

Amicus Brief on Human Rights Principles and TRIPS-Compliant Interpretation Relative to the Petition by Knowledge Ecology International for a Compulsory License on Pfizer's COVID-19 Antiviral, Paxlovid

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Patent application P2021-0232, titled *Compuestos antivirales que contienen nitrilo*, filed by Pfizer on August 6, 2021

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Professor Baker is a senior policy analyst for Health GAP (Global Access Project) and is actively engaged in campaigns for universal access to treatment, prevention, and care for people living with HIV/AIDS, especially expanded and improved medical treatment. More recently he has been working on accelerating research on and equitable global access to vaccines, medicines, and diagnostics to respond to the COVID-19 pandemic. He has written and consulted extensively on intellectual property rights, trade, investor-state dispute settlement, access to medicines, and medicines regulatory policy, including with the African Union, NEPAD, South Africa, Uganda, ASEAN, Thailand, Indonesia, Brazil, Venezuela, CARICOM, UK DfID, the World Health Organization, the Millennium Development Goals Project, the Global Fund to Fight AIDS, Tuberculosis and Malaria, Open Society Institute, UNAIDS, UNDP, Unitaid, the Medicines Patent Pool (MPP), the Global Commission on HIV and the Law and others. He has served as a key, alternative board member and board member of the NGO delegation to Unitaid, which acts to improve market dynamics and early market entry of medicines and diagnostics needed to address HIV/AIDS, TB, Hepatitis C and malaria. He presently is a civil society representative to the Therapeutics Pillar of the Access to COVID-19 Tools Accelerator.

As an intellectual property and human rights scholar currently working on access to COVID-19 therapeutics, Professor Baker has insights to share related to this Paxlovid compulsory license case.

Summary

This submission is limited to four general points relevant to the compulsory license petition pending for decision at the Dominican Republic Patent Office relating to Pfizer's COVID-19 antiviral, Paxlovid. More particularly, it responds to central arguments put forth by Pfizer in its opposition to the compulsory license

petition filed by Knowledge Ecology International (KEI). The first point is that the relevant human rights at stake in this petition are the rights of Dominican Republic people to have expanded, expedited, affordable, and equitable access to nirmatrelvir + ritonavir for outpatient use to prevent disease progression, hospitalization, and even death. The primacy of the people's right health is directly contrary to Pfizer's assertion of a nearly inviolate human right to its intellectual property. However, Pfizer has no enforceable human rights to the patent and data rights it asserts over Paxlovid and to the contrary is violating its human rights duties by filing this opposition. The second point is that even the intellectual property rights that Pfizer does have are constrained ab initio by the possibility of a compulsory license; at the time they filed for a patent application covering Paxlovid, the government's right to issue a compulsory license for stated purposes was fully authorized in Dominican Republic law. The third point is that Pfizer's opposition is duplicitous in that its voluntary license with the Medicines Patent Pool and its sublicensees directly allows for countries like the Dominican Republic, excluded from the territorial coverage of the voluntary license and sublicensees, to issue compulsory licenses that would allow generic sublicensees to sell generic nirmatrelvir + ritonavir to them. By filing its 44-page opposition to this compulsory license request, Pfizer recants and undermines the right it freely negotiated with the MPP.

The fourth point is perhaps the easiest. Neither the TRIPS Agreement nor that Dominican Republic compulsory licensing law requires a separate executive declaration of the need for and grounds for a compulsory license request on a particular medicine. As clarified by the Doha Declaration on the TRIPS Agreement and Public Health, countries have total freedom to decide the "grounds" for compulsory licenses and can do so on stated policy grounds, not merely on the basis of case-by-case advance executive declaration. This understanding of the right to state broad and multiple grounds that justify the issuance of compulsory licenses is codified in the law of virtually every country that issues compulsory licenses. There are particular compulsory licenses rules in the special circumstances where a government faces an emergency or matter of extreme urgency – for example, the elimination of the requirement to engage in negotiations for a voluntary license on reasonable commercial terms – but even in such urgent circumstances a formal executive pronouncement is not a TRIPS requirement. The emergency or urgency can be recognized by the authority that grants the compulsory license. In sum, Pfizer seeks to complicate and undermine widely recognized procedural simplicities by imposing a dual process – first executive declaration on the need for a compulsory license as a gateway barrier and only thereafter and secondarily case-by-case consideration of the actual compulsory license application to be considered, in the case of the Dominican Republic, on broad public interest grounds.

1. Human Rights to Health, to Access-to-Medicines, and to the Benefits of Scientific Progress Benefit the People of the Dominican Republic, Not Pfizer

The Petitioner has previously briefed ONAPI on the right to health for all and right of access to medicines under Article 61 of the Dominican Republic Constitution, and some the interpretation of the international recognized right to health under the decisions of the Inter-American court of Human Rights and resolutions of the Human Right Council. This amicus brief will provide a more detailed analysis of the relevant human rights principles governing the right to health, right of access to medicines, and the right to the benefits of scientific progress and its applications under international law.

