMJ Global Health 2021;6:e006169.

[13] Gold, E.R. What the COVID-19 pandemic revealed about intellectual property. Nat Biotechnol 40, 1428–1430 (2022). https://doi.org/10.1038/s41587-022-01485-x at 1428.

[14] 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?' Journal of Generic Medicines 2021, Vol. 17(2) 61–70.

patents, but other rights too to efforts to provide timely access to vaccines, diagnostics, therapeutics, PPEs.[15] The proposal faced opposition from a few developed states, who favoured a narrow voluntary license based approach for vaccines only.

The TRIPS Waiver Proposal failed and the WTO at its 12th Ministerial Conference adopted a Declaration on COVID-19 and future pandemics[16] and the Ministerial Decision on the TRIPS Agreement (WTO Decision) adopted on 17 June 2022.[17] The waiver, detailed in the decision, fell far short of the proposal as it was limited to patents and is only for vaccines and the use of protected clinical trial data for regulatory approval. Further, footnote 1 of the WTO Decision dissuades developing country member states with existing capacity to manufacture COVID-19 vaccines from using the waiver by encouraging them "to make a binding commitment not to avail themselves of this Decision." WTO member states agreed to make a decision on an extension of the waiver to COVID 19 therapeutics and diagnostics by 17 December 2022. This deadline was not met, has been extended several times and the matter remains open to this day.[18]

Due to the delay and contestation at the WTO, states had to look elsewhere for solutions, either as individual states or collectively within trading blocks. State action is notified to the WTO and is published on the WTO website.[19] Tonight, I will not focus on individual state action, but rather on collective efforts through regional trading blocks such as the EU and the African Continental Free Trade Area (AfCFTA) which state parties used the Protocol on IPRs to consolidate their position.[20] The current global search for future proofing all people, from resource rich and resource-poor states, is centred on the WHO Pandemic Accord. IPR has unsurprisingly become a point of contention in the on-going negotiations, resuscitating familiar debates.There are two recurring arguments that are incessantly brought up in debates and negotiations for reform of exiting instruments or the creation of new ones. These are twin arguments of (1) local manufacturing capacity and (2) the TRIPS flexibilities, which I will discuss in turn.

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[15] Thambisetty S, McMahon A, McDonagh L, Kang HY, Dutfield G. "Addressing Vaccine Inequity During the COVID-19 Pandemic: The Trips Intellectual Property Waiver Proposal and Beyond" (2022) 81(2) *The Cambridge Law Journal* 384-416. doi:10.1017/S0008197322000241; Foss-Solbrekk K. The IP waiver and COVID-19: reasons for unwavering support. Journal Of Intellectual Property Law and Practice. 2021 Dec 11;16(12):1347–59. doi: 10.1093/jiplp/jpab150. PMCID: PMC8754690.

[16] Ministerial Declaration on the WTO Response to the COVID-19 Pandemic And Preparedness For Future Pandemics adopted on 17 June 2022 WT/MIN(22)/31 WT/L/1142 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True

[17] Ministerial Decision on the TRIPS Agreement (WTO Decision) adopted on 17 June 2022 https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/30.pdf&Open=True

[18] WTO ' Members to continue dialogue on extending TRIPS Decision to therapeutics and diagnostics ' 31 October 2023 https://www.wto.org/english/news_e/news23_e/trip_31oct23_e.htm; WTO 'Members continue discussion on TRIPS Decision extension to therapeutics and diagnostics ' 17 March 2023 (https://www.wto.org/english/news_e/news23_e/heal_17mar23_e.htm)

[19] WTO Secretariat compilation - COVID-19: Measures regarding trade-related intellectual property rights https://www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm

[20] dos Santos , F., Ncube, C. B., & Ouma, M. (2022). Intellectual property framework responses to health emergencies – options for Africa. South African Journal of Science, 118(5/6). https://doi.org/10.17159/sajs.2022/12775

Manufacturing Capacity

Some quarters argue that IP is in fact not the problem, and the crux of the matter, they contend, is inadequate or non-existent manufacturing capacity. The argument, to put is crudely or to paint it in broad strokes is: There is no need for regulatory reform because the problem is manufacturing capacity and we will fix that by voluntarily sharing IP and investing in manufacturing capacity. There are three points that can be made to counter this argument.

