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Creating Space for Human Rights vis-à-vis Patents on Medicines under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)

Abstract

This study analyses the scope for establishing human rights obligations related to access to medicines in post-TRIPS Agreement arrangements. The enforcement of patents on medicines has always ignored the human rights aspect of medicines. The World Trade Organisation (WTO), through its laws and interpretation of these laws, has not included the human rights impact of enforcing patents on medicines. Therefore, enforcement of patents in isolation to human rights standards creates two conflicting norms. This human rights debate of accessing medicines have become prominent in the post-COVID era. Therefore, the paper presents a critical analysis of the interaction between access to medicines and patents on medicines. By using the doctrinal research methods, the study relies on the documentary analysis of legal sources to find the space for access to medicines related human rights vis-à-vis patents on medicines.

Keywords: patents, access to medicines, WTO, TRIPS Agreement, right to health

Interpreting Access to Medicine under Right to Life

Most of the research on access to medicine focuses domain of right to health under the ICESCR. As discussed earlier, the enforcement mechanism for human rights is less effective than that of patents under the WTO.[1] Moreover, human rights are protected by two conventions named the ICESCR and the ICCPR. Later enjoyed more enforcement might than the earlier. The right to life falls under the ICCPR while the right to health falls under the domain of the ICESCR.[2] It is pertinent to mention here that the US, a proponent of strong pharmaceutical patent protection, is not a party to the ICESCR. Therefore, more attention focused on protecting pharmaceutical patents globally with less focus on access to medicine, a fundamental part of the right to health. There exists international legal duty towards access to medicine under the right to Life.[3]

The protection of health falls human rights and responsibility of the state as good order (*gutey policey*) in Germany during the 18th century and later in the 19th century, public health became the international norm through international sanitary conventions.[4] League of Nations, in the 20th century, recognised it a commitment

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[1] Joo-Young Lee, *A Human Rights Framework for Intellectual Property, Innovation and Access to medicines* (Ashgate, 2015) 121;

[2] Siva Thambisetty, 'Improving Access to Patented medicines: Are Human Rights Getting in the Way?' (2018) *LSE Law,* Society and Economy Working Papers *3/2018* 2

[3] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (Oxford University Press, 2008) 116

[4] Ibid.

towards, "take steps in the matter of international concerns for prevention and control of diseases".[5] Later the UN Charter was also recognised and the same that was adopted in future human rights conventions.[6]

Access to medicine, in some life-threatening cases, may fall under the right to life. The right to life may enhance the enforcement standards of access to medicines. The ICCPR is effective for its Optional Protocols which enhance its enforceability. Text of ICCPR regarding the right to life provides universal protection of human life and calls all signatories to protect an individual against arbitrary deprivation of it.[7] The right to life is prime of all human rights and is substantively explained and granted by the ICCPR. Moreover, the right to life is significant for enjoying other human rights. Moreover, the right to life is non-derogable. The text of Article 4 of ICCPR calls it an inherent right that one owns with birth through the operation of nature and this why some of the writers recognise it as *Jus Cogens,* a rule of international law that is compulsory for all states. [8]

Various writers have not recognised including access to medicine in the domain of the right to Life under the ICCPR and they that it only extends to state killing and individual without due process of law.[9] Moreover, death by hunger, lack of food, health, and access to medicine does not fall under the scope of Right to Life.[10] The restrictive interpretation of the right to life focus on keeping its effective enforcement as including housing, health, food, and other life necessities will make it domain-wide and less enforceable.[11] Moreover, these are conditions for life, not life in itself. Therefore, the domain of the right to life is the protection of life itself. Interpretative trends among human rights focus negative duty on states not to infringe the individual right to life. The positive aspect of duties such as providing all necessities of life will not fall under the domain of right to life of ICCPR.[12]