The international community has recognized the basic human right to health and right to the health-related benefits of scientific advancement since the formation of the United Nations more than seventy years ago and more particularly since the adoption of the 1948 Universal Declaration of Human Rights

(UDHR) shortly thereafter.¹ Article 25A of the UDHR expressly recognized that every person has a right to a standard of living adequate for his or her health and medical care and Article 27A guaranteed the right to share in the benefits of scientific progress and its applications. The UDHR has achieved the formal status of customary international law and is therefore, at least theoretically, legally binding on all nations.²

1.1 Right to health, including the right of access-to-medicines

The right to health has been further elaborated in Article 12 of the 1966 International Covenant on Economic, Social, and Cultural Rights (ICESCR), now ratified by a 170 countries, including the Dominican Republic:

1. The States Parties to the present Covenant recognize the *right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
 - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
 - (b) The improvement of all aspects of environmental and industrial hygiene;
 - (c) *The prevention, treatment and control of epidemic, endemic, occupational and other diseases;*
 - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness. [Emphases added.]³

1.1.1 Access to essential and non-essential medicines

Subsequently, the U.N. Committee on Economic, Social and Cultural Rights issued its authoritative General Comment 14 on the right to health, which interprets the normative content of Article 12 and formally recognized the right of immediate access to essential medicines as defined by the World Health Organization.⁴ Over time, there has been more detailed elaboration on the right of access-to-medicines,⁵ and in several Reports of Special Rapporteurs for Health.⁶

¹ United Nations, U.N. Charter, 26 June 1945, TS 67 (1946); United Nations, Universal Declaration of Human Rights, G.A. Res. 217A (III), UN GAOR, Res. 71, UN Doc. A/810 (1948), [https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/217\(III\)](https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/217(III)). Article 55 of the U.N. Charter declares that the United Nations shall promote “(a) higher standards of living ... and conditions of economic and social progress and development ... [and] (b) solutions of international ... social, health, and related problems.” Article 56 requires “All members to pledge themselves to take joint and separate action ... for the achievement of the purposes set for in Article 55.”

² Wesley A. Cann, Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 15 PENN J. INT'L L. 776, 776-781, 835-879 (2004).

³ International Covenant on Economic, Social, and Cultural Rights, G.A. Res. 2200A (XXI) (1976), https://treaties.un.org/doc/Treaties/1976/01/19760103%2009-57%20PM/Ch_IV_03.pdf

⁴ U.N. Committee on Economic, Social and Cultural Rights (CESCR), General Comment no. 14, ¶ 12A, U.N. Doc. E/C.12/2000/4 (August 11, 2000), <https://www.refworld.org/pdfid/4538838d0.pdf>.

⁵ For a reasonably comprehensive list of international legal instruments, see Francois-Xavier Bagnoud Center for Health and Human Rights, HEALTH AND HUMAN RIGHTS RESOURCE GUIDE, 10.27-10.47 (5th ed. 2017) [hereinafter FXB Center, HEALTH AND HUMAN RIGHTS RESOURCE GUIDE], https://cdn2.sph.harvard.edu/wp-content/uploads/sites/25/2014/02/HHRRG_Chapter-101.pdf.

⁶ U.N. Special Rapporteur on the Right to the Highest Attainable Standard of Health, Paul Hunt, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 61st Session, UN Doc. A/61/338, (September 13, 2006) [hereinafter *Special Rapporteur Hunt 2006 Report*], https://www.who.int/medicines/areas/human_rights/A63_263.pdf; U.N. Special Rapporteur on the Right to the Highest Attainable Standard of Health, Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, UN Doc. A/63/263, 15-25 (August 11, 2008) [hereinafter *Special Rapporteur Hunt 2008 Report*], https://www.who.int/medicines/areas/human_rights/A63_263.pdf; U.N. Human Rights Council, *Report of the Special*

A human right to health is fundamental to being human; it is universal, and it supports both positive claims of entitlement and negative prescriptions against infringement. It defines what governments (and non-state actors) can, cannot, and should do.⁷ In a moral sense, the human right to health is absolute, immutable, and inalienable, meaning that it has priority over competing claims, including claims arising from treaties and laws protecting intellectual property rights on medicines as discussed further below. However, the right to health is not absolute or self-effectuating. Under relevant declarations, treaties, and constitutions, the human right to health is subject to qualifications and limitations, most especially arising from resource constraints. Even so there is an affirmative duty of gradual and progressive realization to the maximum of available resources in Article 2.1 of the ICESCR. As further clarified in General Comment 14, States are obligated to take steps, which “steps must be deliberate, concrete and targeted towards full realization,”⁸ States must “move as expeditiously and effectively as possible,”⁹ and States must avoid “retrogressive measures.”¹⁰

Although General Comment 14 refuses to specify the exact health facilities, goods and services that States must deliver, partially because of differing health needs and differing levels of development in different countries, there is a basic “core” obligation to guarantee immediate and assured access to essential medicines.¹¹ Pursuant to General Comment 14, the right of equal and timely access to health facilities, goods and services includes the provision of a basic health service, appropriate treatment of prevalent disease, *and* the affordable supply of essential drugs.¹² Special Rapporteur Paul Hunt specified that “access to medicines forms an indispensable part of the right to the highest attainable standard of health.”¹³ Avoiding “discrimination of any kind,” is also a core, non-derogable duty of all Member States.¹⁴ Progressively improving health services and taking other measures to prevent, treat and control epidemic and endemic diseases is also required.¹⁵ The existence of a core duty to immediately deliver “essential medicines” does not mean that there are no human rights obligations with respect to non-essential medicines. Instead, as clarified by Special Rapporteur Paul Hunt, States still have a duty of progressive realization to provide access to non-essential medicines and to take steps to the maximum of their capacity to do so.¹⁶ This duty would clearly apply to nirmatrelvir + ritonavir even though it has not yet been placed on the WHO or Dominican Republic essential medicines lists.

