

UNITED NATIONS SECRETARY-GENERAL'S  
**HIGH-LEVEL  
PANEL ON ACCESS  
TO MEDICINES**



**BACKGROUND PAPER:**

**International legal norms:  
the right to health and  
the justifiable rights of inventors**

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## Introduction

The challenge before the United Nations Secretary-General’s High-Level Panel on Access to Medicines (‘the Panel’) is to “make recommendations that: (a) remedy the policy incoherence between *international human rights law* and *trade rules* in the context of *access to health technologies*; and (b) achieve a better balance of the *justifiable rights of inventors*, *the right to health* and sustainable development” [emphasis added].<sup>1</sup> Given that the Panel will consider and assess various proposals on how to pursue and achieve this goal, it was agreed by Panel members during its first meeting in New York on 11-12 December 2015 that a clearer sense was needed as to the meaning and application of these key legal concepts. To that end, this background document has been prepared in an effort to provide more information on the legal meanings and relative weight of ‘rights of inventors’ and the ‘right to health’.

This background document, therefore, provides an overview of the provisions of international law relating to access to medicines and other health technologies, and to intellectual property (IP), in the domains of both human rights law and trade law. **Part A of this background paper explores the applicable standards in international human rights law related to access to medicines and other health technologies.** The focus in this paper is specifically on the key provisions of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR), the foundational embodiment of the right to the highest attainable standard of health in international law. **Part B then turns to relevant provisions of international law regarding intellectual property rights.** First, it looks at the standards on inventors’ rights articulated in international human rights law (again, the ICESCR specifically). Then it examines the *WTO Agreement on Trade-related Aspects of Intellectual Property Rights* (TRIPS) as the current, most widely ratified exemplar of trade rules on intellectual property (IP), while noting that more extensive, “TRIPS-plus” standards are being pursued in various other agreements or are sometimes demanded of, or adopted by, countries in practice. Finally, having reviewed the aspects of international human rights and international trade law relevant to access to health technologies and inventors’ rights, **Part C presents a brief overview of their relationship within the broader structure of international law.**

## Part A: Access to medicines as a human right in international law

Human rights standards relevant to the right to health — including the specific element of access to health technologies — are articulated in international law with varying degrees of precision and varying degrees of legal weight. The obligation of states to protect and promote health goes back to the

original founding of the United Nations,<sup>2</sup> and its character as a *human rights* obligation has been repeatedly reaffirmed by states themselves by way of numerous treaties and declarations, including the WHO Constitution (adopted mere days before the UN Charter and declaring that “enjoyment of the highest attainable standard of health” is a “fundamental right”),<sup>3</sup> the *Universal Declaration of Human Rights* (UDHR) (adopted the year the WHO Constitution entered into force),<sup>4</sup> and the *International Covenant on Economic, Social and Cultural Rights* (ICESCR).<sup>5</sup> Other core human rights treaties *in the UN system* also contain relevant, binding obligations on states. For example, the right to life (under Article 6 of the UN’s *International Covenant on Civil and Political Rights*) requires states to take positive measures to reduce infant mortality and increase life expectancy, especially in adopting measure to eliminate epidemics,<sup>6</sup> while health-related human rights obligations also arise under UN human rights treaties regarding specific populations (e.g., children, women, racialized groups or persons with disabilities).<sup>7</sup> Various *regional* human rights treaties and related instruments also contain formulations of the right to health as treaty obligations assumed by states parties.<sup>8</sup> The “hard” law of these binding treaty obligations is supplemented by “soft” law norms, which include non-binding instruments adopted by states, as well as authoritative interpretations of states’ treaty obligations by expert committees (known as “treaty bodies”), as well as the expert opinions of special rapporteurs and independent experts — all of which mechanisms and procedures are given the mandate by states to provide this guidance in the interpretation and implementation of those treaty obligations. For the purposes of the Panel’s task, the substance of those obligations can be outlined by reference to the two most relevant provisions of the ICESCR, namely the rights of everyone:

- to enjoy the **highest attainable standard of physical and mental health** (“the right to health”), pursuant to Article 12; and
- to enjoy the **benefits of scientific progress and its applications**, pursuant to Article 15.1(b) (“the right to science”).

### The right to health and access to medicines

While the UDHR (Article 25) guarantees the right to a standard of living adequate for health and well-being, including medical care, the ICESCR represents the clearest, fullest articulation, in a legally binding international treaty, of the right to health in international law and the corresponding obligations of States.



For the Panel’s purposes, the key provisions of the ICESCR establishing the right to health, including access to health technologies as a component of that right, read as follows:

#### **Article 12**

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... infant mortality and for the health development of the child; [...]*
  - (b) *the prevention, treatment and control of epidemic, endemic, occupational and other diseases;*
  - (c) *the creation of conditions which would assure to all medical service and medical attention in the event of sickness.*

This article has been the subject of considerable commentary and interpretation through various mechanisms, including the UN Committee on Economic, Social and Cultural Rights (‘the Committee’), the body of independent experts tasked by Member States with defining the normative content of the rights in the Covenant. This includes the elaboration of General Comments, which provide persuasive and authoritative analysis on the nature and content of the rights described in the Covenant. In its *General Comment No. 14* on the right to health, the Committee has laid out the most authoritative interpretation by expert jurists of ICESCR. Article 12 — including recognizing access to medicines, and particularly to essential medicines, as a fundamental element of the right to the highest attainable standard of health.<sup>9</sup> As the Committee has outlined, this entails at least **four essential elements** – states must ensure medicines are *available* in sufficient quantity; *accessible* (including economically); *acceptable* (including medically and culturally); and of good *quality*.<sup>10</sup> Furthermore, in accordance with the well-established **tripartite typology of legal obligations** applicable to all rights in the ICESCR, the state must:

- *respect* the right to health, which includes refraining from denying or limiting equal access for all persons;
- *protect* the right to health by taking legislative and other measures against violation by third parties; and
- *fulfil* the right, including through the adoption of appropriate legislative, administrative, budgetary, judicial, promotional and other measures.<sup>11</sup>



In addition, states have the legal obligation to take steps, including through “**international assistance and cooperation**,” to fully realize the right to health on a global scale.<sup>12</sup>

Human rights law recognizes that the full achievement of all rights requires time and resources. Nonetheless, there is a legal obligation of “**progressive realization**”: each state party must “take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.”<sup>13</sup> The Committee has underscored that this means “States parties have a specific and continuing obligation to move as expeditiously as possible towards the full realization of article 12 [the right to the highest attainable standard of health].”<sup>14</sup>

Another key norm of particular relevance to the adoption by states of intellectual property provisions, including through trade agreements, is that there is a “strong presumption that **retrogressive measures** taken in relation to the right to health are not permissible. If any deliberately retrogressive measures are taken, the State party has the burden of proving that they have been introduced after the most careful consideration of all alternatives and that they are duly justified by reference to the totality of the rights provided for in the Covenant in the context of the full use of the State party’s maximum available resources.”<sup>15</sup>

Notwithstanding that the right to health can only be realized progressively over time, the Committee has identified that there are nonetheless, several “**core minimum obligations**” of the right to health that are non-derogable and immediately binding on states. Of most direct relevance to the discussion at hand, these include *inter alia* the obligations:

- “to ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalized groups;
- to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;
- to ensure equitable distribution of all health facilities, goods and services; and
- to adopt and implement a national public health strategy and plan of action... [which] shall be devised, and periodically reviewed, on the basis of a participatory and transparent process; they shall include methods, such as right to health indicators and benchmarks, by which progress can be closely monitored; the process by which the strategy and plan of action are devised, as well as their content, shall give particular attention to all vulnerable or marginalized groups.”<sup>16</sup>



Similarly the Committee has noted that of “comparable priority” to these core minimum obligations are states’ obligations “to ensure reproductive, maternal and child health care;” “to provide immunization against the major infectious diseases occurring in the community;” and “to take measures to prevent, treat and control epidemic and endemic diseases.”<sup>17</sup> Naturally, making good-quality, acceptable health technologies available and accessible is key to states respecting, protecting and fulfilling both these *core minimum* and *comparable* obligations.