First, manufacturing capacity is in evidence in many parts of the developing world, including Africa and Asia.[21] Further, it has been enhanced by the World Health Organisation (WHO) mRNA technology transfer programme which aims to create and maintain a sustainable model for mRNA technology transfer to secure equitable access to vaccines and medical technologies for low- and middle-income countries (LMICs). However, even these mRNA hubs have to contend with IPRs in their noble efforts. This is the second counter point, that voluntary sharing of IP did not happen to the extent promised, or at all. Although Moderna had pledged not to enforce its patents against local manufacturers in 92 LMICs,[22] it did not share its patents with the mRNA hub in Cape Town, which was established to serve LMICs. Therefore, the hub developed a COVID-19 vaccine through a process of 'forward integration' using publicly available information.[23] Had local manufacturers had access to existing vaccine-related IP due to the TRIPS Waiver they could have proceeded to produce and distribute vaccines timeously.

Interestingly, these patents over COVID-19 vaccines which have had negative effects on production, distribution and equitable access of vaccines by the mRNA hub are not inviolable. They have sparked disputes between pharmaceutical companies. For example, Moderna[24] sued Pfizer and BioNTech[25] in the U.S. and Germany, Netherlands and the U.K in 2022.[26] In late 2023 the EPO revoked Moderna's patent EP3718565B1, which covered RNA-based vaccines for respiratory diseases.[27] In early April 2024 it was reported that the US litigation has been paused whilst the USPTO confirms whether two of the three Moderna patents at issue are valid. [28]

The third point is that commitments from private firms to voluntarily contribute to building manufacturing capacity have weakened or been withdrawn. For instance, Moderna had committed to invest in building and enhancing manufacturing capacity in Kenya but just it has been reported

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[21] Amin T, Kesselheim AS. A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness. Inquiry. 2022 Jan-Dec;59:469580221124821. doi: 10.1177/00469580221124821. PMID: 36124939; PMCID: PMC9500257"

[22] Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic, October 8, 2020 https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx

[23] WHO Statement: mRNA Technology Transfer Programme moves to the next phase of its development 20 April 2023 https://www.who.int/news/item/20-04-2023-mrna-technology-transfer-programme-moves-to-the-next-phase-of-its-development

[24] Moderna's 'Spikevax' vaccine (2020).

[25] Comirnaty (2020).

[26] https://www.reuters.com/legal/moderna-sues-pfizerbiontech-patent-infringement-over-covid-vaccine-2022-08-26/

[27] EU Commission ' EPO Invalidates Moderna's Vaccine Patent - CJUE Upholds Vespa's 3D trade mark' 7 December 2023 https://intellectual-property-helpdesk.ec.europa.eu/news-events/news/epo-invalidates-modernas-vaccine-patent-cjue-upholds-vespas-3d-trade-mark-2023-12-07_en

[28] https://www.reuters.com/legal/litigation/pfizer-wins-pause-modernas-covid-19-patent-lawsuit-2024-04-12/

that this has been withdrawn, a development which has drawn the ire of Africa CDC, which released a press statement expressing its disappointment.[29]

TRIPS Flexibilities

The second argument of TRIPS flexibilities is one that looms large. Looking around the room this evening, I can see that I do not have to explain the public interest mechanisms that are provided for in the WTO's Agreement on Trade-related aspects of IP rights (TRIPS), commonly referred to as TRIPS flexibilities. It will suffice merely to list them and to explain how Professors Cornish and Liddell addressed them in their 2016 co-authored chapter, in the volume entitled *TRIPS plus 20 From Trade Rules to Market Principles*, in the first section on Revisiting the Policy Rationale of TRIPS. Their chapter entitled is 'The Origins and Structure of the TRIPS Agreement'. [30]This chapter highlights the battle of interests between resource rich and less resourced contexts and emphasises the priority given to the public interest in article 7[31] and 8[32] of the Agreement and how this prioritisation interfaces with the rest of the agreement. Of interest to me this evening, is the authors' discussion of the impact of TRIPS on patent law, which they describe as "tempestuous". [33] They outlined and remarked upon the key aspects of patent law as set out in TRIPS such as a 20-year patent term, without an exclusion of supplementary protection that was granted by states to recoup time lost in obtaining approvals before the product could be taken to market. They devoted much attention to the protection of clinical trial data under article 39.3. Turning to technology transfer, they noted that

> "Where the purpose of a relationship between firms was to transfer technology, it was common for the core technological ideas to be disclosed by the patent specification, while secondary matters would be passed on by the supplier as secret know-how. To permit such arrangements to operate, whereby a novel invention is "sufficiently disclosed" to the public (as was required for a valid patent), while adding that other information was revealed only on terms of secrecy (when that could actually be achieved) might seem a curious instance of having one's own cake while eating it"