Contemporary interpretations of the right to life go a step ahead from classical approaches. For instance, Article 2 of ICCPR put a positive duty on member states to ensure and respect all human rights enumerated in the document. It is further stressed that member states are under obligation to make their laws, executive set-ups, and judicial interpretations in line with international human rights standards. The same article of the covenant puts duties on states to, " take necessary steps, in accordance with their constitutional processes and with the provisions of present convenient, to adopt those laws or measures to give effect to the rights recognised in present covenant".[13] The following paragraph, if critically evaluated, puts positive duty to act beside negative duty to apply restraint on power. Positive duty is exploiting states' constitutional framework and making laws effective for the protection of the right to life. Moreover, life cannot be taken in isolation with access to medicine in case of lifesaving medicine. We may take the example of AIDS, Cancer, Malaria, and other life-threatening diseases where denial of medicine is a denial of the right to life.[14] Moreover, the right to life is accomplished by the protection of all other human rights enumerated in ICCPR and ICESCR. Human rights whenever lead towards survival lead towards the right to life. General Comments 6 of the Human Rights Committee reflected upon the flexible interpretation of the right to life in the following words:

"The Committee has noted that the right to life has been too often narrowly interpreted. The expression "inherent right to life" cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics."[15]

The committee is made of experts on the area and has called for a flexible interpretation of the right to life. Moreover, it calls member states for understanding the protection of rights through positive measures through their constitutional process. Among increasing life expectancy and reducing child mortality, measures to

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[5] H.K. Neilson, *The World Health Organisation; Implementing the right to health* (Europublishers, 2001)12
[6] Ray Monihan, Richard Smith, 'Too Much Medicine? Almost Certainly' (2002) British Medical Journal 324-859, 324
[7] Ibid.
[8] Ibid.
[9] Holger Hestermeyer (n-3)115–116
[10] Ibid.
[10] Ibid.
[11] Ibid.
[12] Ibid.
[13] Ibid.
[14] Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as Right under International Law', (2003) 21 Boston University International Law Journal 325–371, 331
[15] UN Human Rights Committee (HRC), *CCPR General Comment No. 6: Article 6 (Right to Life)*, 30 April 1982 <https://www.refworld.org/docid/45388400a.html> accessed 2 September 2019

eliminate malnutrition, and the epidemic is relevant to the issue of access to medicine.[16] In the case of life-threatening diseases, the issue of access to medicine becomes relevant to the right to life. Member states to ICCPR have a positive duty to *respect, protect, and fulfil* right to life. Keeping in view these arguments, states are under obligation to legislate, administrate and interpret the issue of access to lifesaving medicines as matter of protecting life itself.[17]

Prioritising access to Medicine under Customary International Law

Access to medicine is an integral part of protecting the right to health and life as elaborated earlier. Although access to medicine has not argued under customary international law, however, it may draw relevance through various international arrangements such as Indian production of a generic version of AIDS medicine and others. For a practice to become custom it is generality, not universality that elevates a practice to become custom.[18] In recent times, states' practices regarding solving issues of lifesaving medicines to meet global challenges of pandemics of AIDS, Cancer, and malaria have brought the issue under debate. Principally, the international community of states has no objecting to solving these issues.[19]

International customs are one of the significant sources of international law. The contemporary international legal framework provides due significance to customs and does not consider them inferior to treaties in any way.[20] Rules of recognition for treaty and custom remain the same as both originate from ICJ Charter. Article 38 of the ICJ Charter defines both customs and treaties as sources of international law.[21] Prioritising access to medicine over pharmaceutical patent protection by using customs will be more effective as treaties operate between parties and customs operate universally.[22] Article 38(b) explains customs as, "international customs, as evidence of general practice accepted as law".[23] The underlying principle for establishing a norm as the practice is *opinio juris sive necessitates,* which points that a norm will elevate on status of custom if it is the general usage of states and they believe it is legally binding status.[24] *A North Sea Continental Shelf case explains* the same as:

"in order to achieve this result [mandatory rule of customary international law], two conditions must be fulfilled. Not only must the acts concerned amount to a settled practice, but they must also be such, or be carried out in such a way, as to be evidence of a belief that this practice is rendered obligatory by the existence of a rule of law requiring it. The need for such a belief, i.e., the existence of a subjective element, is implicit in the very notion of the opinio juris sive necessitatis. The States concerned must therefore feel that they are conforming to what amounts to a legal obligation."