As the Committee emphasizes, it is also an obligation “of comparable priority,” not only for States Parties but also “**other actors in a position to assist,**” to provide “international assistance and cooperation, especially economic and technical” (per ICESCR Article 2) which “enable developing countries to fulfil their core and other [comparable] obligations.”<sup>18</sup> Applying this obligation specifically in the context of intellectual property, the Committee has subsequently explained that “it is incumbent upon developed States, and other actors in a position to assist, to develop international intellectual property regimes that enable developing States to fulfil at least their core obligations to individuals and groups within their jurisdictions.”<sup>19</sup> This encompasses the core obligation to ensure access at least to essential medicines.

The Committee also identifies various ways in which states (and others) may **violate the right to health**, contrary to their ICESCR treaty obligations. Of particular relevance to the Panel’s mandate are the following points:

- As noted above, as a *general* rule, because there is an obligation to move progressively toward full realization of the right to health, retrogressive measures are presumptively illegal – but may be justifiable by the state in some circumstances. But the Committee has further specified that no retrogression is permissible at all vis-à-vis core obligations “[t]he adoption of any retrogressive measures incompatible with the core obligations under the right to health, outlined in paragraph 43 above, constitutes a violation of the right to health. Violations through acts of commission include... the adoption of legislation or policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health.”<sup>20</sup>
- The obligation to respect the right to health is violated by State actions, policies or laws that “contravene the standards set out in Article 12 of the Covenant and are likely to result in bodily harm, unnecessary morbidity and preventable mortality. Examples include... the adoption of laws or policies that interfere with the enjoyment of any of the components of the right to health, and the failure of the State to take into account its legal obligations regarding the right

to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations.”<sup>21</sup>

- The obligation to protect the right to health is violated by the “failure of a State to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties.” This includes such omissions as “the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others; [and] the failure to protect consumers... from practices detrimental to health, e.g.,... by manufacturers of medicines...”<sup>22</sup>

In addition to developing the normative content of States’ right to health obligations under the ICESCR, the Committee has begun to articulate what states’ human rights obligations regarding health (including access to medicines) mean — and do not mean — vis-à-vis intellectual property policy. So, too, have the UN High Commissioner for Human Rights,<sup>23</sup> and the independent human rights experts given this mandate by UN Member States – in particular the UN Special Rapporteurs on the right to health<sup>24</sup> and in the field of cultural rights. (See more detail about the latter in Part B below.)

It is also important to note that **States themselves have recognized their specific obligation to promote access to medicines** in various ways. More than 100 countries have provisions in domestic laws regarding the right to health in some form, and in numerous instances those domestic provisions, often alongside international human rights instruments, have been used by courts in ordering remedies to improve access to medicines.<sup>25</sup> In international fora, states have repeatedly reaffirmed the right to health, including access to medicines as a component thereof. This includes resolutions of the UNESCO General Conference,<sup>26</sup> the World Health Assembly<sup>27</sup> and the UN General Assembly.<sup>28</sup>

More specifically in the human rights realm, resolutions adopted by Member States of the former UN Commission on Human Rights (replaced by the UN Human Rights Council in 2006) have repeatedly “recognize[d] that access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the highest attainable standard of physical and mental health.”<sup>29</sup> Among other things, those resolutions have also called upon states “to pursue policies, in accordance with applicable international law, including international agreements acceded to, which would promote” access for all to medicines used to treat pandemics such as HIV/AIDS and accompanying opportunistic infections, as well as to “refrain from taking measures” which limit access and to “adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such... pharmaceuticals or medical technologies from any limitations by third parties.”<sup>30</sup>



Subsequently, in the UN Human Rights Council, Member States have continued to adopt resolutions affirming access to medicines as a fundamental component of the right to health – and furthermore have (i) broadened this beyond simply the context of pandemics such as HIV/AIDS and (ii) urged states to use flexibilities in the WTO’s TRIPS Agreement as part of realizing the right to health.<sup>31</sup> This has been reiterated by Member States in their most recent Political Declaration on HIV/AIDS.<sup>32</sup>

In the context of *non-communicable diseases* (NCDs), Member States of the UN General Assembly have reaffirmed the right to the highest attainable standard of health, and committed themselves to implementing policies and plans to improve and sustain access to “affordable, safe, effective and quality medicines and diagnostics and other technologies, including through the full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities.”<sup>33</sup> The General Assembly has highlighted the value of participation of affected communities in decision-making towards this goal, committing to take steps to “[e]ncourage alliances and networks that bring together national, regional and global actors, including academic and research institutes, for the development of new medicines, vaccines, diagnostics and technologies, learning from experiences in the field of HIV/AIDS, among others, according to national priorities and strategies”.<sup>34</sup>

### The right to benefit from scientific progress

From the outset, the body of modern international human rights law crafted by states has recognized the right “to share in scientific advancement and its benefits” (UDHR, Article 27). As with the right to health, this has been further entrenched as a treaty obligation in the ICESCR: Article 15.1(b) recognizes “the right of everyone...to enjoy the benefits of scientific progress and its applications.” In addition, the Covenant stipulates the accompanying obligation of States Parties to promote the development and diffusion of science (Article 15.2), and States Parties explicitly recognize the benefits to be derived from encouraging and developing international scientific cooperation (Article 15.4). While the normative content of the “right to science” as articulated in the UDHR and the ICESCR has been less well defined than many other rights, including the right to health, there are some important instruments and analyses that have been developed within particularly the last decade as to what obligations for states (and others) the right entails. It is noteworthy that much of this normative definition has taken place since the advent of the WTO in 2004, which represents the first truly global trade regime setting out minimum IP standards in relation to health technologies (the TRIPS Agreement), that are binding on the majority of the world’s states (by virtue of their status as WTO Members).

The work to define the right to benefit from scientific progress has been undertaken both by states themselves and by independent experts. In the *Universal Declaration on Bioethics and Human Rights* (UDBHR, 2005), an authoritative but non-binding interpretation of international law, UN Member States unanimously affirmed that “taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being..., progress in science should advance: (a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good.”<sup>35</sup>

In keeping with the obligation of international assistance and cooperation recognized in the ICESCR (Article 2, noted above), in the UDBHR, Member States further addressed the “sharing of benefits” as follows:

**Article 15.1:**

*Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:*

- (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;*
- (b) access to quality health care;*
- (c) provision of new diagnostic and therapeutic modalities or products stemming from research;*
- (d) support for health services;*
- (e) access to scientific and technological knowledge;*
- (f) capacity-building facilities for research purposes;*
- (g) other forms of benefit consistent with the principles set out in this Declaration.*

The UN Special Rapporteur in the field of cultural rights has also taken up the task of considering what is meant by the “right to science,” as part of her mandate from Member States via the UN Human Rights Council. She has observed that formulations of the right to benefit from scientific progress similar to that found in the UDHR and ICESCR, as well as similar affirmation of the obligations of international cooperation in relation to the benefits of science, are also to be found in other UN declarations<sup>36</sup> and in regional human rights instruments.<sup>37</sup> She has also noted that the right to benefit from scientific progress has also been applied by domestic courts in some instances in compelling state action to ensure access to affordable medicines.<sup>38</sup>