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[29] Africa CDC's Statement on Moderna's plan to reassess commitment to African vaccine manufacturing 15 April 2024 https://africacdc.org/news-item/africa-cdcs-statement-on-modernas-plan-to-reassess-commitment-to-african-vaccine-manufacturing/

[30] William R Cornish and Kathleen Liddell "The Origins and Structure of the TRIPS Agreement" in Hanns Ullrich, Reto M. Hilty, Matthias Lamping, Josef Drexl ed.s *TRIPS plus 20: From Trade Rules to Market Principles* (Springer, 2016), pp. 3-51

[31] Article 7: Objectives
The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

[32] Article 8 Principles
1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

[33] Cornish and Liddell, 2016, p.37.

Owing to differences in national contexts, IP laws and policies need nuance so normative instruments include public policy mechanisms that enable states to customise IP laws to cater for domestic needs and priorities. For example, TRIPS provides for flexibilities for patents, which include 'transition periods, compulsory licensing, parallel importation, the Bolar Provision and exceptions from patentability.'[34] As indicated earlier, due to time constraints, I will not explain the flexibilities and just one example will be given. Under the least developed countries (LDC) transition period LDCs are not required to apply the provisions of the TRIPS Agreement, save for Articles 3, 4 and 5 until 1 July 2034 or when they cease to be an LDC (whichever occurs first). This extension is the third granted to the LDCs, with the first granted in 2005 and the second, which expired on 1 July 2021, granted in 2013. In addition, there is a pharmaceutical transition period until 1 January 2033 or when an LDC ceases to be an LDC, whichever occurs first. Under this transition period, an LDC does not have to issue pharmaceutical patents. However, several LDCs have foregone this flexibility and grant pharmaceutical patents.[35]

Use TRIPS Flexibilities (or you dare not)

The domestication and implementation of these flexibilities has been a sore point with developing countries and LDCs being dissuaded from using them through the application of trade, political and diplomatic pressure. In a recent book chapter, published in 2021,[36] I offered three case studies of such efforts at dissuasion. I will repeat one here, as an example: South Africa's infamous case of *the Pharmaceutical Manufacturers Association & others v the President of the Republic of South Africa & others*[37] which 41 pharmaceutical firms filed an application in 1997 against the South African government. Their claim arose from the amendments to the Medicines and Related Substances Control Act, 1965, were enacted in 1997 and provided for parallel importation, generic substitution and setting up a pricing committee amongst other related measures.[38] These changes have rightfully been characterised as 'modest' by Dutfield, as they were within the scope of the TRIPS Agreement.[39] Yet, the application argued that these amendments were unconstitutional on

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[34] Nicole D, Owoeye O. "Using TRIPS flexibilities to facilitate access to medicines" Bull WHO. 2013;91:533–539. https://doi.org/10.2471/BLT.12.115865. Cornish and Liddell noted that from its adoption, it was clear that TRIPS would have to adopt a phased approach to standardizing patent law. On this they wrote:

> "In 1994, at the height of that free trade triumph, the creation of the World Trade Organisation, the industrial world thrust obligations under TRIPS upon developing countries, requiring them to maintain high-level patent systems for all industries, including those involved in health and agriculture. The developed world has since had to accept, at Doha in 2001, that the timetable for this last step must be moved further into the future" at p.35

[35] dos Santos, F., Ncube, C. B., & Ouma, M. (2022). Intellectual property framework responses to health emergencies – options for Africa. *South African Journal of Science*, *118*(5/6). https://doi.org/10.17159/sajs.2022/12775

[36] Caroline B Ncube 'Limiting Access to Life-Saving Medications: Three South African Case Studies' in Enrico Bonadio and Aislinn O'Connell (ed.s) *Intellectual Property Excesses: Exploring the Boundaries of IP Protection* (2022) Hart 163 – 177

[37] Case no 4183/98, High Court of South Africa (Transvaal Provincial Division) now the Gauteng Division of the High Court of South Africa.

[38] The Medicines and Related Substances Control Amendment Act 90 of 1997, ss 15C, 22F and 22G.

