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I, Devdatta Mukherjee, hereby declare that this Essay is my original work, and it is free from any type of plagiarism. This Essay has neither been published anywhere nor submitted for consideration at any other place. The existing literature in the domain referred to in this work has duly been acknowledged herein in the form of footnotes.

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Thanking You,

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Devdatta Mukherjee,

M.Phil. Semester III,

CILS, SIS, JNU.

International Intellectual Property Regime and Public Health: Global Administrative Law as an Instrument of Resistance

Abstract

Amidst the severe legitimacy crisis faced by the WTO, the TRIPS Agreement could appropriately be viewed as perhaps the most controversial one. It reaffirms the allegation that power plays a key role in the formulation and implementation of Administrative Law in the distributed administration of the WTO, assigning priority to the trade-related market-friendly facet of the access to essential medicines at the expense of basic-need related human right of such access. It is painful to note such unjustified disregard of the interests of weaker class by the components of the nascent imperialist global state. Therefore, abiding by a doctrinal mode of research, this normative analytical endeavour shall venture into the scheme of protection of patents in essential drugs under the WTO regime, and the inadequacies thereof in addressing the global endemic and epidemic diseases, especially in the developing and the least developed countries. The emerging discourse on Global Administrative law is replete with pleas to subject such administrations to certain safeguards, albeit procedurally. Glimpsing through the prism of a Third World perspective which transcends the geographical criterion and borders on the class dimension, this Essay proposes that the substantive rules under the TRIPS Agreement deterring the human right of access ought to be revised, prior to subjecting their implementation rhetoric to review. Despite the several efforts at the behest of the international community, the obstacles created by the TRIPS Agreement have not yet been dismantled, and yet the insistence on the trend of upward harmonization of IP rights persists. Perceiving a skewed balance in favour of trade in the perusal of the distorted discourse on IP rights by the Global North, this Essay has referred to the proposed compensating strategies to facilitate the effective use of existing flexibilities, and pens down the means to utilize the strategies in the ardent quest to reconceptualise the contours of Global Administrative Law as an instrument of resistance and as an articulate voice of socialist concerns.

I. Introduction

In this era marked by dilution of actual sovereignty of states, international governance by a network of international institutions is an acknowledged reality. The transverse intonation imbibed by the supra-structure of institutions to an otherwise horizontal corpus of international law has necessitated the incorporation of certain administrative rules of law, analogous to municipal systems, for the effective functioning of these institutions. The precepts of good administration and legal standards concerning transparency, participation, accountability and the like, when imbued, ought to advance the global democratization and justice agenda. The indeterminacy appertaining to the connotation of Global Administrative Law (hereinafter, GAL), the formalist ambiguity on the content thereof, and the role of GAL in strengthening operational, structural and normative issues have solicited the contemplation of the renowned scholars. A perusal of the scholarly works appertaining to the emergence of GAL in the arena of international regulation sets the backdrop of this essay. The fact that such regulatory bodies, comprising a nascent imperialist global state, tend to advance the interests of the transnational capitalist class is acknowledged, and the consequent problem of 'unjustified disregard' sought to be addressed. Perceiving a confirmation of the understanding that power plays a key role in the formulation and implementation of administrative law in the distributed administration of World Trade Organization (WTO), via the eponymous Trade Related Intellectual Property Rights Agreement (TRIPS), the rationale of the Intellectual Property (IP) regime calls for a revisit. When the human right of access to essential medicines is concerned, *i.e.* from the perspective of basic needs-oriented human rights and not trade related market-friendly aspect thereof in this globalizing era,[1] GAL ought to be re-conceptualized in sync with the third world perspective, in a fashion that the international economic institutions and their trade policies are less inimical to the health concerns of the marginalized populace.

Abiding by a doctrinal mode of research, this primarily normative analytical endeavour shall venture into a single positive domain- that of the scheme of protection of IP rights under the WTO regime. Since the inception of GAL is premised on adoption of the national administrative law mechanisms in the scheme of regulatory functions of international bodies, analogies from the domestic plane, always from India, have been reverted to in this Essay.

