Drug Company Practices: Is COVID-19 a New Dawn for Human Rights Norms or Business as Usual?

Perehudoff, K.; Jager, T.J.

Publication date
2021

Document Version
Final published version

Menu

HHR Health and Human Rights Journal

MARCH 16, 2021

Drug Company Practices: Is COVID-19 a New Dawn for Human Rights Norms or Business as Usual?

Katrina Perehudoff and Tessa Jolan Jager

Drug company decisions about COVID-19 products reveal insights about the changing contours of responsible and rights-based corporate conduct in a health crisis. Those holding the intellectual property (IP) rights to COVID-19 medicines can prevent others from manufacturing, selling, or using their product while it is under protection. In the last two decades drug company strategies ranged from staunchly defending their proprietary rights (for example, for new cancer medicines) to agreeing to license or otherwise share knowledge for increased global production and access (for example, with HIV/AIDS, TB, and hepatitis C medicines in the Medicines Patent Pool). These actions have had a tremendous impact on the availability and affordability of those medicines. Now, the range of company decisions relating to COVID-19 medicines and vaccines is no different. Drawing on examples from the 2021 Good Covid-19 Company Practices scorecard we interpret drug companies' recent statements and actions regarding their medicines IP to understand how the COVID-19 pandemic could possibly rebalance health and trade norms for access to medicines.[1]

Companies' human rights responsibilities towards medicines

Recent Viewpoints

Health Workers on the Political Frontlines
Gideon Lasco, Raudah Mohd Yunus, Edward Christopher Dee, and Martin McKee
12 January 2022

The Right to a Healthy Environment is a Powerful Sword for Climate Justice
Timothy Arvan
8 December 2021

The Climate Emergency is a Human Rights Issue
Vicente Silva Didier
7 December 2021

Contradictions Between Pledges, Declarations, and Action at COP26
Stephen Gasteyer
2 December 2021

Human Rights, Public Health, and Disability Awareness Training of Police
Gautam Gulati, Brendan D. Kelly, Alan Cusack, Shane Kilcommins, and Colum P. Dunne
5 December 2021

In the wake of the HIV/AIDS crisis in the 2000s the understanding that pharmaceutical companies have human rights responsibilities towards access to medicines emerged. The 2002-2008 UN Special Rapporteur on the Right to Health, Paul Hunt, developed the 2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (the Guidelines).[2] These identified both the obstacles posed by certain pharmaceutical company behaviours and good company practices that assist States in protecting and promoting the right to health.. The Guidelines state pharmaceutical sector's "central societal mission" is to develop medicines that are accessible to all who need them.[3] The Guidelines have been complemented by the more general 2011 Guiding Principles on Business and Human Rights that were endorsed by the Human Rights Council.[4] The 2016 UN High Level Panel on Access to Medicines proposed incremental monitoring and enforcement strategies aiming to keep trade in medicines and their IP protection from taking priority over public health. Although these guidelines and principles were legitimised by UN bodies, a clear institutional mandate and global mechanism to enforce companies' human rights responsibilities is missing. Part of the challenge of enforcing companies' human rights responsibilities is that they have generally not been matched by strong *formal norms*—that is, legally binding rules in international law.

Pandemic medical products: A unique market

COVID-19 has laid bare the ways in which the market-driven model of drug development and production can work against the equitable distribution of pandemic medical products. In December 2020, the UN Committee on Economic, Social, and Cultural Rights (UN CESCR) notes that "it is fair that they [private companies developing vaccines] receive reasonable compensation for their investments and research" while instructing companies not to utilize their IP rights in a way that impinges on access to a safe and effective COVID-19 vaccine.[5] (It is important to note that COVID-19 vaccine development benefitted from 88.3 billion

First Responders with a Rights-Based Approach to Mental Health Crises
Tamar Ezer and Denise Tomasini-Joshi
10 October 2021

Trans-institutionalisation in Ireland: New and Emerging Congregated Settings for People with Disabilities
Gautam Gulati, Alan Cusack, Brendan D. Kelly, Valerie E. Murphy, Shane Kilcommins, and Colum P. Dunne
13 August 2021

Inequity is an Iniquity: Speaking Up for Aspiring African Researchers
Adelaide M. Lusambili and Constance S. Shumba
9 August 2021

STUDENT ESSAY: Is Compulsory COVID-19 Vaccination a Violation of Human Rights?
Aaron Chia
14 July 2021

Kashmir: Public Health and Human Rights Crises
Nida S. Zubairi and Omar J. Baqal
6 July 2021

Five Years After Security Council's Resolution to Protect Health Care in Conflict: Still at Zero?
Leonard Rubenstein

Euro in public funding from governments, which should be taken into account when considering reasonable compensation of companies' R&D investments.[6]) The UN CESCR clearly positions the use of intellectual property rights in the scope of companies' human rights responsibilities.