Besides various conditions for a norm to become international customs such as practice and long duration of its observance, the aforementioned case has provided a modern interpretation of international customs. It declares that the condition of long-term practice may become flexible because of states' recognition of a rule as international binding. In this way, stress is on the binding and enforceability of the norm. Moreover, for a practice to become custom it is generality, not universality that elevates a practice to become custom.[25]

As discussed earlier, various state practices solving the issue of access to medicine regarding AIDS, cancer, and malaria-like pandemics are representing customary international law.[26] UN General Assembly (UNGA) resolution 58/179 is a first significant step in this regard that recognises the issue of access to medicine for meeting pandemics as an integral part of the right to health.[27] The resolution specifically asked states to adopt all necessary national measures to develop national health and health care systems with specific reference to

[16] Ibid.
[17] Ibid.
[18] Javaid Rehman, *International Human Rights Law* (Pearson Education Ltd, 2010) 75
[19] Holger Hestermeyer (n-3)128
[20] Joost Pauwelyn, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law* (Cambridge University Press, 2003) 133
[21] Statute of the International Court of Justice, Article 28
[22] Anglo-Norwegian Fisheries, United Kingdom v. Norway, Order, 1951 I.C.J. 8 (Jan. 10) 131.
[23] Statute of the International Court of Justice, Article 38 (b)
[24] Ibid.
[25] Javaid Rehman (n-18)75
[26] Tina S. Bhatt, 'Amending THE TRIPS: A New Hope for Increased Access to Essential Medicines' (2008) 33 (2) Brooklyn Journal of International Law 597-628, 602
[27] UN General Assembly, Declaration of Commitment on HIV/AIDS, 2 August 2001, A/RES/S-26/2 <https://www.refworld.org/docid/3dda1a037.html> accessed 2 September 2019

provide indiscriminate access to health care infrastructure to people infected by life-threatening diseases such as AIDS, cancer, and malaria.[28] The resolution directly pointed out the issue of access to medicine by calling upon all states to adopt policies for availability, affordability, and indiscriminate accessibility of medicines and medical technologies essential for life-threatening diseases.[29] General Comments no. 14 of the CESR comprehensively points the same by asking states to refrain from adopting measures affecting access to medicine and put positive duty to align their laws in a way that they facilitate access to lifesaving medicines. Moreover, the same comments elevate this to international legal responsibility by asking international organisations to adopt some measures for creating access to lifesaving medicines. In 2010, UNGA stressed the same in its resolution 65/1 for Millennium Development Goals.[30]

Customary international legal status of access to medicine, in a way, is recognised on almost all forums of adoption of TRIPS Agreement and later Doha Declarations. UN Special Rapporteurs, on many occasion, have pointed out the same issue declaring issue of access to medicine that, "[a]t the international level, legal and political commitments have been made to improve access to essential drugs for all, particularly in the context of the TRIPS Agreement and the Declaration of Commitment on HIV/AIDS".[31]

Although, access to medicine have attracted good deal of international consensus establishing it as custom but it remains theoretical as practical enforcement of access to medicine remains 'moral obligation'.[32] In order to establish access to medicine on level of *opinio juris*, a good deal of jurisprudential and later legal developments are required. Overall, issue of access to medicine is taken on moral basis rather than legal enforcement. Not only access to medicine but also the overall framework of human rights is not successful in its recognition as internationally enforceable obligations.