[1] Upendra Baxi (2002), *The Future of Human Rights*, Oxford University Press: Oxford.

II. Global Administrative Law: Delving into the Normative Connotation of the Emerging Concept

II. I. Adoption of Administrative Law Mechanisms in the Global Regulatory Regime

A glimpse into the structure of global regulation today reveals a massive proliferation and differentiation of the International Organizations (IOs), and the expanded range and significance of their activities.[2] The plethora of such global administrative regulatory bodies operates and interacts in a global administrative space which is kaleidoscopic in nature,[3] conducting global regulation. Global regulation has been broadly defined as encompassing a wide range of programs and activities that adopt and implement rules and other norms in order to steer and coordinate conduct by numerous actors for achievement of common objectives,[4] including the facilitation and management of markets; law enforcement and security; health, education, and human development; and human rights.[5] Global regulators generally rely on distinct institutions and entities that implement their norms, decisions, and policies. Such bodies constitute the 'distributed administration' of global regulatory regimes, and they operate within frameworks and pursuant to norms and procedures established by the global body.[6] The IP regime envisaged under TRIPS is an example of such distributed administration of the WTO. The endeavour of global regulation is undertaken by the global administrative regulatory authorities in the capacity of agents to single or multiple principals with inherent discretionary decision making powers.[7] However, such agents retain an appreciable quantum of their substantial discretion, despite the administrative law mechanisms and availability of independent review of administrative decisions by the

[2] Benedict Kingsbury and Lorenzo Casini (2009), "Global Administrative Law in the Operations of International Organizations", *International Organizations Law Review,* 6: 319.
[3] Edith Brown Weiss (2010), "On Being Accountable in a Kaleidoscopic World", *ASIL Proceedings,* 104: 477.
[4] Richard B. Stewart (2012), "Enforcement of Transnational Public Regulation", in Fabrizio Cafaggi (ed.) *Enforcement of Transnational Regulation,* Elgar: Cheltenham, 41.
[5] Benedict Kingsbury *et.al.* (2005), "The Emergence of Global Administrative Law", *Law & Contemporary Problems,* 68: 15.
[6] Richard B. Stewart (2014), "Remedying Disregard in Global Regulatory Governance: Accountability, Participation, and Responsiveness", *American Journal of International Law*, 108(2): 211-270.
[7] Arthur Lupia and Mathew McCubbins (1994), "Designing Bureaucratic Accountability", *Law & Contemporary Problems,* 57: 91.

principal aspiring to constrain the discretion, in order to promote rule of law.[8] Administrative law requirements for decision making, including notice of proposed decisions, opportunity for comment, reason giving, and opportunity for some form of review, also constrain on the other hand, in different ways, the ability of powerful principals to dictate specific decisions to limit the agent's freedom of action.[9] Such checks and balances, in a way, operate to promote the rule of law, at least procedurally, in the functioning of the organizations. Thus, this increasing adoption of techniques for disciplining administrative decision making, familiar in domestic law, in the sphere of global regulatory bodies, has been the primeval cause of fostering the emergence of GAL.[10] However, having precluded the substantive aspect from its domain, this adoption becomes necessarily insufficient.

The need for the aforesaid adoption solicits attention herein. The overall pattern of global regulatory regimes through the myriad and fragmented, mission-oriented authorities tend systematically, due to deep-seated structural factors, to give greater regard to the interests and concerns of some actors, especially powerful states and well-organized economic actors, and lesser regard to the often peripheral interests and concerns of more weakly organized and less powerful groups and of vulnerable individuals.[11] This imperialistic character of the international institutions has been underlined,[12] and the emergence of a Transnational Capitalist Class which shapes international laws and institutions to its advantage noted.[13] The intuitive understanding that power plays a key role in the framing, invocation, and implementation of administrative law, and that for the disadvantaged and marginal populations, the use of administrative law is often a mere theoretical possibility is confirmed, and the similar saga of class divide is unveiled in the national discourse as well, which has prompted Prof. Baxi to observe that 'administrative law in India is an archive of