[39] G Dutfield, *That High Design of Purest Gold: A Critical History of the Pharmaceutical Industry, 1880–2020* (World Scientific, 2020), p 2.

four grounds.[40] First, they argued the power given to the Minister of Health[41] were unlimited as there were no policy considerations nor guidelines to constrain it which fell foul of Constitutional provisions on legislative authority which require such constraints.[42]Second, they argued that permitting and enabling parallel imports would amount to the deprivation or expropriation without compensation of intellectual property rights held in pharmaceutical products of such property.[43] Third, they also argued that the section discriminated against 'patent rights in the pharmaceutical field' and this was in contravention of article 27. 1 of the TRIPS Agreement which prohibits discrimination between technological fields. It was said that this would be so because, patented pharmaceutical products would be treated differently from other patented products which were not subject to the Medicines and Related Substances Control Act. Finally, it was argued that since the amendments were in breach of the TRIPS Agreement, they also were non-compliant with Constitutional provisions that require compliance with binding international agreements.[44]

The merits of the applicants' legal arguments were weak and on 'shaky legal grounds'[45] because article 6 of the TRIPS Agreement leaves the choice of which principle of exhaustion to apply to a state party. Consequently, in accordance with international exhaustion, South Africa could permit the import of medication which had lawfully been put on the market anywhere in the world. Similarly, generic substitution laws are lawful and viable policy options for developing countries.[46] Indeed, they are found in many parts of the globe including in developed countries such as the US,[47] Sweden (since 2002)[48] and Finland (since 2003).[49] As rightly noted by Dutfield, challenging these amendments, in a developing country faced with dire need for access to medicines, only served to demonstrate pharmaceutical industry resistance 'to any serious attempts to challenge its profit maximising business model.'[50] The collective impact of the amendments would not be to unfairly discriminate against pharmaceutical patents, and similar arguments failed in the EU-Canada WTO Dispute.[51] They were in compliance with TRIPS and in fact the wording of the provisions was taken from 'a draft legal text produced by the WIPO

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[40] Notice of Motion available at http://www.cptech.org/ip/health/sa/pharmasuit.html.
[41] Section 15C gave the Minister of Health power to 'determine "prescribed conditions" for the supply of "more affordable medicines" in "certain circumstances."
[42] Notice of Motion, above, n **Error! Bookmark not defined.**, para 2.1, relying upon sections 43 and 44 of the Constitution, 1996.
[43] ibid, para 2.3 and para 4.3.
[44] The Constitution, s 44(4) read with ss 231(2) and 231(3).
[45] Dutfield (2020) supra p 2.
[46] WA Kaplan, V Wirtz, A Nguyen, M Ewen, S Vogler and R Laing *Policy Options for Promoting the Use of Generic Medicines in Low and Middle-income Countries* (2016) p 7 available at https://haiweb.org/wp-content/uploads/2017/02/HAI_Review_generics_policies_final.pdf; WA Kaplan, LS Ritz, M Vitello, VJ Wirtz, 'Policies to promote use of generic medicines in low and middle income countries: a review of published literature, 2000-2010' (2012) 106(3) *Health Policy* 211, 211-24; TA Nguyen, R Knight, EE Roughead, G Brooks, A Mant, 'Policy options for pharmaceutical pricing and purchasing: issues for low- and middle-income countries' (2015) 30(2) *Health Policy and Planning* 267, 267–280.
[47] Y Song, D Barthold, 'The effects of state-level pharmacist regulations on generic substitution of prescription drugs' *Health economics* (2018) 27(11) 1717, 1717–1737.
[48] K Andersson, C Sonesson, M Petzold, A Carlsten, K Lönnroth, 'What are the obstacles to generic substitution? An assessment of the behaviour of prescribers, patients and pharmacies during the first year of generic substitution in Sweden' (2005) 14(5) *Pharmacoepidemiol and Drug Safety* 341, 341-8.
[49] J Timonen, R Heikkilä, R Ahonen, 'Generic substitution in Finland: lessons learned during 2003–2008' (2013) 4(3) *Journal of Pharmaceutical Health Services Research* 165, 165–172.
[50] Dutfield (2020) supra at p.2.
[51] Canada-Patent Protection of Pharmaceutical Products, Report of the Panel, WTO, WT/DS114/R (2000).