1.1.2 State duties to ensure medicines are available, accessible including affordability, acceptable, and of good quality; and their duties to respect, protect, and fulfil the right of access-to-medicines

Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, A/HRC/11/12, (March 31 2009) [hereinafter Special Rapporteur Grover 2009 Report], <https://www.refworld.org/docid/49faf7652.html>.

⁷ FXB Center, HEALTH AND HUMAN RIGHTS RESOURCE GUIDE, *supra* note 5 at 10.4-10.5.

⁸ General Comment 14, *supra* note 4, ¶ 30.

⁹ *Id.* ¶ 31.

¹⁰ *Id.* ¶ 32.

¹¹ *Id.* ¶ 12(a).

¹² *Id.* ¶ 17.

¹³ *Special Rapporteur Hunt 2006 Report, supra* note 6, ¶ 40.

¹⁴ General Comment 14, *supra* note 4, ¶ 30 and ¶ 43(d).

¹⁵ *Id.* ¶ 44(c).

¹⁶ *Special Rapporteur Hunt 2006 Report, supra* note 6, ¶ 58.

At its most basic level, meaningful access-to-medicines refers to the ability of all persons to receive the medicines necessary for the treatment of any condition afflicting them, and that these medicines are available, accessible, acceptable, and of good quality.¹⁷ *Availability* requires that there must be sufficient quantities of the medicine,¹⁸ meaning that needed medicines must be procured and that stock-outs should be avoided. *Accessibility* entails (1) physical accessibility “within safe physical reach,” including in rural areas, (2) economic accessibility such that medicines are “affordable for all,” including those who are poor, and (3) informational accessibility, including “the right to seek, receive and impart information and ideas concerning health issues;” all such accessibility must be provided without discrimination, especially for the most vulnerable and marginalized sections of the population.¹⁹ The obligations of accessibility and affordability require States to be health-cognizant “when entering into bilateral or multilateral agreements with other states, international organizations and other entities, such as multilateral corporations.”²⁰ Special Rapporteur Paul Hunt emphasized that the duty to make medicines affordable might require countries to use TRIPS flexibilities, including compulsory licenses.²¹ *Acceptability* refers to the need to “be respectful of medical ethics” and sensitive to the cultural norms of individuals and communities.²² Finally, the medicine “must also be scientifically and medically appropriate and of good *quality*.”²³

General Comment 14 also clarifies that States have clear obligations to respect, protect, and fulfil the right to health:

[T]he obligation to fulfil contains obligations to facilitate, provide and promote. The obligation to *respect* requires States to refrain from interfering directly or indirectly with the enjoyment of the right to health. The obligation to *protect* requires States to take measures that prevent third parties from interfering with article 12 guarantees. Finally, the obligation to *fulfil* requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health.²⁴

It is a violation of the duty to protect to fail to regulate the domestic activity of drug companies so as to prevent them from violating the right to health of others or to protect consumers practices detrimental to health.²⁵ The duty to fulfil the right to health, as it relates to medicines, requires States to reduce inequitable distribution of health goods including medicines.²⁶

Special Rapporteur for Health Anand Grover in his 2013 Report²⁷ addressed multiple additional steps that States must take in order to fulfil access-to-medicines duties, including establishment of essential

¹⁷ General Comment 14, *supra* note 4, ¶ 12; see ¶¶ 16 and 17.

¹⁸ *Id.* ¶ 12(a)

¹⁹ *Id.* ¶ 12(b).

²⁰ *Id.* ¶ 50.

²¹ *Special Rapporteur Hunt 2006 Report, supra* note 6, ¶ 47.

²² General Comment 14, *supra* note 4, ¶ 12(c).

²³ *Id.* ¶ 12(d)

²⁴ *Id.* ¶ 33. Footnote 23 to paragraph 33 further clarifies “According to general comments Nos. 12 and 13, the obligation to fulfil incorporates an obligation to *facilitate* and an obligation to *provide*. In the present general comment, the obligation to fulfil also incorporates an obligation to *promote* because of the critical importance of health promotion in the work of WHO and elsewhere.

²⁵ *Id.* ¶ 51.

²⁶ *Id.* ¶ 52.

²⁷ *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, on access to medicines, A/HRC/23/42, (May 1, 2013) (hereinafter Special Rapporteur Grover 2013 Report),* <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G13/135/08/pdf/G1313508.pdf?OpenElement>.

medicines lists,²⁸ assuring efficient procurement²⁹ and distribution systems,³⁰ and promoting rational and appropriate use of medicines³¹. Countries must procure medicines in the right quantity and at the best sustainable price, and must also have good distribution systems to ensure that medicines of assured quality are at the right place at the right time in the right quantities. Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their individual requirements, for right period of time, and at the lowest cost to them and their community.