While there has not yet been any general comment from a UN human rights treaty body regarding the right to science, UN Special Rapporteurs have recognized the applicability of this right as complementary to the rights to food<sup>39</sup> and to health<sup>40</sup> that are also recognized in the UDHR and ICESCR. Most recently and directly, the UN Special Rapporteur in the field of cultural rights has also produced a number of expert analyses exploring the various elements of the right to science, informed by dialogue with Member States, UN and other international organizations, jurists and civil society organizations. In particular, in her first report on the subject (in 2012), the Special Rapporteur noted that the normative content of the right to benefit from scientific progress and its applications includes both “access to the benefits of science by everyone, without discrimination,” as well as “an enabling environment fostering the conservation, development and diffusion of science and technology.”<sup>41</sup>

With regard to the former (i.e., the question of access), the Special Rapporteur:

- observed that “affordability is crucial and may require delinking research and development costs from product prices, as proposed by the World Health Organization in its global strategy and plan of action on public health, innovation and intellectual property;”<sup>42</sup>
- highlighted models for financing and market-shaping such as the International Drug Purchase Facility (UNITAID) and its Medicines Patent Pool to improve access to medicines and create incentives for developing new treatments;<sup>43</sup> and
- noted that existing “minimum standards of protection” under intellectual property treaties, and proposals for surpassing those, may not always be compatible with human rights standards and this should be assessed.<sup>44</sup>

With regard to the latter question (i.e., the development and diffusion of science), the Special Rapporteur has observed this demands state commitments through such things as national programs of action to strengthen publicly-funded research and to develop partnerships with private enterprises and other actors.<sup>45</sup> The Special Rapporteur has also noted the importance of States taking measures to influence the actions of private actors for better realization of the right to science, including through various policies regarding the licensing of intellectual property with a view to ensuring more equitable access to science and its applications, including health technologies.<sup>46</sup>

## Part B: The rights of inventors in international law

This Part of this background paper first examines the rights of inventors under international human rights law, identifying the nature of the moral and material rights to which inventors are entitled under

human rights law, as well as distinguishing the definition of ‘inventors’ in human rights law (referred to as “authors” in the relevant instruments) from the status of being the holder of an intellectual property right under intellectual property law. It then outlines the basic legal norms of intellectual property, in particular exclusive patent rights as set out in international trade law treaties (using the WTO TRIPS Agreement as the principal example).

## Rights of inventors in international human rights law

International human rights law recognizes the human rights of inventors. Article 27 of the UDHR is the original reference, which is then repeated essentially verbatim as a treaty obligation in the ICESCR as follows (notably, in the same article recognizing the right to benefit from scientific progress):

### Article 15

1. *The States Parties to the present Covenant recognize the right of everyone:*

...

*(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*

In fleshing out the interpretation of this provision of the ICESCR, the Committee first issued, in 2001, a *Statement on Human Rights and Intellectual Property*, following a general day of discussion among Member States, UN entities and experts, and civil society organizations.<sup>47</sup> Building on that statement, in 2006, the Committee published a lengthier, more detailed *General Comment 17* on the normative content of this provision, “with a view to assisting States parties’ implementation of the Covenant.” (As described above, General Comments provide persuasive and authoritative analysis on the nature and content of the rights described in the Covenant.) As the Committee observed in that General Comment, the ICESCR recognizes “the right of authors to benefit from some kind of protection of the moral and material interests resulting from their scientific... productions, without specifying the modalities of such protection,” and the protection required under international human rights law such as ICESCR Article 15 “need not necessarily reflect the level and means of protection found in present copyright, patent and other intellectual property regimes, as long as the protection available is suited to secure for authors the moral and material interests resulting from their productions.”<sup>48</sup>

In its *General Comment 17*, the Committee also clarified that the purpose of protecting “**moral interests**” is to “proclaim the personal character of every creation of the human mind and the ensuing durable link between creators and their creations,” and therefore the “moral interests in the ICESCR include “the right of authors to be recognized as the creators of their... productions and to object to



any distortion, mutilation or other modification of, or other derogatory action in relation to, such productions, which would be prejudicial to their honour and reputation.”<sup>49</sup> With reference to other provisions in international human rights law regarding the right to own property and the right of every worker to adequate remuneration, the General Comment also identified that the purpose of protecting the “**material interests**” of inventors is to enable an adequate standard of living for the author — which, the Committee noted, could be achieved in different ways, including one-time payments to the author or vesting the author, for a limited period of time, with the exclusive right to exploit the production.<sup>50</sup>

Importantly, as the word “author” in ICESCR Article 15.1(c) refers exclusively to **natural persons**,<sup>51</sup> a company that has acquired the legal rights to the product or process created by the innovation of a natural person cannot enjoy, *as a matter of human rights law*, the moral and material interests which may result from a patented invention. A company may, of course, have a legal claim, under relevant provisions of intellectual property law, to profits generated from the use and sale of that invention as property that it has acquired, but as noted by the Committee, there is no human right of the company to any particular form of protection for such material interests.

In light of these and other considerations, in *General Comment 17*, the Committee clarified the fundamental **distinction between the human rights of inventors and legal rights related to intellectual property**:

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 is a human right, which derives from the inherent dignity and worth of all persons. This fact distinguishes article 15, paragraph 1 (c), and other human rights from most legal entitlements recognized in intellectual property systems. **Human rights are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances, groups of individuals and communities.** Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.

**In contrast to human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else.** While under most intellectual property systems, intellectual property rights, often with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas the human



right to benefit from the protection of the moral and material interests resulting from one's scientific, literary and artistic productions safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments. **Moreover, the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.**

**It is therefore important not to equate intellectual property rights with the human right recognized in article 15, paragraph 1 (c) [of the ICESCR]. [...]<sup>52</sup>**

Since the Committee's initial Statement in 2001, and its subsequent *General Comment 17* in 2006, the UN Special Rapporteur in the field of cultural rights, appointed by Member States of the UN Human Rights Council in 2009, has taken up the task of fleshing out the human "right to science," a short-hand phrase that encompasses the right to benefit from scientific progress, as guaranteed both in UDHR Article 27.1 and ICESCR Article 15.1(b). In her 2015 report to the UN General Assembly, which examined the implications of patent policy for the right to science, she underscored the propositions that the ICESCR "does not recognize a human right to protection of intellectual property along the lines set out by intellectual property treaties," and that "[t]he entitlements of legal entities under the intellectual property treaties, because of their different nature, are not protected at the level of human rights."<sup>53</sup> The Special Rapporteur also concluded that:

"the obligations of States under intellectual property treaties must not jeopardize the implementation of their obligations under human rights treaties. Implementing unreasonably strong patent protection may constitute a violation of human rights.[...]<sup>54</sup>

There is no human right to patent protection under Article 15 of the International Covenant on Economic, Social and Cultural Rights. This provision does not obligate States parties to enact any particular form of patent protection. Patents are one policy tool among many for encouraging innovation and technological research and development... Human rights law operates as a limit to prevent the overreaching of economic claims by patent-holders in contexts where the rights to health, food, access to technology or other human rights would be compromised.<sup>55</sup>

Consistent with these observations, the Special Rapporteur offered a number of specific additional recommendations for States' consideration, in keeping with their human rights obligations, including

the avoidance of “TRIPS-plus” provisions and a “positive obligation to provide for a robust and flexible system of patent exclusions, exceptions and flexibilities based on domestic circumstances.”<sup>56</sup>

## Rights of inventors in intellectual property and international trade law

As noted above, in human rights law, it is the “author” of a scientific production — referring only a natural person — that can claim a *human right* to some form of protection of the moral and material interests resulting from a pharmaceutical product or other health technology. However, a multitude of public, private, for profit and not-for profit organizations make inputs in the different stages of health technology development, from the funding of basic research and development, to undertaking clinical trials to bringing a drug to final development and gaining marketing approval. In most instances, by the time such a product reaches the market, the question of any human rights claim to the material interests resulting from that product is largely irrelevant; the question at that stage is one of who has the legal right, under applicable intellectual property laws, to make, use and sell that product (and related information) and reap the material benefits thereof. Inventors retain their original human right to the protection of their moral and material interests in the invention, while often transferring to a corporate entity their legal rights attaching to a patent granted on that invention, including the right to exclusive use and marketing of the patented product or process.