Presuming access to medicine as a peremptory norm of International Law

Access to medicine has not yet achieved a status of peremptory norms of international law. In case of connecting access to medicine towards the right to health or right to life will give impetus to its enforcement. Moreover, in case of including access to medicine as peremptory norms, it will have precedence over all other international obligations. Peremptory norm is defined as "a norm accepted and recognised by the international community of states as a whole as a norm from which no derogation is permitted".[33] The international legal framework obliges member states to give due care to peremptory norms while drafting treaties between them. A violation of the peremptory norm as discussed earlier will leave the treaty void. Moreover, these peremptory norms are an essential part of treaties beyond states' consent to agreements.[34] *Jus cogens* are considered as superior obligations or norms in national and international legal frameworks.[35]

For a norm of the rule to become *jus cogens*, it needs recognition from the international community of states. International consensus on elevating a norm to peremptory status involves some kind of social and political discourse. Access to medicine involves a difference between developed and developing countries. Normativity for developing countries is enhancing access to medicine through protecting patents while developing and LDCs call for easing patent protection standards to achieve the goal. Access to medicine has to face politics for developing it as a peremptory norm of international law.[36] A critical analysis of norms recognised as peremptory norms such as the use of force, self-defense, slavery, genocide, the prohibition of torture, and prohibition and piracy are very closely related to the right to life. The list of peremptory norms is not conclusive and Forman argues that "the circumscribed list of accepted peremptory norms is itself reflective of normative priorities within international law that could reasonably be interpreted to include health-related interests".[37] The same

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[28] Ibid.

[29] Ibid.

[30] UN General Assembly, Resolution 65/1. Keeping the Promise: United to Achieve the Millennium Development Goals (UN Doc. A/RES/65/1; 2010) < http://www.unwomen.org/en/docs/2010/10/un-general-assembly-resolution-65-1> accessed 8 November 2018

[31] Jennifer Anna Sellin*, 'Access to Medicines The Interface between Patents and Human Rights. Does one size fit all?'* (Intersentia Publishing Ltd, 2014) 245

[32] Ibid.

[33] Ibid.

[34] Lisa Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2013) 14 (2) The Journal of World Intellectual Property 155-175, 157

[35] Ibid.

[36] Ibid.

[37] Ibid.

stance has been adopted by ILC for VCLT saying *jus cogens* are not conclusive and they are explained through subject matter related to principles defined earlier. Although, ICJ has not specifically used the term *jus cogens* in their findings expressions like 'intransgressible principles of international law' and others are used to express the concept. *Jus cogens* comprise various concepts related to life and the protection of various aspects of it.[38] In the case of lifesaving medicine, one may relate the norm to the right to life where access to medicine is essential for saving it from life-threatening diseases. Cases of pandemics and national emergencies in diseases such as AIDS, Cancer, and other infectious diseases are direct threats to life. The significance of the issue of access to medicine in AIDS cases has been established by international recognition in various international commitments. Literature available on the subject suggests that access to medicine is considered an integral part of the right to health, not life.

The concept of *jus cogens* is evolving and the international community of states includes new aspects of various aspects of the right to life.[39] The point to understand is the denial of access to essential lifesaving medicine. One may understand that positive duties towards the right to health may not include in *jus cogens* or international norms accepted by all states. On the other hand, it is a denial of essential lifesaving medicines, which may tantamount towards the end of life. Article 103 of the UN Charter explains the mode of solving the conflict between two conflicting international norms as: "in the event of a conflict between the obligations of the members of the United National under the present Charter and their obligations under any other international agreement, their obligations under the present Charter shall prevail."[40] It is mentioned earlier that international norms accepted by the international community of states will prevail over other norms or treaty obligations.