[8] Mathew McCubbins *et.al.* (1987), "Administrative Procedures as Instruments of Political Control", *Journal of Law, Economics and Organization*, 3: 243.
[9] Mathilde Cohen (2008), "Reason-Giving in Court Practice: Decision-Makers at the Crossroads", *Columbia Journal of European Law*, 14: 257; Glen Staszewski (2009), "Reason-Giving and Accountability", *Minnesota Law Review*, 93:1253.
[10] *Supra* note 5.
[11] *Supra* note 6.
[12] B.S. Chimni (2004), "International Institutions Today: An Imperial Global State in the Making", *European Journal of International Law*, 15: 1.
[13] B.S. Chimni (1999), "Marxism and International Law: A Contemporary Analysis", *Economic and Political Weekly*, 337.

violent social juridical exclusion of suffering of the Indian 'masses' and a saga of solicitude for the Indian 'classes.''[14]

It is from such 'unjustified disregard' springs the consequent harm to interests and concerns, to the attainment of objective material conditions of welfare as well as the satisfaction of the value-loaded justice oriented dimension thereof, of the weaker groups and targeted individuals.[15] The 'problem of disregard' relates substantively to adoption of decisions that unjustifiably harm those, whose interests and concerns have been procedurally disregarded. In the present context, it can be amply deduced from the extant global scenario that TRIPS and TRIPS-plus regimes have slighted the needs of the least developed and the developing country populations[16] for access to essential medicines,[17] generating an example of the problem of unjustified disregard. The structural roots of this systemic disregard have been traced to decisional externalities resulting from global decision makers' focus on specialized missions (institutional tunnel vision) and the interests of dominant members; and to the structural disregard resulting from the uneven pattern of global regulation that leaves gaps in protections for the disregarded. Therefore, the domestic administrations of WTO members are obliged by TRIPS to respect and enforce the IP rights held by citizens of other WTO members. The TRIPS requirements, backed by WTO dispute settlement procedures, are calculated to overcome domestic authorities' disregard of foreign competitors, via the mode of 'upward harmonization.'[18] While addressing this form of disregard, the TRIPS regulatory regime may itself disregard and harm individuals who, as a consequence, can no longer afford essential medicines but whose interests and concerns lie outside its mission and represent 'omitted voices'.[19] The latter disregard ought to weigh heavily the global conscience, as a basic-need oriented human right is being trodden by considerations to facilitate trade.

[14] Upendra Baxi (2001), "Introduction" to I.P. Massey, *Administrative Law,* Eastern Book Company: 5th edn., xiii.
[15] *Supra* note 6.
[16] Such people undeniably are entitled to regard, under the Roman Law principle of *quod omnes tangit ab omnibus tractari et approbari debet;* Nicklaus Luhmann (1996), "Quod Omnes Tangit: Remarks on Jurgen Habermas' Legal Theory", *Cardozo Law Review,* 17: 883.
[17] Rochelle Dreyfuss and Cesar Rodriquez-Garavito (eds.) (2014), *Balancing Wealth and Health*; Amy Kapczynski (2008), "The Access to Knowledge Mobilization and the New Politics of Intellectual Property, *Yale Law Journal,* 117: 804.
[18] Amy Kapczynski (2009), "Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector", *California Law Review,* 97: 1571.
[19] *Supra* note 17.

The fact of increasing adoption of techniques for disciplining administrative decision making analogous to domestic legal systems in the arena of international institutions, and the need thereof, thus perused, makes it imperative to enunciate the contents and the discontents of the concept of GAL, and the idea of global administrative space.

II.II. Envisaging Global Administrative Space and Conceptualizing GAL: Necessity to Widen the Horizon

Amidst the classical dichotomy between an administrative space in national polities on the one hand and inter-state coordination in global governance on the other, realization has dawned that the two realms are closely intertwined in many areas of regulation and administration. The rise of regulatory programs at the global level and their infusion into domestic counterparts means that the decisions of domestic administrators are increasingly constrained by substantive and procedural norms established at the global level. Moreover, the global administrative bodies making those decisions in some cases enjoy too much de facto independence and discretion to be regarded as mere agents of states. Therefore, current circumstances undeniably call for recognition of a global administrative space, distinct from the space of inter-state relations governed by international law and the domestic regulatory space governed by domestic administrative law, although encompassing elements of each.[20] Allegations have been voiced that on the pretext of utilization of global administrative space, crucial national policy space has been intruded into or ceded, exemplified in the current context by the obligation to harmonize national IP policy with global trade-oriented vision, irrespective of local concerns.