Unlike fundamental human rights that are inherent to persons and inalienable, intellectual property rights are legal rights granted by the state, usually to a private actor, in accordance with domestic and any applicable regional or international law (e.g., TRIPS or other such treaty), subject to certain conditions and for certain purposes. The rationale for patent protection is that the grant of a patent operates as an incentive to publish the details of inventions, rather than keeping them as closely held secrets, in order that society may benefit from the invention through the use of the patented product or process, and through further innovation. This section provides some background information on the nature of patent protection as a particular form of granting intellectual property rights. (It should be noted that intellectual property law also includes other aspects that can be relevant to accessing health goods, services and information, such as copyright, trademark rights, rights in industrial designs, etc. In particular, intellectual property provisions regarding *data exclusivity* rights in information submitted by pharmaceutical manufacturers for obtaining regulatory approval of products can have a significant impact on access to those products. For the purposes of this background paper, the focus is kept on patent rights specifically, but the basic analysis, including under human rights law, is the same.

## Key points on patent rights

Intellectual property – including the terminology used, and the particular extent of protection and enforcement of various rights – vary, but commonly include the following basic concepts and provisions in relation to patents:

- Patents can be applied for in relation to products or processes as long as they are (1) novel, (2) useful and (3) involve an inventive step (which countries have some flexibility in defining to help prevent overly broad patenting). The patent office may grant a patent if the details of the invention are disclosed with sufficient specificity that a person skilled in the relevant art would be able to reproduce the invention.
- Patents may be applied for by the inventor of the product or process or some other person with relevant rights, such as a person to whom the rights were assigned (e.g., an employer or funder) or the inventor's successor in title. Patent rights are usually granted for 20 years from the time of filing the application.
- A *process* patent precludes others, without the patent-holder's consent, from making use of that process to produce a product (e.g., a medicine) and, therefore, from using, selling or importing a product obtained through use of that patented process. But it remains permissible to produce and sell an equivalent version of that product using a different, non-patented process. In contrast, obtaining a *product* patent would preclude the manufacture and sale of an equivalent product, regardless of the process used to produce it (which in any event, would also likely be patented in such a circumstances). Allowing only process patents in the pharmaceutical sector leaves greater leeway for manufacturing and distributing equivalent generic versions of a medicine or other technology, whereas also allowing patents on the medicines or technologies themselves results in a greater degree of monopoly during the patent period. Under TRIPS, all WTO Members must grant both process and product patents, including in relation to pharmaceutical products.
- Usually, civil and administrative remedies such as damages and injunctions are usually available to remedy breach of these exclusive patent rights. In some instances, domestic law may also provide for criminal penalties for breach.
- Domestic patent laws often include provisions which allow for some limitations on absolute monopoly rights of the patent-holder during the term of a (valid) patent. For example, either the grant of the patent itself or other provisions elsewhere in law may allow for compulsory licensing (including government use) of the patented invention without consent of the patent-holder, in exchange for some remuneration in accordance with applicable law, or other "limited exceptions" to exclusive patent rights. Other flexibilities may include transition



periods for implementation of intellectual property obligations, more strictly defining patentability criteria (as noted above), or allowing for “parallel importation” (i.e., importation of a patented product into a country once it has been sold by the patent-holder in another country). These are in keeping with the “flexibility” reflected in TRIPS, but the presence and scope of such provisions varies considerably among countries, and as a result of other regional or bilateral trade agreements, may be more limited than what is permitted by TRIPS.

TRIPS is the most widely ratified international agreement on intellectual property. All states belonging or seeking accession to the WTO are legally required to bring their domestic legislation into conformity with the terms of TRIPS, subject to any exceptions or waivers agreed upon by WTO Members. This includes granting patents in relation to pharmaceutical processes and products: “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced” (Article 27). The agreement set a minimum patent protection period of 20 years from the date of filing a patent application (Article 33). (Before TRIPS, subject to any other legal obligations they may have assumed under other bilateral or regional treaties, countries were free to determine their own patent protection periods and some also chose to exclude pharmaceutical products and/or processes from patentability.)

International trade law generally provides for far stronger measures of enforcement of treaty obligations—including for IP-related obligations—than those associated with international human rights law. The WTO Dispute Settlement Body (DSB) is the adjudicative mechanism for enforcing trade rules, including the provisions of TRIPS. A negative finding by the DSB can authorize a WTO Member to impose “counter-measures” against another Member for breach of WTO treaty obligations, including obligations under TRIPS. Similar dispute settlement measures exist in bilateral and regional trade agreements for disputes between states; sometimes those treaties also include “investor-state dispute settlement” provisions allowing private rights-holders direct access to panels or tribunals in seeing to enforce claims that their private property rights under the treaty have been breached (including, under some treaties, “expectations” of profit). Counter-measures permit a Member to impose import restrictions (otherwise impermissible under WTO law) against goods and services from a country found in breach of a covered WTO agreement; such restrictions may affect goods and services valued at billions of dollars and can be substantially damaging to national industries and budgets.

In light of various public interest objectives of concern to states, TRIPS does provide for various “flexibilities” in relation to the intellectual property obligations it imposes on WTO Members. These have been reaffirmed by WTO Members on several occasions, which is significant in understanding the



relationship between intellectual property rights under international trade law and states' obligations under international human rights law. Most notably, in the 2001 "Doha Declaration," states unanimously affirmed that TRIPS "does not and should not prevent [WTO] Members from taking measures to protect public health" and that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."<sup>57</sup> In this regard, WTO Members explicitly reaffirmed the "right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose,"<sup>58</sup> and more specifically noted, by way of example, the right of each Member "to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."<sup>59</sup> WTO Members also recognized that, because of other restrictions in TRIPS on the use of compulsory licensing for purpose of exporting pharmaceutical countries, countries with inadequate domestic pharmaceutical manufacturing capacity "could face difficulties in making effective use of compulsory licensing" under TRIPS.<sup>60</sup> Therefore, in 2003, they adopted an ostensible solution to this problem, so as to enable effective use by such countries of compulsory licensing,<sup>61</sup> although it has been used but a single time to date and its utility has been the subject of ongoing debate.<sup>62</sup>

Increasingly, a growing number of bilateral or regional trade agreements (or similar agreements such as "bilateral investment treaties" or "economic partnership agreements") include provisions that exceed the minimum IP standards required by TRIPS. States enter such agreements to secure commitments of preferential access to other countries' markets and agree to more stringent IP rules as a consequence. Such "TRIPS-plus" provisions often restrict the ability of countries to make use of flexibilities permitted under TRIPS, including those flexibilities repeatedly affirmed by states as available to be used to promote and secure greater access to medicines (e.g., compulsory licensing). Such developments further contribute to the tension between these trade treaty obligations and states' obligations under human rights treaties.<sup>63</sup>

## **Part C: Relationship between human rights and IP obligations in international law**

The previous two sections have outlined how international legal norms related to access to medicines and to the rights of inventors arise in both the human rights and international trade regimes, and described the salient content of those norms. The High-Level Panel is tasked with remedying the policy incoherence between these norms and to "achieve a better balance of the justifiable rights of inventors, the right to health and sustainable development."<sup>64</sup> This section identifies key points for consideration by the Panel in that task.