Committee of Experts.'[52] Finally, the respondents' opposing arguments were based on undeniable human rights obligations of South Africa to people in dire need of access to life saving medication.[53]

This matter provoked significant national and international resistance. Domestically, the Treatment Action Campaign (TAC) applied for, and was granted, friend of the court (amicus curiae) status.[54] The TAC led a robust public awareness campaign and demonstrations were held in support of the 1997 amendments.[55] On the other hand, seemingly in support of the apploicants' case, the US Trade Representative (USTR) included South Africa in its annual Special 301 Report,[56] in the watch list category in 1998[57] and 1999.[58] Cornish and Liddell characterise the pressure brought to bear by the "denunciatory approach" of Special 301 listing as "considerable".[59] They described its continued use after the coming into force of the TRIPS Agreement in1995, as a 'diplomatic sleight of hand", explaining:

> "The US modified its approach—and has committed to securing WTO authorisation before imposing retaliatory trade sanctions—but the Special 301 reporting would continue to be applied to laggard countries, whether or not they were WTO Members during the period for which the USTR review was undertaken. This puts considerable policy and trade pressure on these countries, whilst strategically stopping short of unilateral trade sanctions that more clearly transgress WTO dispute settlement rules. In this use of bi- and pluri-lateral FTAs to enhance the protective effects of IPRs there may accordingly be a conflict over the certainty of norms: where TRIPS lays down a requirement (mostly as a minimum) and a bilateral trade agreement is more demanding, which is to be regarded as predominant?"

There was significant outcry against these Special 301 listings and it became untenable for the US to continue censuring South Africa and following an agreement between the two governments, South Africa was removed from the USTR 301 list. In May 2000, the Clinton administration then passed an executive order which prohibited Special 301 listing with 'respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement.'[60]

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[52] E FM't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' 2002 3(1) *Chicago Journal of International Law* Spring 39, 44.

[53] E George, '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' (2011) 18(1) Indiana *Journal of Global Legal Studies* 167, 185 - 186. Available at http://www.repository.law.indiana.edu/ijgls/vol18/iss1/8.

[54] M Heywood 'Debunking "Conglomo-talk": A case study of the amicus curiae as an instrument for advocacy, investigation and mobilisation' (2001) 5(2) *Law, Democracy & Development* 133, 139–144.

[55] See for example, Treatment Action Campaign (TAC) 'TAC Fact Sheet: The Medicines and Related Substances Control Amendment Act 90 of 1997: A Step Towards Ending Apartheid in Health Care' available at https://www.tac.org.za/wp-content/uploads/2020/04/TL-pmavsgov.pdf; P Sidley, 'Drug companies sue South African government over generics' (2001) 322 BMJ (Clinical research ed.) 447.

[56] Issued annually since 1989 under the Trade Act of 1974.

[57] USTR 1998 Special 301 Report 21 available at https://ustr.gov/sites/default/files/1998%20Special%20301%20Report.pdf.

[58] USTR 1999 Special 301 Report 22 available at https://ustr.gov/sites/default/files/1999%20Special%20301%20Report.pdf.

[59] 2016, p18.

[60] Executive Order 13155 of May 10, 2000 Access to HIV/AIDS Pharmaceuticals and Medical Technologies para 10(a) available at https://www.govinfo.gov/content/pkg/FR-2000-05-12/pdf/00-12177.pdf.

At the same time, there were sustained and robust to reform TRIPS, making it more responsive to public health needs and priorities led to the adoption of the 2001 Doha Declaration on TRIPS and Public Health at the Ministerial Conference held in November.[61] As Barnard puts it, the matter was to be tried in the High Court and 'the court of world opinion.'[62] By the first quarter of 2001 it was clear that the application flew against stronger legal arguments, the wind of global opinion and had been reputationally ruinous, so the applicants settled their matter with the South African government and withdrew it in April 2001.[63] Following this, the Minister promulgated the necessary parallel importation regulations, which have been implemented, alongside the generic substitution provisions [64] which has greatly improved the availability of, and access to, medicines,[65] achieving what Vanni characterises as 'a human focussed patent regime.'[66]

Manufacturing Capacity and the TRIPS Flexibilities in the Pandemic Accord

Currently, the use of TRIPS flexibilities is again the subject of much angst as it is part of the contested provisions of the WHO Pandemic Accord, found in art 11, the technology transfer clause. I would like to draw attention to the peace clause, which appeared in text dated 27 March 2024. To get to that clause, I need to take a few steps back and introduce clause 11. Clause 11 is the "heart" of chapter 2 of the draft pandemic accord. You will recall that Cornish and Liddell highlighted that meaningful technology transfer is premised on access to patent information and confidential information. Accordingly, the provisions in art 11 must address both. Further, earlier on I also highlighted the twin themes of TRIPS flexibilities and manufacturing capacity. They are also addressed in clause 11. This five-paragraph article covers extensive ground. The text of 22 April 2024 is used for purposes of discussion with the caveat that this is "text in motion" which will likely change as negotiations proceed. Reports from the negotiation sessions indicated that most of the text was "yellow" and not yet "green" or agreed.