1.2 The human rights duties of pharmaceutical companies

In many ways, the pharmaceutical and biotech industry wield more power with respect to access-to-medicines than do States, especially as States have become captive to corporate interests. Although General Comment 14 primarily addresses the obligations of sovereign States, it also emphasizes that the private business sector has responsibilities regarding the realization of the right to health.³² The obligations of private, for-profit pharmaceutical companies with respect to the right of access-to-medicines was explored at great length by Paul Hunt in his 2008 report. After initially detailing the human rights obligations of both states and pharmaceutical companies with respect to access-to-medicines,³³ he subsequently expanded his analysis of pharmaceutical companies' access-to-medicines responsibilities in his Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.³⁴ Among the most significant guidelines, Special Rapporteur Hunt recommended that pharmaceutical companies increase their research commitments on neglected diseases,³⁵ that they respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public health and further respect for the right of countries to use, to the full, TRIPS flexibilities, including compulsory licensing, parallel importation, and LDC transition periods, and that they should not lobby for TRIPS-plus provisions.³⁶ He urged pharmaceutical companies to grant non-exclusive voluntary licenses, to waive data exclusivity, and to avoid applying for patents in LMICs for insignificant or trivial modifications of existing medicines.³⁷ With respect to pricing for all medicines, including for non-communicable conditions, Special Rapporteur Hunt recommended that pharmaceutical companies use all arrangements that their disposal to ensure that medicines are affordable to as many people as possible, mentioning differential pricing, voluntary licenses, donation programs, and public-private partnerships that take into account a country's state of economic development and differential purchasing power within a country.³⁸

1.3 Right to the benefits of scientific progress and its applications

In addition to codifying the right to health, the ICESCR also codified a right to the benefits of scientific progress in Article 15(1)(b): "State parties to the present Covenant recognize the right of everybody ... to

²⁸ *Id.* ¶¶ 40-46, 73.

²⁹ *Id.* ¶¶ 47-53, 74.

³⁰ *Id.* ¶¶ 54-56, 74; see also Special Rapporteur Hunt 2006 Report, *supra* note 6, ¶¶ 68-70.

³¹ *Special Rapporteur Grover 2013 Report, supra* note 27, ¶¶ 57-60.

³² *Id.* ¶¶ 42, 48 and 64

³³ See *Special Rapporteur Hunt 2006 report, supra* note 6.

³⁴ See *id.*

³⁵ *Id.* ¶¶ 23-25.

³⁶ *Id.* ¶¶ 26-29.

³⁷ *Id.* ¶¶ 30-32.

³⁸ *Id.* ¶¶ 33-35.

enjoy the benefits of scientific progress and its applications [emphasis added].”³⁹ In 2020, Committee on Economic, Social and Cultural Rights drafted a new General Comment 25 elaborating rights under Article 15(1)(b).⁴⁰ General Comment 25 starts by noting: “The intense and rapid development of science and technology has had many benefits for the enjoyment of economic, social and cultural rights. At the same time, the risks – and the unequal distribution of these benefits and risks – have prompted a rich and growing discussion on the relationship between science and economic, social and cultural rights.”⁴¹ States have duties to ensure that scientific progress takes place, that its fruits are widely distributed and are available to vulnerable and marginalized groups, and that open science is promoted, including the publication of publicly funded research results.⁴² “States parties should ensure that everyone has equal access to the applications of science, particularly when they are instrumental for the enjoyment of other economic, social and cultural rights.”⁴³ As is typical in human rights, States have a duty of progressive realization, of taking steps to the maximum of their resources, to support the right to the benefits of science and its applications, and further duties to eliminate all forms of discrimination against individuals and groups in their enjoyment to scientific benefits.⁴⁴

Paragraph 37 has particular poignancy:

As equality is at the core of human rights, States must make every effort to break this vicious circle between substantive inequality and unequal access to the right to participate in and to enjoy the benefits of scientific progress and its applications.

Paragraph 47 clarifies the duty to ensure access to the fruits of science:

The obligation to fulfil is particularly important in creating and guaranteeing access to the benefits of the applications of scientific progress. States should use the maximum of their available resources to overcome hurdles that any person may face to benefit from new technologies or other forms of applications of scientific advancements. This is particularly relevant for disadvantaged and marginalized groups. Scientific progress and its applications should be, as far as possible, accessible and affordable to persons in need of specific goods or services.

There are core obligations to ensure “access to those applications of scientific progress that are critical to the enjoyment of the right to health.”⁴⁵

While admitting that the right to the benefits of science may depend in part research carried out by business enterprises and non-state actors, the General Comment also states “large-scale privatization of scientific research without any other consideration might sometimes have negative effects on the

³⁹ *Id.*

⁴⁰ UN Human Rights Office of the High Commissioner, *General comment No. 25 (2020) on science and economic, social and cultural rights (article 15 (1) (b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights)*, E/C.12/GC/25 (April 30, 2020), <https://undocs.org/E/C.12/GC/25>.

⁴¹ *Id.* ¶ 1.

⁴² *Id.* ¶ 16. “[O]pen science cannot be achieved by the State alone. It is a common endeavour to which all other stakeholders should contribute, nationally and internationally, including scientists, universities, publishers, scientific associations, funding agencies, libraries, the media and non-governmental institutions. All these stakeholders play a decisive role in the dissemination of knowledge, especially when it comes to outcomes of research financed with public funds.” ¶ 49.

⁴³ *Id.* ¶ 17.

⁴⁴ *Id.* ¶¶ 23, 25. States have an obligation to make budgetary allocations to fulfill the right to science, ¶ 46. There are more detailed description of avoiding discrimination against women, persons with disabilities, people living in poverty, and indigenous communities in ¶¶ 28-40.

⁴⁵ *Id.* ¶ 52.

enjoyment of this right.”⁴⁶ Noting that private scientific research has been associated with the development of international and national intellectual property regimes, with some positive effects on stimulating innovation, the General Comment also identifies three negative effects: (1) distortions of funding towards commercially profitable investments only and away from neglected diseases, (2) limitations on the dissemination of scientific information, and (3) high prices arising from the right to exclude competition.⁴⁷ In response to this last problem, States should: prevent “unreasonably high costs for access to essential medicines.”⁴⁸ The State must ensure that the exercise of IP rights are not detrimental to the right to health:

[I]ntellectual property regime should be interpreted and implemented in a manner supportive of the duty of States “to protect public health and, in particular, to promote access to medicines for all”. Thus, States parties should use, when necessary, all the flexibilities of the TRIPS Agreement, such as compulsory licences, to ensure access to essential medicines, especially for the most disadvantaged groups.⁴⁹

Ultimately, the right to the benefits of science and its application is instrumental to the right to health.