Barcelona Traction Case explains the concept of *erga omnes* obligations. ICJ distinguishes between international obligations in personum and in rem, obligation between or among states and obligations between whole international communities of states.[41] These obligations require all member states to act following standards defined such as human rights standards. States, by members of the UN, are obligated to incorporate their laws in the light of global standards of human rights. Although, there is not sanction defined for violation of *erga omnes* a violation attracts international isolation. Obligations related to human rights are not bilateral or trilateral as they are generally applied to states in general and most of them are interrelated.[42] Enforcement of human rights is a national subject matter that may be adopted universally.[43] If we compare human rights obligations with pharmaceutical patent protection, we may observe that obligation of the patent is through treaties with specific enforcement. While human rights obligations are general in rem.[44]

The global practice of prioritising international obligations put human rights far behind in practice. Although access to medicine is not only an integral part of the right to health but also the right of life in case of life-threatening diseases, yet it has not achieved the status of *jus cogens* or fundamental principles of international law. As quoted earlier, the concept of *jus cogens* is evolving and various subject matters are included over time. One can be optimistic that one-day access to medicine towards lifesaving medicines will be included in the domain of *jus cogens* to civilised framework of the international legal framework.

Do human rights get primacy over other rights?

Human rights remain prime objectives of the international legal system after the maintenance of global order by avoiding major international armed conflicts.[45] The international legal framework has always tried focusing on enforcement of human rights and avoiding any hindrances in their absorption in various national jurisdictions. UN was skeptical of TRIPS Agreement and reported as:

"Since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, there are apparent

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[38] Ibid.
[39] Jennifer Anna Sellin (n-31)
[40] Charter of United Nations, Article 103
[41] Jennifer Anna Sellin (n-31) 245
[42] Lisa Forman (n-31)
[43] Joost Pauwelyn (n-20) 549
[44] James Harrison, *The Human Rights Impact of the World Trade Organisation* (Oxford/Portland: Hart Publishing, 2007) 65–66, 69
[45] Joost Pauwelyn (n-20) 155

conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other".[46]

The concerns related to the right to enjoy scientific and technological developments, right to food, and especially right to health were in jeopardy after the adoption of the TRIPS Agreement. The agreement was an international legislative document implementing identical intellectual property protection on states with different scientific and technological capacities. The aforementioned observation doubts the anticipated impact of global economic developments on human rights.[47] Moreover, UN Sub-Commission on Human Rights called for states to protect the 'primacy of human rights' obligation in case economic rights impact them anyway.[48] Moreover, sub-commission reported that "the WTO qua an international organization, created and functioning under general principles of international law, is bound to respect fundamental principles of international human rights law which form part of those general principles of law."[49] Report of sub-commission received WTO criticism because of unsubstantiated pieces of evidence through empirical evidence. WTO questioned the methodology and conclusion of the report.[50] The report did not gather effective mass to prove the stance of public health against patent protection.

Reconciling right to health of ICESCR with patent protection obligations under TRIPS

The right to health is a universal obligation of state members to ICESCR and other international agreements protecting human rights.[51] The issue of access to medicine has gone complex and about a billion people do not have access to essential lifesaving medicine. This denial of essential medicine in violation of the international legal obligation of states towards ICESCR. States, through their governments and judicial system, bear duty towards the protection of health as one of the norms of international human rights.[52] The obligation of member states towards ICESCR is explained as, "States parties have specific and continuing obligations to move as expeditiously and effectively as possible towards the full realisation of the right to health".[53] After the adoption of the TRIPS Agreement, the objective was to emancipate protection of health by interpreting it in a way that it reconciles with member states' obligations towards protecting the rights of their populations and international trade.[54] Post-TRIPS international obligations of the pharmaceutical patent have favoured property rights of individuals or companies.[55]

Article 12 of ICESCR obligates all member states to protect the right to health including access to essential medicines.[56] Later, the same was stressed by CESCR that obligation towards the right to health extends to accessibility, availability, and affordability of essential medicines.[57] Text of article 12 of ICESCR asks members states to adopt both legislative and regulatory measures for ensuring the protection of the right to health and access to medicine.[58] The CESCR reports, while explaining the domain of right to health, describe it as essential