## Human rights approach to balancing international obligations

In its original 2001 statement on human rights and intellectual property, the UN Committee on Economic, Social and Cultural Rights provided some normative guidance highlighting the need for domestic IP regimes to take account of states' human rights obligations. It emphasised that “[w]hen adopting and reviewing intellectual property systems, States should bear in mind the need to strike a balance between” the protection of public and private interests in knowledge; specifically, the right to enjoy the benefits of scientific progress and its applications as well as the right to benefit from the protection of the moral and material interests resulting from any scientific production of which a person is the author (both of which rights are guaranteed in ICESCR Article 15).<sup>65</sup> Reflecting this obligation, the Committee recalled that States parties to the ICESCR

*... have a “core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights” enunciated in the Covenant. As the Committee observes: “without such a core obligation, the Covenant “would be largely deprived of its raison d’être.” The Committee wishes to emphasize that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.<sup>66</sup>*

The Committee further stressed, in its subsequent General Comment of 2006, that authors' rights must be balanced against other ICESCR rights. Therefore, States should ensure their legal or other regimes for protecting authors' rights

*... constitute no impediment to their ability to comply with their core obligations in relation to the rights to...health..., as well as to... enjoy the benefits of scientific progress and its applications, or any other right enshrined in the Covenant. Ultimately, intellectual property is a social product and has a social function. States parties thus have a duty to prevent unreasonably high costs for access to essential medicines...from undermining the rights of large segments of the population to health. Moreover, States parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health... e.g., by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of those rights.<sup>67</sup>*

The Committee noted that “national and international intellectual property regimes must be consistent with the obligation of States parties to ensure the progressive realization of full enjoyment of all the rights in the Covenant. Furthermore, all parties are urged to ensure that intellectual property regimes contribute, in a practical and substantive way, to the full realization of all the Covenant rights.”<sup>68</sup> This



includes, of course, the rights to health and to benefit from scientific progress through realizing access to medicines.

The Committee also observed that “[i]nternational rules concerning intellectual property should not necessarily be uniform if this might lead to forms of intellectual property protection inappropriate for development goals. The Committee encourages the adoption and implementation of effective international mechanisms for special and differential treatment for developing countries concerning intellectual property protection.”<sup>69</sup>

## Hierarchy of international legal regimes

It is contentious whether public international law, as a whole, has a discernible hierarchy. Certainly it would be over-reaching to suggest that any such normative hierarchy is well-defined. But it may nonetheless be possible at least to identify the *relative* position in international law of States’ human rights obligations on the one hand and their obligations under trade agreements regarding intellectual property standards on the other. In this regard, some observations can be made.

The *UN Charter* is the foundational document of the modern international legal order, with the following noteworthy features of this treaty binding on all UN Member States:

- It identifies (in Article 1) the realization of human rights among the four fundamental purposes of the UN, alongside solving international problems of an economic, social, cultural or humanitarian character as another such fundamental purpose.
- UN Member States accept as a treaty obligation (in Article 2) that they “shall act” in accordance with a number of principles, including that all members “shall fulfil in good faith the obligations assumed by them in accordance with the present Charter.”
- The Charter sets out a number of specific treaty obligations relevant to human rights, in language evidencing States’ concern for health. Article 55 declares that the UN “shall promote... solutions of international economic, social, health and related problems” and “universal respect for, and observance of, human rights and fundamental freedoms for all.” In Article 56, Member States accept the following binding treaty obligation: “All Members pledge themselves to take joint and separate action” with the UN to achieve the purposes set out in Article 55 (i.e., to promote solutions of international health problems and to promote universal human rights).<sup>70</sup>



While the claim is not universally accepted by jurists, the preponderance of expert academic opinion reflects the proposition that the UN Charter is of a *constitutional* character in the international legal order; that is to say, not only in the *structural* sense of constituting the mechanisms of international legal relations and specifying the sources of international law, but in the *normative* sense of articulating higher-order norms governing the conduct of states and other actors.<sup>71</sup> In fact, the Charter explicitly creates a hierarchy of norms, “another characteristic feature of any constitution.”<sup>72</sup> Specifically, Article 103 states that: “[i]n the event of a conflict between the obligations of the Members of the United Nations under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail.” [emphasis added] The precedence of States’ obligations under the UN Charter has been affirmed by the International Court of Justice,<sup>73</sup> by States in other treaties (including the treaty that sets out the rules governing the interpretation of treaties)<sup>74</sup> and in numerous UN General Assembly resolutions.<sup>75</sup>

If one accepts the constitutional nature of the UN Charter, the combination of Article 103 of the UN Charter with the treaty obligations assumed by Member States under Articles 2, 55 and 56 can leave little doubt that states’ obligation to act in the furtherance of universal human rights must take priority over any conflicting (treaty) obligation. Those human rights obligations are detailed in the core human rights instruments drafted, adopted and repeatedly reaffirmed by Member States themselves, in particular the UDHR, the ICCPR and the ICESCR (discussed in detail above) — commonly referred to as the “International Bill of Rights.” The latter two Covenants, ratified by the substantial majority of states, are more detailed articulations of the human rights first set out by States in the UDHR. The ICCPR and ICESCR may not be universally ratified by all states, and therefore not directly binding on all states—although the large majority of states have ratified both.<sup>76</sup> But the UDHR is indisputably and explicitly recognized by all states as their common, authoritative elaboration of the human rights provisions of the UN Charter, which all UN Member States *are* treaty-bound to fulfil.<sup>77</sup>

Aside from being the authoritative interpretation of those states’ human rights obligations under the (constitutional) *treaty* that is the UN Charter, the provisions of the UDHR may be thought to give rise to binding legal obligations for states in other ways. For example, although the UDHR is not a *treaty*, but rather a declaration of the UN General Assembly repeatedly and unanimously endorsed by all Member States, it is considered by many experts to have achieved the status of *customary* international law and therefore binding in its own right in this fashion. (This characterization is contested by some other jurists, who nonetheless accept the narrower claim that at least some of the rights elaborated in the UDHR have matured into rules of customary international law.) In addition, or alternatively, the



UDHR is considered to embody binding *general principles* of international law applicable to all states, the third principal source of binding international legal obligations.<sup>78</sup>

Such supra-normative status does not exist in international law for the provisions of WTO law (including the TRIPS Agreement) or other trade treaties. They have not been vested with such status by various treaties, declarations, resolutions, tribunal decisions or “soft” international law interpretations. The clear wording of Article 103 of the UN Charter establishes that UN Member States’ obligations to promote solutions to health problems and to respect and fulfil human rights take priority over any other conflicting treaty obligations — and there is nothing in the texts of WTO (or other) trade treaties indicating states parties intended to dispense with this long-settled feature of international law (i.e., to somehow attempt to ‘contract out’ of this international legal order). As discussed above, this relative position in international law of human rights obligations (such as realizing the highest attainable standard of health, including through access to medicines) and TRIPS (or other treaty) obligations regarding minimum IP standards reflects the *fundamental* nature of basic human rights versus the *instrumental* nature of IP rights.