States should promote scientific research, through financial support or other incentives, to create new medical applications and make them accessible and affordable to everyone, especially the most vulnerable. In particular, in accordance with the Covenant, States parties should prioritize the promotion of scientific progress to facilitate better and more accessible means for the prevention, control and treatment of epidemic, endemic, occupational and other diseases.⁵⁰

The Special Rapporteur in the field of cultural rights, Farida Shaheed issued two relevant reports interpreting the right to the benefits of science and its applications even before General Comment 25 was issued.⁵¹ In her first report, the Special Rapporteur stressed the strong link of the right to the benefits of scientific progress with the right to participate in cultural life, as well as other human rights. She clarified Article 15(1)(b)’s normative content to include access by everyone without discrimination to the benefits of science and its applications, including scientific knowledge and an enabling environment fostering the conservation, development, and diffusion of science and its related technologies.⁵² Her second report, which has much more direct impact on interplay between the right to the benefit of scientific progress and patent rights, was summarized as follows:

In the report, the Special Rapporteur addresses the implications of patent policy for the human right to science and culture. She reaffirms the distinction to be made between intellectual property rights and human rights, emphasizing that the right to the protection of the moral and material interests of authors does not necessarily coincide with the prevailing approach to intellectual property law. There is no human right to patent protection. The right to protection of moral and material interests cannot be used to defend patent laws that inadequately respect the right to participate in cultural life, to enjoy the benefits of

⁴⁶ *Id.* ¶ 58.

⁴⁷ *Id.* ¶ 61.

⁴⁸ *Id.* ¶ 62.

⁴⁹ *Id.* ¶ 69.

⁵⁰ *Id.* ¶ 67.

⁵¹ Report of the Special Rapporteur on Cultural Rights: *The right to enjoy the benefits of scientific progress and its applications*, Farida Shaheed, A/HRC/20/26 (May 14, 2012) (hereinafter *Special Rapporteur Shaheed 2012 Report*), https://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session20/A-HRC-20-26_en.pdf; *Report of the Special Rapporteur in the field of cultural rights: Cultural Rights*, Farida Shaheed, G.A. A/70/279 (August 4, 2015) (hereinafter *Special Rapporteur Shaheed 2015 Report*), https://www.un.org/en/ga/search/view_doc.asp?symbol=A/70/279.

⁵² *Special Rapporteur Shaheed 2012 Report*, *supra* note 51.

scientific progress and its applications, to scientific freedoms and the right to food and health and the rights of indigenous peoples and local communities.

Patents, when properly structured, may expand the options and well-being of all people by making new possibilities available. Yet, they also give patent-holders the power to deny access to others, thereby limiting or denying the public's right of participation to science and culture. The human rights perspective demands that patents do not extend so far as to interfere with individuals' dignity and well-being. Where patent rights and human rights are in conflict, human rights must prevail.

Whereas from the perspective of trade law, exclusions, exceptions and flexibilities under international intellectual property law, such as the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights, remain optional, from the perspective of human rights, they are often to be considered as obligations.⁵³

Focusing on misuse of patents, the Special Rapporteur for Culture urged the adoption, protection, and use of TRIPS flexibilities.⁵⁴ If nothing else, Special Rapporteur Shaheed has emphasized that the right to the benefit of scientific progress completely reinforces the right of access-to-medicine previously established under the right to health.

1.4 Pfizer's Intellectual property is not a human right

The discussion undertaken by the Special Rapporteur emphasizing the preeminence of human rights over intellectual property necessarily interrogates the claim that IP rightholders have an enforceable human right in their intellectual property,⁵⁵ specifically the right under UDHR Article 27 and ICESCR Article 15(1)(c) to "protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author."⁵⁶ But this IP-as-a-human-right claim is strongly opposed, in substantial part because Article 15(1)(c) must be interpreted in light of Article 15.1(b), discussed above, which recognizes everyone's right "to enjoy the benefits of scientific progress and its applications." Opponents of IP as a human right argue that human rights protection for IP is incompatible with the need to balance the interests of consumers and rights' holders in circumstances where those interests clearly deserve priority, such as ensure access-to-medicines.⁵⁷ Professor Peter Drahos suggests that IP rights are highly distinguishable from fundamental human rights and thus are not subject to the obligation of international human rights enforcement.⁵⁸ This view is supported by the Committee on Social, Economic, and Cultural Rights, which in General Comment 17 took the view that "intellectual property regimes, although they

⁵³ *Special Rapporteur Shaheed 2015 Report*, *supra* note 51.

⁵⁴ *Id.* ¶¶ 63-72, 102-107.

⁵⁵ See Mary Robinson & Kamil Idris, *Foreword* to WIPO and OHCHR, *INTELLECTUAL PROPERTY AND HUMAN RIGHTS*, WIPO Doc. 762(E) (1999) (stating that "[i]ntellectual property rights are enshrined as human rights in the [Universal Declaration on Human Rights]."); Ruth L. Okedifi, *Does Intellectual Property Need Human Rights?*, 51 J. INT'L L. & POL. 1, 18 (2018) ("To the extent other provisions in international human rights instruments purport to place limits on the scope and exercise of IP rights, those limits certainly have not displaced the political, moral, or legal premium associated with the unequivocal recognition of authorial interests found in Article 15 of the ICESCR and Article 27 of the UDHR.").