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[46] David Weissbrodt and Kell Schoff, 'Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7' (2003) 5 (1) Minnesota Intellectual Property Review *1-46*
[47] David Weissbrodt and Kell Schoff, 'Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7' (2003) 5 (1) Minnesota Intellectual Property Review *1-46*
[48] Jennifer Anna Sellin (n-31) 242
[49] J. Oloka-Onyango, Deepika Udagama, 'UN Sub-Commission On The Promotion And Protection Of Human Rights, Progress Report Submitted by on Globalisation and Its Impact on the Full Enjoyment of Human Rights' (UN Doc. E/CN.4/Sub.2/2001/10) 58.
[50] Chakravarthi Raghavan, 'WTO Concerned over Human Rights Appraisal Report' < https://www.globalpolicy.org/component/content/article/211/44803.html> accessed 10 November 2018
[51] Jennifer Prah Ruger, 'Toward a Theory of a Right to Health: Capability and Incompletely Theorized Agreements' (2006) 18 Yale Journal of Law & the Humanities 273, 312
[52] Hurst Hannum, 'The Status of the Universal Declaration of Human Rights in National and International Law' (1995/1996) 25 Georgia Journal of International and Comparative Law 287,292.
[53] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, Para 31, 11 August 2000, E/C.12/2000/4 <https://www.refworld.org/docid/4538838d0.html> accessed 2 September 2019
[54] Daniel Gervais, *The THE TRIPS Agreement-Drafting History and Analysis* (2nd edition, Sweet & Maxwell, 2003) 3-26
[55] Ping Xiong, 'Pharmaceutical Patents in the THE TRIPS Agreement and the Right to Health: Can These Rights Be Reconciled?' (2012) 36 (1) University of Western Australia Law Review 115-142, 142
[56] International Covenant on Economic, Social and Cultural Rights, Article 12
[57] UN Committee on Economic, Social and Cultural Rights (CESCR) (n-53)
[58] Ibid.

for enjoying all other human rights. Although protection of public health has not been defined in ICESCR, however, the text of article 12 includes all parts of it.[59] In this way, states got both national and international duties towards protecting public health.

States' obligations towards public health and access to medicine often conflict with responsibilities towards protecting pharmaceutical patent standards of the TRIPS Agreement.[60] As argued earlier, the conflict needs interpretative tools of customary international law.[61] Interpretative approaches are available in VCLT and customary norms against any conflicting obligations. States enter into new obligations keeping in mind their existing obligations towards the international community. Theoretically, the international legal framework does not recognise any conflict between states' human rights obligations and protecting pharmaceutical patents but practically protecting pharmaceutical patents provide more room for deciding the prices of medicines. High prices affect the right of access to medicine.

Conclusion

The arguments find that the enforcement of patents on medicines in isolation to access to mediciens-related human rights are not tenable in the post COVID-19 world. The human rights standards for minimising the impact of patent enforcement on medicines are inevitable. The interpretation of enforcement standards on medicines should include the human rights aspects of accessing the medicines. To do this, the study suggest the interpretative scope of harmonising the patents on medicines with the human rights standards of access to medicines. The courts can benefit from the treaty interpretation standards of VCLT as well as the flexibilities found in the TRIPS Agreement to accommodate the issue of accessing medicines. The post-COVID era demands finding the balance between access to medicines and patents on medicines to protect the ideals of universal, interrelated, and indivisible human rights.

[59] Alexandre Charles Kiss, 'Pennissible Limitations on Rights' in Louis Henkin (ed), The International Bill of Rights - The Covenant on Civil and Political Rights (Colombia University Press, New York, 1981) 290, 302

[60] Frederick M Abbott, 'The 'Rule of Reason' and the Right to Health: Integrating Human Rights and Competition Principles in the Context of THE TRIPS' in Thomas Cottier, Joost Pauwelyn and Elisabeth BUrgi (eds) Human Rights and International Trade (Oxford University Press, New York, 2005) 279, 280

[61] Ibid.