## Conclusion

In realising its mandate, the High-Level Panel attempts to identify ways for states’ obligations regarding rights of inventors under international human rights law and international trade law to better align with their human rights obligations, particularly in relation to the rights to health and to benefit from scientific progress. In its deliberations and in formulating its recommendations to the UN Secretary-General, the High-Level Panel must consider the recognised and entrenched legal intellectual property rights under international or domestic laws, but also the foundational position of human rights in the international legal system.

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<sup>1</sup> United Nations Secretary-General’s High-Level Panel on Access to Medicines, *Terms of Reference* (2015), online via <http://www.unsgaccessmeds.org/reports-documents/>.

<sup>2</sup> *Charter of the United Nations*, 26 June 1945, TS 67 (1946), Articles 55 & 56.

<sup>3</sup> *Constitution of the World Health Organization*, 22 July 1946, 14 UNTS 185 (entered into force 7 April 1948).

<sup>4</sup> UN GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc. A/810 (1948). Although it is not a *treaty*, but rather a declaration of the UN General Assembly, the *Universal Declaration of Human Rights* (a) is the founding instrument of the body of modern international law of human rights, (b) is considered the original basis for the further elaboration of the



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two foundational human rights treaties of the UN ultimately adopted in 1967 (the *International Covenant on Civil and Political Rights* and the *International Covenant on Economic, Social and Cultural Rights*), and (c) has been unanimously endorsed repeatedly by UN Member States over nearly 70 years. As such, it is considered by some jurists to have achieved the status of binding *customary* international law. Article 25 guarantees the right to a standard of living adequate for health and well-being, including medical care, Article 27 guarantees the rights to share in scientific advancement and its benefits, as well as the right of everyone to the protection of the moral and material interests resulting from any scientific production of which he or she is the author, and Article 28 guarantees the right to a social and international order that enables the full realization of the rights set forth in the UDHR. These are the three UDHR provisions most relevant to the three sections of this background paper.

<sup>5</sup> 999 UNTS 3 (1966), Article 12. See also Article 15 regarding the right to enjoy the benefits of scientific progress and its applications. Furthermore, note also the relevant right to life in the companion *International Covenant on Civil & Political Rights*, 999 UNTS 171 (1966), Article 6, and the General Comment No. 6 (1982) by the UN Human Rights Committee that includes the obligation to take positive measures to eliminate epidemics, which necessarily includes access to medicines in some cases.

<sup>6</sup> UN Human Rights Committee, *General Comment No. 6: The right to life (art. 6)* (1982), online: [www.ohchr.org/english/bodies/hrc/comments.htm](http://www.ohchr.org/english/bodies/hrc/comments.htm). Note also that, at least in some circumstances, denial of access to medicines by the state (or its agents) may constitute torture or amount to other cruel, inhuman or degrading treatment or punishment contrary to the UN *Convention Against Torture*: Report of the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, UN Doc. A/HRC/22/53 (2013).

<sup>7</sup> *Convention on the Elimination of All Forms of Racial Discrimination* (1969), 660 UNTS 195, Article 5; *Convention on the Elimination of All Forms of Discrimination Against Women* (1981), 1240 UNTS 13, Article 12; *Convention on the Rights of the Child* (1990), 1577 UNTS 3, Article 24(1); *Convention on the Rights of Persons with Disabilities* (2006), 2515 UNTS 3, Article 25; *International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families* (1990), 2220 UNTS 3, Articles 43 & 45. Note that 196 states have ratified the *Convention on the Rights of the Child*, including its Article 24 on children's right to health, making its treaty obligations universal. This includes all but two of the 193 UN Member States; the exceptions (USA and Somalia) have nonetheless signed the treaty and are therefore subject, under international law, to a legal obligation of good faith requiring them to refrain from acts calculated to frustrate its object and purpose: *Vienna Convention on the Law of Treaties*, Article 18.

<sup>8</sup> E.g. *American Declaration of the Rights of Man*, OAS Res. XXX (2 May 1948), Article 11; *Protocol of Buenos Aires* (1970), 721 UNTS 324; *American Convention on Human Rights* (1969), 1144 UNTS 123, Article 26; *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights* ("Protocol of San Salvador") (1988), OAS TS 69, Article 10; *African Charter on Human and Peoples' Rights* (1981), OAC Doc. CAB/LEG/67/3 rev. 5, Article 16; *Protocol to the African Charter on Human and Peoples' Rights on the Rights of Women in Africa* (2000), OAU Doc. CAB/LEG/66.6, Article 14; *African Charter on the Rights and Welfare of the Child* (1990), OAU Doc. CAB/LEG/24.9/49, Article 14; *Revised European Social Charter* (1996), 5 ETS 163, Part I(13) and Part II, Articles 11 & 13.

<sup>9</sup> UN Committee on Economic, Social and Cultural Rights, *General Comment 14: The right to the highest attainable standard of health (Art. 12)*, UN Doc. E/C.12/2000/4 (2000). It should be noted that the General Comment refers to both "essential medicines" as defined from time-to-time by the WHO as part of the "minimum core obligation" of states, but also refers repeatedly elsewhere, outside the context of minimum core obligations, to essential medicines without adding this limiting reference — and in the most recent resolution on the matter from the UN Human Rights Council (albeit one adopted without consensus, on a vote with some abstentions but no outright opposition), Member States themselves have confirmed that the right to access to medicines extends beyond just "essential" medicines: Human Rights Council, "Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," Resolution 23/14, UN Doc. A/HRC/23/L.10/Rev.1 (June 11, 2013).

<sup>10</sup> *Ibid.*, para. 12.

<sup>11</sup> CESCR, General Comment 14, paras. 33-37.

<sup>12</sup> ICESR, Article 2; CESCR, General Comment 14, paras. 38-42.

<sup>13</sup> ICESCR, Article 2; CESCR, General Comment 14, para. 30. [emphasis added]

<sup>14</sup> CESCR, General Comment 14, para. 31.



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<sup>15</sup> Ibid., para. 32.

<sup>16</sup> Ibid., para. 43(a), (d), (e).

<sup>17</sup> Ibid., para. 44.

<sup>18</sup> Ibid., para. 45.

<sup>19</sup> CESCR, “Human rights and intellectual property: Statement by the Committee on Economic, Social and Cultural Rights,” UN Doc. E/C.12/2001/15 (2001), para. 13. For further discussion of how obligations may apply to a particular relevant set of private actors, see: Special Rapporteur on the Right to the Highest Attainable Standard of Health, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, Report to the UN General Assembly, UN Doc. A/63/263 (2008); and the discussion co-authored by the (former) Special Rapporteur in: J-Y Lee & P. Hunt, “Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines,” (2012) 40 *Journal of Law, Medicine & Ethics* 220.

<sup>20</sup> Ibid., para. 48.

<sup>21</sup> CESCR, General Comment 14, para. 51.

<sup>22</sup> Ibid., para. 52.

<sup>23</sup> Report of the High Commissioner, “The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights,” UN Doc. E/CN.4/Sub.2/2001/13 (2001).

<sup>24</sup> See, in particular, the Special Rapporteur’s 2006 report to the General Assembly, discussing the human to medicines and including implications of IP provisions in agreements such as TRIPS: UN Doc. A/GA/61/338 (2006); and his 2009 report to the UN Human Rights Council, dedicated to the question of the relationship between IP provisions in trade agreements (including TRIPS) and access to medicines: UN Doc. A/HRC/11/12 (2009). The Special Rapporteur recommended that, in keeping with their obligations to progressively realize the right to health, developing countries should use TRIPS flexibilities to improve access to medicines.

<sup>25</sup> H.V. Hogerzeil, M.Samson & J.V. Casanova, *Ruling for Access: Leading court cases in developing countries on access to essential medicines as part of the fulfillment of the right to health* (World Health Organization, 2004).