A_INB9_3Rev1 text 22 April 2024 PROPOSAL FOR THE WHO PANDEMIC AGREEMENT

1. Each Party shall, in order to enable the sufficient, sustainable and geographically diversified production of pandemic-related health products, and taking into account its national circumstances:
(a) promote and otherwise facilitate or incentivise the transfer of technology and know-how for pandemic-related health products, in particular for the benefit of developing countries and for technologies that have received public funding for their development, through a variety of measures such as licensing, on mutually agreed terms;
(b) publish the terms of its licenses for pandemic-related health technologies in a timely manner and in accordance with applicable law, and shall encourage private rights holders to do the same;

[61] Doha WTO Ministerial 2001 'Declaration on the TRIPS Agreement and Public Health' adopted November 1 2001. For a discussion of the African Group's contribution see Ncube, above, n **Error! Bookmark not defined.**.
[62] D Barnard, 'In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries' (2002) 12(2) *Kennedy Institute of Ethics journal* 159, 159–174.
[63] Heywood, above, n 54.
[64] The General Regulations, Medicines and Related Substances Regulations Government Gazette 24727 GN R510 of 10 April 2003 (date of commencement 2 May 2003).
[65] AL Gray, Y Santa-Ana-Tellez and V J Wirtz, 'Impact of the introduction of mandatory generic substitution in South Africa: private sector sales of generic and originator medicines for chronic diseases' (2016) 21(12) *Trop Med Int Health* 1504, 1511.m
[66] A Vanni, *Patent Games in the Global South: Pharmaceutical Patent Law Making in Brazil, India and Nigeria* (Oxford, Hart Publishing, 2019) p 1.

(c) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to forgo or reduce, for a limited duration, royalties on the use of their technology for the production of pandemic-related health products;
(d) promote the transfer of relevant technology and related know-how for pandemic-related health products by private rights holders, on fair and most favourable terms, including on concessional and preferential terms and in accordance with mutually agreed terms and conditions, to established regional or global technology transfer hubs or other multilateral mechanisms or networks, as well as the publication of the terms of such agreements;
(e) encourage the holders of relevant patents that received public funding and, where appropriate, other holders of relevant patents for pandemic-related health products, to forgo royalties or otherwise license any relevant patents at reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related health products; and
(f) encourage manufacturers within its jurisdiction to share as appropriate, during pandemics, information that is relevant to the production of pandemic-related health products when the withholding of such information prevents or hinders the urgent manufacture of a pharmaceutical product that is necessary to respond to the pandemic.
2. Each Party shall provide, within its capabilities and subject to available resources and applicable law, support for capacity-building for the transfer of technology and know-how for pandemic-related health products on mutually agreed terms, especially to local, subregional and/or regional manufacturers based in developing countries.
3. Consider supporting, within the framework of relevant organizations, appropriate measures to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase the availability and adequacy of affordable pandemic-related health products during pandemics.
5. The Parties shall, working through the Conference of the Parties, establish regional or global technology and know-how transfer hubs, coordinated by WHO, to increase and geographically diversify the transfer of technology and know-how for the production of pandemic-related health products by manufacturers in developing countries.

The article sets out obligations for state parties in relation to enabling "the sufficient, sustainable and geographically diversified production of pandemic-related health products," a necessary goal following the vaccine inequity seen in the last pandemic. Significantly, the article mentions the "transfer of technology and know-how" which, as emphasised by Cornish and Liddell, are the core twin elements for meaningful technology transfer. Several comments can be made about this proposed text. First, it opens with an intention of benefitting developing states and indicates a focus on products that have received public funding. This is due to an appreciation of (a) the disadvantages and inequities experienced by developing states and (b) of the significant contribution public funds make to R&D which necessitate intentional public returns. Second, repeated use of terms that indicate a voluntary approach is noteworthy. States are obliged to encourage patent holders who received public funding and research and development institutes and manufacturers, particularly those who received "significant public funding" to "forgo or reduce, for a limited duration, royalties on the use of their technology for the production of pandemic-related health products" (paragraphs c and e). In relation to private rights holders, states are required to promote technology "on fair and most favourable terms, including on concessional and preferential terms and in accordance with mutually agreed terms and conditions, to established regional or global technology transfer hubs or other multilateral mechanisms or networks, as well as the publication of the terms of such agreements." Third, there is an emphasis on publication of license terms by state parties and others which would enhance transparency and expose inequitable terms and conditions. The main shortcoming of this iteration of article 11 is the absence of mandatory, compulsory or non-voluntary transfer. The text opens with a reference to using state parties using "a variety of measures such as licensing, on mutually agreed terms". This wording is broad enough to include compulsory licenses (CL) but the failure to refer, even once, to CL whilst repeatedly referring to voluntary means, gives the impression of a preference for the voluntary approach. Further, when it comes to undisclosed