⁵⁶ Arts 27(2) of UDHR, *supra* note 1, and 15(1)(c) of ICESCR, *supra* note 3.

⁵⁷ See Peter K. Yu, *Reconceptualizing intellectual property interest in a human rights framework*, 40 U. CAL. (DAVIS) L. REV. 1039 (2007); Duncan Matthews, *Intellectual property rights, human rights and the right to health* in *INTELLECTUAL PROPERTY RIGHTS AND HUMAN RIGHTS: A PARADOX*, 118 (Edward Elgar ed. 2010); Smita Narula, *The rights-based approach to intellectual property and access to medicines: Parameters and Pitfalls* in *BALANCING WEALTH AND HEALTH: GLOBAL ADMINISTRATIVE LAW AND THE BATTLE OVER INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES IN LATIN AMERICA* (Rochelle Dreyfuss and César Rodríguez Garavito, eds. 2014); Stephen P. Marks, *Access to essential medicines as a component of the right to health* (2009), https://cdn1.sph.harvard.edu/wp-content/uploads/sites/580/2012/10/marks_access_to_essential_medicines-2009.pdf.

⁵⁸ Peter Drahos, *The universality of intellectual property rights: Origins and development*, (1998), https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf

traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments,” and thus fall outside the ambit of human rights protection.⁵⁹ According to General Comment 17, the material interests of authors and other creators must be protected, but the precise form of that protection is unspecified – but “need not necessarily reflect the level and means of protection found in present copyright, patent and other intellectual property regimes”⁶⁰ Although States can adopt higher levels of protection of moral and material interests in their domestic laws, they cannot enact standards that “unjustifiably limit the enjoyment by others of their rights under the Covenant,” including the right to health.⁶¹ Accordingly, Article 15.1(b) should always be interpreted to prioritize human rights over property rights.⁶² In further support of this interpretation, WTO Member States have unanimously agreed that the TRIPS Agreement should be interpreted “in a manner supportive of WTO members’ right to protect the public health and, in particular, to promote *access-to-medicines for all* (emphasis added).”⁶³ In addition, commentators,⁶⁴ agreeing with General Comment 17, reject the view that IP rights are human rights and argue that IP rights have lesser normative weight in international law than human rights, including the right of access-to-medicines.

1.5 ONAPI should ensure the availability, accessibility, and affordability of nirmatrelvir + ritonavir by granting KEI’s compulsory licensing petition

As discussed extensively above, governments must assure that medicines are available, physically and economically accessible (affordable), acceptable, and of assured quality.⁶⁵ Medicines must be made equitably available on a non-discriminatory basis,⁶⁶ and that non-discriminatory basis includes poverty.⁶⁷ State have a core duty to make essential medicines available immediately, to add priority medicines as appropriate to their essential medicines list, to progressively provide access even to non-essential medicines to the maximum of their ability, and to adopt appropriate treatment guidelines. They must regulate the activities of private companies to prevent human rights violations with respect to access-to-medicines. In sum, they must respect, protect, and fulfil the right to medicines.

The COVID-19 pandemic, however, is teaching us new lessons. Not only do patent rights and data exclusivities lead to high prices, they also lead to artificially limited supply. Although vaccine and medicines developers are taking steps to increase their production capacity and are entering into agreements with contract manufacturing organizations, they are studiously avoiding efforts to more broadly license their medicines to all qualified generic and biosimilar companies. In the wake of anticipated shortages, we are experiencing an explosion of vaccine and therapeutics nationalism by the U.S., U.K., European Commission, and other rich countries that have entered into preferential advance

⁵⁹ Committee on Economic, Social and Cultural Rights, General Comment No. 17, *The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author (article 15, paragraph 1 (c), of the Covenant)*, E/C.12/GC/17, ¶¶ 1, 2, and 3 (January 12, 2006) (hereinafter General Comment 17), <https://www.refworld.org/docid/441543594.html>.

⁶⁰ *Id.* ¶ 10.

⁶¹ *Id.* ¶ 11.

⁶² See Philippe Cullet, *Patents and medicines: The relationship between TRIPS and the human right to health*, J. INT’L AFFAIRS 139, 159 (2003).

⁶³ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, ¶ 4 (Nov, 2001).

⁶⁴ See discussion in Holger Hestermeyer, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES (2007).

⁶⁵ See e.g., General Comment 14, *supra* note 4, ¶ 12.

⁶⁶ *Id.* ¶¶ 18-27.