<sup>26</sup> *Universal Declaration on Bioethics and Human Rights*, 33 C/Res. 36 (2005), at Article 14(2).

<sup>27</sup> E.g., “WHO medicines strategy,” WHA Res. WHA54.11, 54<sup>th</sup> World Health Assembly (2001), at para. 1(2), online: [www.who.int/gb/e/e\\_wha54.html](http://www.who.int/gb/e/e_wha54.html). [update]

<sup>28</sup> E.g., *Global Crisis – Global Action: Declaration of Commitment on HIV/AIDS*, GA Res. S-26/2, UN GAOR, 26<sup>th</sup> Spec. Sess., Supp. No. 1, UN Doc. A/RES/S-26/2 (2001) at paras. 55 & 58 [“Declaration of Commitment”]. Access to medication as a human rights obligation has also been articulated by UN Member States in the context of outcome documents from international human rights conferences: e.g., *Programme of Action*, adopted at the 2001 World Conference Against Racism, Racial Discrimination, Xenophobia and Related Intolerance, Durban, South Africa, UN Doc. A/CONF.189/5 (2001) at para. 3. It was more than a decade ago, and at first in the context of pandemics such as HIV/AIDS, that the General Assembly, having taken note of developments at the WTO regarding intellectual property and access to medicines, went so far as to call upon states to not only pursue policies promoting access, but also called on states “to refrain from taking measures that would deny or limit equal access to said goods, and to adopt legislation and other positive measures to safeguard and promote effective access to them,” as well as “to take steps to facilitate access to medicines in other countries.” See: UN General Assembly, “Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria”, GA Resolution 58/179, UN Doc. A/RES/58/179 (December 22, 2003), at paras. 6-7. The resolution was adopted with 181 votes in favour, 1 vote against (United States) and no abstentions. The General Assembly has subsequently unanimously adopted two resolutions affirming access to medication is a fundamental element of realizing the right to health, and also reaffirming and even urging the use of flexibilities in agreements on intellectual property such as the WTO TRIPS Agreement, to achieve this objective: *Political Declaration on HIV/AIDS*, UN Doc. A/RES/60/262 (2006), paras. 12, 42-48; *Political Declaration on HIV/AIDS*, UN Doc. A/RES/65/277 (2011), paras. 32, 71-72.

<sup>29</sup> UN Commission on Human Rights, “Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria”, Resolutions 2001/33, 2002/32, 2003/29, 2004/26, 2005/23, all online: [www.ohchr.org/english/bodies/chr/index.htm](http://www.ohchr.org/english/bodies/chr/index.htm). Note that while the initial 2001 resolution on this subject was adopted by a vote of 52 in favour, none against, and only one abstention, all of the subsequent resolutions were then “adopted



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without a vote” (i.e., by consensus). Such consistent unanimity is strong evidence of an accepted norm in international law.

<sup>30</sup> *Ibid.*

<sup>31</sup> See Human Rights Council Resolutions 12/24 (2009) (which also refers to states’ right to use TRIPS flexibilities), 12/27 (2009) (reaffirming that TRIPS should be interpreted to promote production of generic ARVs and other medications to treat people living with HIV); 15/22 (2010) (extending that reaffirmation beyond HIV medications); 16/28 (2011) (on HIV and human rights, including reaffirming use of flexibilities and objective of universal access to treatment); 17/14 (2011) (broad reaffirmation of access to medicines as fundamental element of the right to health); and 23/14 (2013, adopted with abstentions) (urging states to take various measures to promote access to medicines, including using TRIPS flexibilities to the full), all online via [www.ohchr.org](http://www.ohchr.org). Note also the early Decision of the Human Rights Council, at its second session, to request the UN Secretary General, in a future report on access to medication, “to include an assessment of the impacts of intellectual property rights on access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria from the perspective of human rights”: HRC Decision 2/107 (2006), UN Doc. A/HRC/DEC/2/107, online via [www.ohchr.org](http://www.ohchr.org).

<sup>32</sup> UN General Assembly, *Political Declaration on HIV/AIDS*, UN Doc. A/RES/65/277 (2011), paras. 71-72.

<sup>33</sup> UN General Assembly, *Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases*, UN Doc. A/RES/66/2 (2011), paras. 5-6, 45 (l), (p), 52. Member States subsequently reaffirmed the right to use TRIPS flexibilities to improve access to medicines in the outcome document of their High-Level Meeting on NCDs in 2014 (see UN Doc. A/RES/68/300 (2014), para. 35), and again most recently in the Sustainable Development Goals adopted unanimously in 2015: see *Transforming our world: the 2030 Agenda for Sustainable Development*, UN Doc. A/RES/70/1 (2015), Goal 3.b.

<sup>34</sup> *Ibid.*, para 45(r).

<sup>35</sup> *Universal Declaration on Bioethics and Human Rights*, 33 C/Res. 36 (2005), at Article 14(2). The Declaration is non-binding but was unanimously adopted by 191— i.e., virtually all — UN Member States.

<sup>36</sup> UN General Assembly, *Charter of Economic Rights and Duties of States*, GA Res. 3281 (XXIX) (12 December 1974), Article 13.

<sup>37</sup> See references to the inter-American, African, European and Arab regional instruments in: Human Rights Council, *Report of the Special Rapporteur in the field of cultural rights: “The right to enjoy the benefits of scientific progress and its applications,”* UN Doc. A/HRC/20/26 (14 May 2012), at paras. 9-12, online: <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G12/134/91/PDF/G1213491.pdf?OpenElement>.

<sup>38</sup> E.g., *NA et al v. Ministerio de Sanidad y Asistencia Social*, Supreme Court of Justice of Venezuela, Case No. 14.625, Judgment of 14 August 1998; *Cruz del Valle Bermudez y otros c. Ministerio de Sanidad y Asistencia Social*, Supreme Court of Justice of Venezuela, Case No. 15.789, Judgment No. 916 (15 July 1999); *López y otros c. Institute Venezolano de los Seguros Sociales (IVSS)*, Supreme Court of Venezuela (Constitutional Chamber), Judgment No. 487 (6 April 2001). See discussion in R. Elliott et al, *Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV* (Canadian HIV/AIDS Legal Network & UNAIDS, 2006), at pp. 64-68.

<sup>39</sup> The UN Special Rapporteur on the right to food has also addressed the implications of the right to benefit from scientific progress, as a companion to the right to food in ICESCR Article 11, for intellectual property policies affecting access to seeds and other technologies needed for agriculture: UN General Assembly, *Report of the Special Rapporteur on the right to food: “Seed policies and the right to food: enhancing agrobiodiversity and encouraging innovation,”* UN Doc. A/64/170 (2009). Having explored the tension between IP policy and the rights to food and to benefit from science, which parallels in many respects the tension observed in the context of access to medicines, the Special Rapporteur offers a number of recommendations similar to those made by UN human rights bodies in relation to access to medicines.

<sup>40</sup> In various reports addressing access to medicines as part of the right to health, the UN Special Rapporteur on the right to health has also made reference to the companion right to benefit from scientific progress as a basis for state obligations to improve access. For example, the Special Rapporteur’s 2003 report to the UN Commission on Human Rights observes that WTO Members’ *Declaration on the TRIPS Agreement and Public Health* reflects these two rights in stressing that TRIPS “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”: UN Doc. E/CN.4/2003/58 (2003), para. 87.