information or know-how, article 11.1(f) does not go far enough because it only requires states to encourage sharing of information "as appropriate." It should be mandatory to disclose information that is required to enable the "urgent manufacture of a pharmaceutical product that is necessary to respond to the pandemic." Mandatory approaches are discussed below, after the discussion of the proposal for a peace clause.

The "peace clause"

Article 11.4 reads : "The Parties that are World Trade Organization (WTO) members reaffirm that they have the right to use, to the full, the flexibilities in the TRIPS Agreement, including those reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health in future pandemics, and shall fully respect the use of the TRIPS Agreement flexibilities by WTO members." Bearing in mind the bitter experience of states attempting to use flexibilities (such as the example of South Africa above), and the caution given by Cornis and Liddell about the application of considerable trade and political pressure in such cases, this provision does not go far enough. Hence the proposal for the peace clause which read:

"4bis. The Parties shall not challenge, or otherwise exercise any direct or indirect pressure on the Parties that undermine the right of WTO Members to use TRIPS flexibilities at any multilateral, regional, bilateral, judicial or diplomatic forum."

This proposal has not made it in into the text being considered in the negotiations held this week (INB9). It is quoted from the 27 March text (which was published on 2 April by Politico). KEI online has provided extensive commentary on this proposed text.[67] It was proposed because of bitter experience of undue political and trade pressure applied to states seeking to rely on TRIPS flexibilities. Since all states aver that they have not, are not, and will not exert any pressure against other states to dissuade them from using flexibilities, this is a clause that should not have generated any opposition and should have been easily incorporated into the text. Its rejection, alongside the insistence on the inclusion of voluntary and mutually agreed terms whilst omitting CL language is worrisome. Its inclusion would have reaffirmed the foundation for the proposal for mandatory transfer clauses outlined below.

Mandatory approaches

Interestingly, the EU, whilst opposing mandatory approaches in article 11, has gone ahead to begin the process of enacting provisions for a compulsory Union license.[68] The text was adopted on 13 March 2024 at the first parliamentary reading and further steps are pending. However, even this early development is instructive. The key points of the text, for the topic under discussion, are:

[67] (https://www.keionline.org/39585)

[68] European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) 816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

(1) the creation of a temporary and non-exclusive Union compulsory license for crisis relevant[69] products which may be granted to protect the public interest in the context of cross-border crisis or emergency situations in the Union.
(2) Such licenses would be granted "as a last resort... if no prior voluntary agreement has been reached within four weeks between right holder and licensee." Negotiations tend to be stretched over very long periods of time, so setting this four week deadline is important.
(3) The Commission would be the body/entity to grant such a Union compulsory license.
(4) Under the new recital (32a) the Commission is empowered, where appropriate to "oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence".
(5) The Commission would determine adequate remuneration to be paid to the rights holders.

These are the very same key aspects that should be included in article 11 of the WHO Pandemic Accord.

Another example of a regional approach is found in the AfCFTA Protocol on IP Rights. Article 12.3(a) on patents reads: "State Parties shall, in particular ensure that their patent law does not hinder access to medicines, vaccines, diagnostics, therapeutics, and other healthcare essential tools consistent with intellectual property treaties to which they are party to." The article, in para.s (b) - (c) require ratification of the TRIPS Amendment or national provision for procedures that enable the export of pharmaceutical products produced under CL for the benefit of state parties with limited or no domestic pharmaceutical manufacturing capacity. Paragraphs (d) and (e) require state parties to enact exceptions to patents to "permit research, experimentation, and testing for obtaining information about the subject matter of a patented invention" and "to permit acts done on a subject matter of patent solely for uses related to the development and submission of information for regulatory review purposes required under any law of the State Party or any other country that regulates the making, use, sale or import of the product." Article 15.2 expressly reaffirms "the right of a State Party to provide exceptions and limitations to the protection of undisclosed information and related rights including those that secure access to test data for scientific and research purposes consistent with intellectual property treaties to which they are party to, in line with their developmental interests and priorities. "This approach is noteworthy as it provides a very sound base for national exceptions which would cover undisclosed information, know-how and clinical test data. However, in its omission of a regional CL mechanism, it falls far short of the EU approach. As can be seen from these two divergent regional approaches, it is necessary to include a mandatory global approach in the WHO Pandemic Accord.