⁶⁷ *Id.* ¶ 12(b); *Special Rapporteur Hunt 2006 Report*, *supra* note 7, ¶¶ 38, 49, 52.

purchase agreements locking up initial supplies of Pfizer's Paxlovid. Once again, the risk is that the Global South in general and the Dominican Republic in particular will be left behind.⁶⁸

2. Pfizer's patent rights are not fundamental, ab initio they were subject to the Republic's right to issue compulsory licenses

Pfizer argues in paragraph 25 of its opposition that "article 52 of the Political Constitution establishes: 'Right to intellectual property. The exclusive property right of scientific, literary, artistic works, inventions and innovations, denominations, trademarks, distinctive signs and other productions of the human intellect are recognized and protected, for the time, and in the manner and with the limitations established by law.'" Then it blithely argues, without merit, that the clause "with the limitations established by law" has no real meaning and that it is only truly exceptional circumstances that allow derogation of patent rights to any degree whatsoever. However, the compulsory licensing provisions in Articles 46 and 47 of the Law 20-00 were in full effect as "limitations established by law" when Pfizer filed for patent protection. According to Pfizer's logic, nothing could ever be done by the government of the Dominican Republic that would adversely affected Pfizer's patent rights in Paxlovid, not just with respect to a compulsory license but in any respect whatsoever. There could be no price controls, there could be no mandatory disclosure controls, there might not even be any regulatory controls. Get a patent, according to Pfizer and it has a carte blanche except in rare and extreme circumstances where the limitation is "fully justified and necessary, and [only] as long as there are no other reasonable ways to achieve the objectives that are invoked for limitation." We already know that the government must act so as to protect and fulfill the rights to health, medicines, and scientific progress, but according to Pfizer those rights could never match its fully justified/necessity standard.

Contrary to Pfizer's interpretation, its patent rights have been circumscribed by general laws, not just in the Dominican Republic but everywhere in the world. The length of the patent is circumscribed with no separate constitutional requirement of full justification and necessity to establish that a 20-year term is more necessary and justified than a 21-year term. There are standards of patent eligibility and disclosure. There are patent filing requirements and fees. There are research rights, early-working rights, prior use rights, and many other limited exceptions and exclusions. In Pfizer's IP fairy land, however, IP rights are so "fundamental" that every single time limitation, manner of recognition and enforcement, and limitation established by law must be rigorously and ruthlessly forced through the eye of two needles.

3. Pfizer has duplicitously provided for a compulsory licensing exception to territorial limitations in its license with the MPP, but then challenged the Dominican Republic's right to issue a properly motivated compulsory license

The Petitioner has already pointed out the relevant provisions of Pfizer's license with the Medicines Patent Pool authorizing its sublicensees to supply nirmatrelvir + ritonavir to countries that issue compulsory licenses, so this Amicus Brief will not repeat Petitioner's argument. However, it is important to emphasize that even though allowance of supply pursuant to a compulsory license is a routine requirement of MPP licenses, Pfizer freely entered into its voluntary license with this clause. At the very least, this clause represents implied consent to countries and applicants to pursue compulsory licenses in good faith and that Pfizer will respect their rights to do so.

⁶⁸ Andrew Green, *The Looming COVID-19 Treatment Equity Gap*, DEVEX (March 10, 2022), <https://www.devex.com/news/the-looming-covid-19-treatment-equity-gap-102816>.

Despite this implied consent, Pfizer now launches a blistering attack on the Petitioner's application, challenging it on every conceivable ground while misinterpreting Dominican Republic law in the process. It argues – preposterously – that compulsory licenses are only justified in situations of extraordinary and very serious crisis (paragraph 28), a proposition directly contrary to Article 31 of the TRIPS Agreement and the Doha Declaration, both of which clearly allow countries to define grounds for compulsory licenses and list emergencies and matters of extreme urgency only with respect to relaxing a procedural requirement. Pfizer borrows and misapplies the “states of exceptions” rule from international human rights jurisprudence, citing no Dominican Republic law in support of its application to compulsory licenses.

Pfizer's scorched earth opposition to the compulsory license petition is at the very least in bad faith and more probably duplicitous given its voluntary license with the MPP and its sublicensees.

4. Pfizer's purposeful misinterpretation of the relationship between “public interest” compulsory licenses and “emergency and national security” licenses requiring a declaration by “Executive Power” should be rejected.

Pfizer's central argument seeking to derail the compulsory licensing application is found in Paragraph 30 of its Opposition:

The petitioner incorrectly argues: “COVID-19 is a public interest ground under article 46 of the Law 20-00.” That statement is incorrect because said article 46 clearly indicates that the reasons of “(...) public interest, and in particular for reasons of emergency or national security...” must be so declared by the Executive Power. That is, it is not up to ONAPI to make these declarations, nor to make an assessment of what should be considered as “public interest, and in particular, for reasons of emergency or national security”, but it is up to the competent authority to do so (the Executive Power) and, in that case, to ONAPI to determine, in response to a request for a compulsory license, whether or not a declaration in the sense indicated is valid or not and that such a state of exception is linked to the invention for which the compulsory license is requested; and, if “public interest” is invoked, that there is a specific declaration regarding that invention and the corresponding patent (if granted) or patent application.

Pfizer's central error is its misreading of the relevant statutory provision. Law 20-00 contemplates a broad public interest ground for a compulsory license while recognizing special public interest grounds arising from a declared national emergency or national security crisis. The construction of the operative sentence itself defines public interest grounds, and in a separate clause describe the “particular” circumstances of emergency or national security declared by the “Executive Power.” The required of Executive Power declaration does not apply the more general and broader public interest ground, but only to the special emergency and national security grounds established by constitutional or legislative grant in the Dominican Republic and most other countries in the world. Although the parliament may well have been concerned with not wanting ONAPI to be in the position of declaring national emergencies or national security crises, there is no such concern with respect to the broader “public interest” grounds treatment separately in Article 46.

It is quite common for there to be multiple stated grounds for compulsory licenses in national legislation and it is perfectly permissible for one of them to be the “public interest,” which give governments maximum flexibility. It is worth repeating that Article 31 of the TRIPS Agreement places no limitations whatsoever on WTO Members' right to define the grounds for compulsory licenses including with respect to the public interest. The World Intellectual Property Office has conducted a survey of countries about

their grounds for compulsory and government use licenses.⁶⁹ It is worth quoting WIPO's report at some length.