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- <sup>41</sup> *Report of the Special Rapporteur in the field of cultural rights: “The right to enjoy the benefits of scientific progress and its applications,”* UN Doc.A/HRC/20/26 (2012), para. 25.
- <sup>42</sup> *Ibid.*, para. 34.
- <sup>43</sup> *Ibid.*, paras. 35, 62.
- <sup>44</sup> *Ibid.*, para. 59.
- <sup>45</sup> *Ibid.*, paras. 47-48.
- <sup>46</sup> *Ibid.*, paras. 70-73.
- <sup>47</sup> CESCR, Statement, *supra* note 20.
- <sup>48</sup> UN Committee on Economic, Social and Cultural Rights, *General Comment 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)*, UN Doc. E/C.12/GC/17 (2006), para. 10.
- <sup>49</sup> *Ibid.*, para. 13.
- <sup>50</sup> *Ibid.*, para. 16.
- <sup>51</sup> *Ibid.*, para. 7.
- <sup>52</sup> *Ibid.*, paras. 1-3. The Committee specifically notes (para. 2, fn. 1) that “relevant international agreements” to which it is referring include the WTO TRIPS Agreement and other international treaties on various aspects of intellectual property.
- <sup>53</sup> UN General Assembly, *Report of the Special Rapporteur in the field of cultural rights [on the implications of patent policy for the right to science and culture]*, UN Doc. A/70/279 (2015), para. 32.
- <sup>54</sup> *Ibid.*, para. 89.
- <sup>55</sup> *Ibid.*, para. 90.
- <sup>56</sup> *Ibid.*, paras. 103-106.
- <sup>57</sup> WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc. WT/MIN(01)/DEC/2 14 November 2001), para. 4, online: [https://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).
- <sup>58</sup> *Ibid.*
- <sup>59</sup> *Ibid.*, para. 5(b).
- <sup>60</sup> *Ibid.*, para. 6.
- <sup>61</sup> WTO General Council, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Decision of the General Council of 30 August 2003, WTO Doc. IP/C/W/405, online: [https://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm). See also the accompanying “General Council Chairperson’s Statement of 30 August 2003,” in WTO Doc. WT/GC/M/82 at p. 6, online: [https://www.wto.org/english/news\\_e/news03\\_e/trips\\_stat\\_28aug03\\_e.htm](https://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm).
- <sup>62</sup> See dedicated WTO webpage for notifications of use of this system: [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm).
- <sup>63</sup> UNDP & UNAIDS, *Issue Brief: The potential impact of free trade agreements on public health* (2012).
- <sup>64</sup> United Nations Secretary-General’s High-Level Panel on Access to Medicines, *Terms of Reference* (2015), online via <http://www.unsgaccessmeds.org/reports-documents/>.
- <sup>65</sup> CESCR, Statement, para. 17.
- <sup>66</sup> CESCR, Statement, para. 12, with reference to the Committee’s earlier *General Comment No. 3: The Nature of States Parties’ Obligations (Art. 2, para. 1)* (1991).
- <sup>67</sup> CESCR, General Comment 17, para. 35, with reference to *General Comment No. 3, supra*.
- <sup>68</sup> CESCR, Statement, para. 11.
- <sup>69</sup> *Ibid.*, para. 15.
- <sup>70</sup> One of the leading international law jurists has observed that these treaty provisions (Articles 55 and 56) “are of paramount importance” and that “the political and judicial organs of the United Nations have interpreted the provisions as a whole to constitute legal obligations”: I. Brownlie, *Principles of Public International Law*, 5<sup>th</sup> ed. (Oxford: Oxford University Press, 1998), at p. 574.
- <sup>71</sup> E.g., B. Fassbender, “The United Nations Charter as Constitution of the International Community,” (1998) 36 *Columbia J Transnat’l L* 529; C.J. Schwindt, “Interpreting the United Nations Charter: From Treaty to World Constitution,” (2000) 6 *UC Davis J Int* 193; B. Simma & A.L. Paulus, “The ‘International Community’: Facing the Challenge of Globalization,” (1998)

9 EJIL 266; B. Sloan, "The UN Charter as a Constitution," (1989) 1 Pace YB Intl L 61; O. Schacter, "United Nations Law" (1994) 88 AJIL 1.; P-M Dupuy, "The Constitutional Dimension of the Charter of the United Nations Revisited," (1997) 1 Max Planck YBUNL 1; B. Conforti, *The Law and Practice of the United Nations*, 2<sup>nd</sup> rev. ed. (The Hague: Kluwer Law International 2000); C. Tomuschat, "Introduction" in C. Tomuschat, ed., *The United Nations at Age Fifty: A Legal Perspective* (The Hague: Kluwer Law International, 1995); I.I. Lukashak, "The Law of the International Community," in *International Law on the Eve of the Twenty-first Century: Views from the International Law Commission* (New York: United Nations, 1997) at 59; R. St. J. Macdonald, "UN Charter in Constitutional Perspective," (1999) 20 Austl. YB Int'l L 205; R. Bernhard, "Article 103," in B. Simma, ed., *The Charter of the United Nations: A Commentary*, 2<sup>nd</sup> ed., Vol. II (Oxford: Oxford University Press, 2002). Some international law experts question whether the UN Charter can constitute a constitution *per se* or constitutes a *complete* constitution, but nonetheless acknowledges its constitutional aspects and/or suggest it forms part of a larger, diffuse constitutional order in international law: e.g., J. Crawford, "The Charter of the United Nations as a Constitution," in H. Fox., ed., *The Changing Constitution of the United Nations* (1997); I. Seiderman, *Hierarchy in International Law: The Human Rights Dimension* (Antwerp: Intersentia-Hart, 2001); E. de Wet, "The International Constitutional Order," (2006) 55 ICLQ 51. And even while questioning whether it amounts to a "constitution," these commentators acknowledge the Charter's supra-normative or "higher order" status in international law vis-à-vis order instruments.

<sup>72</sup> Fassbender, *supra* at 577.

<sup>73</sup> *Aerial Incident Over Lockerbie Case*, [1992] ICJ Rep 3.

<sup>74</sup> *Vienna Convention on the Law of Treaties*, 1155 UNTS 331 (1969).

<sup>75</sup> E.g., *Declaration on Principles of International Law Concerning Friendly Relations and Cooperation Among States in Accordance with the Charter of the United Nations*, GA Res. 2625 (XXV), UN Doc. XXXX (1970) 122.

<sup>76</sup> As of February 2016, according to the Office of the UN High Commissioner on Human Rights, 168 states had ratified the ICCPR and 164 had ratified the ICESCR: "Chart disclosing the status of ratifications of human rights treaties," online via: <http://www.ohchr.org/EN/HRBodies/Pages/TreatyBodies.aspx> (accessed February 23, 2016).

<sup>77</sup> *UDHR*, Preamble; Brownlie, *supra* at 575; *Proclamation of Teheran*, Final Act of the International Conference on Human Rights, UN Doc. A/CONF.32/41 (1968), endorsed by UN General Assembly Res. 2442 (XXIII) (1968); *Vienna Declaration and Programme of Action*, UN Doc. A/CONF.157/23 (1993), declaring the promotion and protection of human rights to be "the first responsibility of Governments" regardless of political, economic and systems; endorsed by the General Assembly in *World Conference on Human Rights*, GA Res. 48/121, UN Doc. A/RES/48/121 (1993).

<sup>78</sup> The statute creating the International Court of Justice, an annex to the UN Charter, explicitly recognizes three principal sources or forms of binding international law: (1) international conventions (i.e., treaties); (2) customary international law; and (3) "general principles of law recognized by civilized nations." Judicial decisions and the teachings of the most highly qualified jurists are also explicitly recognized as subsidiary means for determining rules of law. See *Statute of the International Court of Justice* (1945), Article 38.