Drug company behaviour shifting human rights norms

The COVID-19 pandemic has catalysed a shift bringing some corporate policies in line with the spirit of their human rights responsibilities. Moreover, the Coronavirus outbreak has swiftly re-ignited questions about the legitimacy of IP enforcement in times of crisis, this time with key actions from industry. For example, Moderna pledged not to enforce its COVID-19-related patents during the pandemic, and committed to consider requests from others to license its IP on COVID-19 vaccines.[7] Curevac's CEO has called for the general suspension of patents during the pandemic.[8] In March 2020, AbbVie made a commitment not to enforce its patent rights on its (then) experimental treatment for COVID-19, lopinavir/ritonavir (Kaletra®), for any indication worldwide.[9]

Although these examples remain the exception, not the rule, they illustrate a critical recognition by companies that IP has a social function and plays a critical role in pandemic response and recovery. It also suggests that some companies recognise access is a more legitimate goal than profit, at least in a global health crisis.

Voluntary sharing

Drug company proposals and/or commitments not to enforce some of their private rights signals a potential turning point for the access to medicines norm in relation to trade norms. The Guidelines and other 'soft' human rights law consistently promote various voluntary company actions for access to medicines that are consistent with the rules and flexibilities of the IP regime (for example, issuing voluntary licenses).

29 June 2021

Latest Blogs

December 8, 2021
EDITORIAL Health Rights and the Urgency of the Climate Crisis

November 20, 2021
Human Rights Must Guide a Pandemic Treaty

October 8, 2021
A Healthy Environment Becomes a Human Right

The Guidelines instruct companies to waive test data exclusivity when this would be an "appropriate way" to improve access to medicines for disadvantaged people, communities, and populations.[10] Although the Guidelines refer to "test data exclusivity" and not to IP more generally, Guideline number 31 illustrates the responsibility of companies to waive some of their IP to provide access to medicines for vulnerable groups. However, waiving a 'negative' patent right alone is not sufficient to resolve the legal and technical barriers to scaling-up the production of COVID-19 medical products.[11]

Expanding the timely global production of IP-protected medical technologies requires rights holders to take positive steps to share all forms of intellectual property (for example, patents, know-how, data, …) that are needed to manufacture, license, and sell these products. Taking these steps to increase access in low- and middle-income countries is part of companies' human rights responsibilities towards medicines.[12]

WHO's COVID-19 Technology Access Pool (C-TAP) is one way for COVID-19 product developers to voluntarily share their intellectual property, knowledge, and know-how.[13] C-TAP was established to pool the necessary knowledge and resources required to scale-up the global production of and access to COVID-19technologies worldwide.

While C-TAP struggles to secure the support of drug companies, some firms have independently taken steps in a similar direction. Having inherited vaccine license agreements from Oxford University, AstraZeneca has granted specific manufacturers access to its vaccine IP and the exclusive right to produce and commercialise its vaccine in particular territories.[15] Through these agreements, Astra Zeneca and its partners aim to supply one billion doses to low- and middle-income countries.[16] Such agreements permitting a supply specifically for low-resourced countries increase access in markets least able to pay.

Binding IP waiver as a last resort

There is growing discontent with the reticence of some companies to share their IP, knowledge, and know-how in order to alleviate the legal and technical barriers to scaling up the production and extreme delivery delays of COVID-19 vaccines.[17] As a result, proposals for a binding suspension of IP rights to pandemic medical technologies contribute to the growing calls for a new standard of socially responsible company conduct. Global shortages and the statements by Moderna, Curevac, and AbbVie lend further support for a time-bound exception to IP enforcement on COVID-19 medical products.

In October 2020 India and South Africa (later joined by Kenya, Eswatini, Pakistan, Mozambique, Bolivia, Venezuela, Mongolia, Zimbabwe, Egypt, the African Group and the Least Developed Countries Group) proposed to the World Trade Organization (WTO) a temporary waiver on certain IP related to the prevention, containment and treatment of COVID-19. The WTO proposal, which has been highly contested by some (wealthy) countries, continues to be discussed.

Conclusion

Drug companies hold the keys to addressing many of the legal and technical barriers to scaling up global production of COVID-19 medical products, such as vaccines. During the pandemic some drug companies have supported the non-enforcement of IP related to these medical products in a radical break from the industry's historical narrative. The COVID-19 vaccine is an example of how these statements will need to be matched with steps by private companies and support by the public sector for sharing a range of IP, if the world is to significantly increase its available supply. The escalating public and political debate about access to COVID-19 medical products, coupled with supportive statements by companies, signals a new dawn on the horizon for companies' human rights responsibilities

towards medicines.

Katrina Perehudoff is a post-doctoral research fellow at the Law Centre for Health and Life, University of Amsterdam, and a fellow at the Amsterdam Institute for Global Health & Development and the WHO Collaborating Center for Governance, Accountability, and Transparency in the Pharmaceutical Sector, University of Toronto. She is a member of the Advisory Board of the Pharmaceutical Accountability Foundation and is affiliated with Medicines Law & Policy. Email: katrina.perehudoff@ gmail.com

Tessa Jolan Jager is a recent graduate of the Utrecht University School of Law. She coordinated the first edition of the Pharmaceutical Accountability Foundation's 'Good Covid-19 Company Practices' scorecard.