[69] Defined as "products or processes that are indispensable for responding to a crisis or emergency or for addressing the impacts of a crisis or emergency in the Union and for which the granting of a compulsory license is the only means of ensuring the sufficient and timely availability and supply of such products or processes, as determined by the Commission."

A proposal for such mechanism has been put forward by Gurgula and McDonagh[70] building upon an earlier proposal by Medicines, Law and Policy.[71] The proposal includes infrastructural and process aspects. WHO would provide the infrastructural elements by (1) creating and maintain a list of pandemic related products and technologies, similar to their essential medicines lists; (2) create and maintain a list of rightholders and the states in which these rights are protected, known as "facilitating states" and (3) create technology and know-how transfer hubs or similar entities to support technology transfer. The establishment of these hubs (article 11.5) is contested, with some states proposing that they should be established in a later instrument and not in the accord.

The process to be followed after the declaration of a pandemic would be (1) a suitable manufacturer in a state party would ask that state to make a request for technology transfer to enable that manufacturer to produce the pandemic related product or technology. That state (known as the requesting state) would then make the request to the facilitating state. (2) The facilitating state would then be required to take the necessary steps to mandate the technology transfer. To enable the transfer to ocurr each state has responsibilities to discharge. The requesting state would have to make the necessary IP arrangements for the receipt of the technology transfer, such as granting a CL. It also has to make sure that the necessary arrangements have been made for marketing exclusivities. It would be responsible for assessing the suitable manufacturer to ensure that it has the capability to produce the product or technology and to ensure that it would protect any know-how/undisclosed information transmitted to it. For its part, the facilitating state needs to enable the transfer of "all relevant info including unpublished patent applications, trade secrets, knowhow and clinical data required for the production and marketing authorisation of a pandemic-related product or technology."

Conclusion

There have been three pivotal normative opportunities in the last 25 years. The first was the late 1999s in the height of the HIV/AIDS endemic, the second was in the last 4 years incorporating the TRIPS Waiver proposal negotiations and we are in the third moment, during the negotiation of the Pandemic Accord. So far, each time the regulatory solutions do not go far enough to deliver public welfare outcomes. Thirty years since their inclusion in the TRIPS Agreement, the use of flexibilities remains contested. One then is very disappointed, when proposals for more radical public policy tools like the TRIPS waiver are countered with "use the existing flexibilities." Based on past experience, some states (mostly developing states and LDCs) find it difficult to proceed with domestication and implementation of TRIPS flexibilities in the face of opposition and pressure from others. This predicament is worsened when states that are net exporters of technology refuse to give assurances that they will desist from applying undue pressure. In the current context, is norm-setting moving forward, informed by developmental goals and human rights, to craft new approaches and procedures to meet the prevailing challenges? The negotiation

[70] Olga Gurgula & Luke McDonagh "Proposal for a new Article 11bis in the WHO Pandemic Accord: a Pandemic Technology Transfer Mechanism" https://www.southcentre.int/southviews-no-261-23-april-2024/

[71] Medicines Law & Policy https://apps.who.int/gb/inb/pdf_files/INB9-written-statements/Medicines-Law-and-Policy.pdf

of the WHO Pandemic Accord indicates that we are stuck in a time warp, relying on the (tired) twin arguments of manufacturing capacity and TRIPS flexibilities. So, in closing, IP remains omnipresent and relevant, but falls far short of delivering public welfare outcomes like equitable access to vaccines, diagnostics and therapeutics. Thus, IPRs are distracting, because in Prof Cornish's words they "achieve little of their essential purpose, but cause persistent itching" The current wording of the pandemic accord indicates that this state of affairs is likely to persist into the foreseeable future. One way of remedying this, would be to take on board the very useful proposals for a peace clause and the TT mechanism suggested by Gurlag and McDonagh. However, as new text is not being accepted from states in the current negotiation round, this appears to be an unlikely outcome meaning that the world remains in an intractable nervous condition in the face of future health emergencies and a polycrisis.