Promoting the public interest at large

9. Many other Member States in describing the public policy objectives of the compulsory licensing provisions, as provided in their applicable laws, focused on the interest of the State or the public at large, which are described as, for example, "public interest and interest of society", "public interest considerations", "urgent needs of the society", "development of the economy and the well-being of the society", "vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the country's needs" and "situations of public interest and emergency motivated by considerations of public health, nutrition and national security".⁷

10. The response from Cyprus highlighted the importance of using patents "in order to encourage innovation and the further advancement of science and technology by other interested persons" and to "promote trade and to boost the economy of [the] country by using patents as a source of potential income not only to the patentees but also to the whole of [the] country". The response of Netherlands stated that in the case of "exceptional circumstances and national security [...], the right of the patentee should be put aside", it also noted that "innovation would be hampered if a patent holder could prevent, by not providing licenses [for dependent patents], the use and further improvements of an invention".

11. Many Member States pursued multiple policy objectives through provisions on compulsory licenses, including the above. For example, the response from Portugal stated that policy objectives of the compulsory licensing provisions were "to avoid abuse of the monopoly [...]; to avoid obstacles to technological and economical development; to promote public health; to guarantee national security". In the response from China, it was stated that the policy objectives of the exception were "to prevent right holders from abusing their rights, to promote application of inventions and creations, to guarantee the normal operation of the patent system, and to safeguard the interests of the State and the public". Similarly, the response from Mexico noted that such objectives were: "to avoid misuse on behalf of patent owners, [...] [to] contribute to the transfer and dissemination of technology [...]. The use of the technology for the benefit of the economy and [...] the preservation of national health and security as the supreme interest above and beyond all the rights of the patent owner".⁸

12. Some other Member States also highlighted that the policy objectives for compulsory licenses included access to products and "consumer protection" so that the "businesses and consumers have reasonable access to patented products at reasonable prices" and products were "available to potential users".⁹ The response from the United Kingdom stated that the compulsory licensing provisions, inter alia, could act as "an incentive for parties to negotiate and agree voluntary licensing agreements rather than go through what is essentially inter partes

⁶⁹ WIPO Standing Committee on the Law of Patents, *Exceptions and Limitations to Patent Rights: Compulsory Licenses and/or Government Use*, SCP/21/4 REV (2014), https://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_4_rev.pdf.

litigation in order to attempt to obtain a compulsory license” which could “prevent or repress anti-competitive behavior”.

13. Some Member States (or territories) also noted specific public policy objectives on public health. Hong Kong (China) referred to the specific policy objectives which were “to make use of the system under the Protocol amending the TRIPS Agreement (adopted by the General Council of the WTO on December 6, 2005) to import medicine” and to “export pharmaceutical products to other WTO Members” in situations of a national emergency or other circumstances of extreme urgency. Similarly, the response from Canada stated the policy objective was to “to give effect to Canada’s and Jean Chrétien’s pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”¹⁰ The response from a few Member States, in responding to the question on public policy objectives, referred in general to obligations under the TRIPS Agreement and/or EU directives.¹¹

7. See, for example, responses from Burkina Faso, Congo, Gambia, Honduras, Hungary, Poland, the Republic of Belarus, the Russian Federation, the South Africa, Spain, the United Kingdom, Viet Nam and Zambia. See also responses submitted by France (stating that “the patentee’s monopoly may be restricted by economic or social imperatives of general interest, which are considered more important”), Norway (stating that “the main objective is to meet important public interests. The patented invention should benefit the technical development and society.”), Pakistan (stating that the objective of the compulsory license is “to curb monopolization and cartelization and to safeguard the national interest”) and the United Kingdom (stating that the objective is “to prevent the monopoly conferred by the patent working against the public interest. The Patents Act 1977 provides for the granting of compulsory licences as a way of correcting or remedying problems where certain conditions in the market are not being met or where licences are available but only under unreasonable terms.[...]”).

8. Some other Member States also indicated multiple public policy objectives for the provision of compulsory licensing provisions in their laws, for example, see responses to question 68 of the Questionnaire from Djibouti, India, Poland and the Russian Federation.

9. See, for example, the responses from Netherlands, Serbia and Sri Lanka.

10. The reference was made to sections 21.02 to 21.2 of Patent Act of Canada. See also the response from Jordan.

11. See responses of Israel, Latvia, Lithuania, Netherlands and Turkey to question 68 of the Questionnaire.

For Pfizer to suggest that there is something unusual in the Dominican Republic’s articulation of the “public interests” as grounds for a compulsory license is laughable. Even more so is its suggestion that it might be common practice to require a two-step process before invoking the public interest when applying for a compulsory license. No such two-step process is required by the TRIPS Agreement. Although a few countries listed in its opposition have required prior declaration, there is no such explicit requirement in the Dominican Republic’s law. In this regard, it is important to note that U.S. law has no such declaration requirement for the issuance of a government use license under 28 U.S.C. section 1498(a).⁷⁰

⁷⁰ Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner’s reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity

Conclusion:

For the above-stated reasons, the Amicus recommends the Petitioner's compulsory license request be granted.

Respectfully submitted,



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that had no more than 500 employees at any time during the 5-year period preceding the use or manufacture of the patented invention by or for the United States. Notwithstanding [1] the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust. For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.