This post draws from Dr. Perehudoff's seminar for the WHO Collaborating Center for Governance, Accountability and Transparency in the Pharmaceutical Sector on January 28, 2021, and given as part of the Strategic Institutional Partnership between the Universities of Ghent and Toronto.

References

[1] Farma ter Verantwoording [Pharmaceutical Accountability Foundation], *The Good Covid-19 Company Practices Scorecard* (January 2021) Available at: https://www.farmaterverantwoording.nl/en/covid-19-practices/gccp-scorecard/.

[2] Paul Hunt, Report of the Special Rapporteur on the Right to Health, UN Doc.A/63/263. Available at https://www.who.int/medicines/areas/human_rights/A63_263.pdf.

[3] R. Khosla and P. Hunt, Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: the Sexual and Reproductive Health Context (Essex: Human Rights Center, University of Essex), p. 11.

[4] Office of the United Nations High Commissioner for Human Rights UN Doc. HR/PUB/11/04, *Guiding Principles on Business and Human Rights* (New York/Geneva, 2011).

[5] UN CESCR, Statement on universal and equitable access to vaccines for the coronavirus disease (COVID-19), UN Doc. E/C.12/2020/2 (2020), para 7. Available at: https://docstore.ohchr.org/SelfServices/FilesHandler.ashx?enc=4slQ6QSmlBEDzFEovLCuW1AVC1NkPsgUedPlF1vfPMJkWuaq4cQpQv6lITVLtxnVJXSPaoQw4sk4hLso%2bxppPSLMq5FKpqwvX2OdrCRfmFw8OwEDCBDpubC4wy8gyzz9

[6] Businesswire, Governments Spent at Least €93bn on COVID-19 Vaccines and Therapeutics During the Last 11 Months, *Businesswire* (11 January 2021) https://www.businesswire.com/news/home/20210110005098/en

[7] Moderna, *Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic* (8 October 2020). Available at: https://investors.modernatx.com/node/10066/pdf.

[8] J. Dorfs and A. Guhlich, 'Curevac: Patente für Impfstoffe aussetzen', *Stuttgarter Zeitung* (16 December 2020) https://www.stuttgarter-zeitung.de/inhalt.kampf-gegen-corona-curevac-patente-fuer-impfstoffe-aussetzen.568f0c24-6dd1-4724-a46f-8683d53c8444.html.

[9] Ellen 't Hoen, Covid-19 and the comeback of compulsory licensing (23 March 2020). Available at: https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/

[10] See note 2, Paul Hunt, number 31.

[11] Christopher Garrison, "What is the 'know-how gap' problem and how might it impact scaling up production of Covid-19 related diagnostics, therapies and vaccines?" (December 2020). *Medicines Law & Policy*, Amsterdam,

Netherlands. Available at: https://medicineslawandpolicy.org/2020/12/what-is-the-know-how-gap-problem-and-how-might-it-impact-scaling-up-production-of-covid-19-related-diagnostics-therapies-and-vaccines/

[12] See Note 2, Paul Hunt.

[13] Katrina Perehudoff and Jennifer Sellin, COVID-19 Technology Access Pool (C-TAP): A Promising Human Rights Approach (4 June 2020), *Health and Human Rights Journal* website. Available at: https://www.hhrjournal.org/2020/06/covid-19-technology-access-pool-c-tap-a-promising-human-rights-approach/.

[14] See Note 1, Farma ter Verantwoording.

[15] Christopher Garrison, "How the 'Oxford' Covid-19 vaccine became the 'AstraZeneca' Covid-19 vaccine" (October 2020). *Medicines Law & Policy*, Amsterdam, Netherlands. Available at: https://medicineslawandpolicy.org/wp-content/uploads/2020/10/How-the-Oxford-Covid-19-Vaccine-became-the-AstraZeneca-Covid-19-Vaccine-Final.pdf

[16] AstraZeneca. *AstraZeneca takes next steps towards broad and equitable access to Oxford University's COVID-19 vaccine*. (4 June 2020) https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-covid-19-vaccine.html

[17] Virginia Pietromarchi, Patently unfair: Can waivers help solve COVID vaccine inequality? (1 March 2021) *AlJazeera.* Available at: https://www.aljazeera.com/news/2021/3/1/can-a-waiver-on-ip-rights-solve-vaccine

Categories: viewpoints

PREVIOUS
Applying a Human Rights Lens to the Work of the Biden Task Force on Separated Families

NEXT
Doctors in India Need Human Rights Training to Advocate for Prison Reform

HEALTH AND HUMAN RIGHTS JOURNAL ON TWITTER

@MehdiAli98 @UN @CHR_HumanRights @humanrights1st @humanrightslaw @hhrjournal @JulianBurnside surely something can be done for these people?

@MehdiAli98 This is shock @humanrights1st @human

677 Huntington Avenue Boston, MA 02115 • +1 (617) 495-1000