Despite the warning that conceiving the field of GAL 'in broad terms would likely generate an unmanageable research agenda at this early stage in its development and would obfuscate the normative commitments entailed in work on global administrative law',[21] it is amply clear that a formalistic and narrow definition of GAL that excludes the content of substantive rules from its ambit entirely, confining it to 'the operation of existing or possible principles, procedural rules and reviewing and other mechanisms relating to accountability,

[20] *Supra* note 5.
[21] *Ibid.*

participation, and assurance of legality in global governance'[22] is grossly inadequate. Administrative law, at the most basic level requires us to articulate more specifically the type of democratic society in which we live and to have some vision of the political theory which that society espouses.[23] A Third World perspective requires GAL to inform both the procedural as well as substantive content of the eponymous TRIPS regime. In view of the problems that this globalizing era, arguably marked by neo-colonization, is posing, a strict separation of the content of substantive rules and GAL, which in the narrow interpretation is deemed to be largely procedure, is not tenable 'as states slowly evolve into administrative agencies of international institutions, and because the operation of GAL can impact the content of substantive rules or be co-opted and subverted by them'.[24] Therefore, without a concurrent concern with substantive law, in the absence of criticism and reform of those substantive laws and institutions, GAL has only a limited potential to further the cause of democracy and justice and might end up legitimizing unjust laws and institutions. [25] Thus, it is imperative that GAL be re-conceptualized in a non-nihilistic manner, via modes that do not dictate the complete separation between substantive and procedural administrative rules. Likewise, the substantive rules under TRIPS deterring the human right of access to essential medicines ought to be revised, prior to subjecting their implementation rhetoric to review.

II.III. Assessing the Available Normative Administrative Frameworks to Address the Issue of Unjustified Disregard

In order to address the problem of disregard a general four-pronged strategy has been suggested, which if applied to the specific issue of addressing the global access to essential medicines under the WTO regime, might render it effective in true sense. The crucial problems are engendered by the general dearth in global governance of checks and

[22] *Ibid*.
[23] P.P. Craig (2003), *Administrative Law*, Sweet and Maxwell: 5th edn., 3.
[24] B.S. Chimni (2005), "Cooption and Resistance: Two Faces of Global Administrative Law", *New York University Journal of Law and Politics*, 37: 799.
[25] *Ibid.*

balances,[26] more so in the substantive rules. An assessment of the probable effect of the strategies in the current context is attempted hereinafter.

Firstly, the domestic political and legal controls over global decision-making are suggested to be strengthened via modes like universalization of the national deference principle. Such strengthening has the capacity to prevent the ongoing undermining of domestic health protection objectives. However, this strategy suffers from significant limitations as a general solution for disregard owing to two reasons. Global regulatory regimes entrusted with securing welfare are primarily established and governed by the domestic executive. The ability of domestic courts and legislatures to play a significant role is limited by their institutional circumstances and ineluctable principal-agent problems.[27] Further, only the most powerful nations can assert significant control over global regulatory rules and programs, which can also cause the disregard of the interests of citizens in smaller and weaker countries, including citizens in developing countries whose interests are ignored and disserved by their own governments. For example, the strong socialist message against a strong product patent regime sent by the Indian Judiciary in the *Bayer*[28] and *Novartis*[29] judgments has elicited much criticism from the Global North,[30] and the declaration by a government minister to formulate an IP policy conducive to global trade[31] denies and defies the extant socialist model sought to be up kept by the Judiciary.

A second strategy for the disregarded is engendered in contestation and resistance to implementation of global norms and decisions by distributed administration including domestic administrative agencies. The disregarded may be able to use domestic courts and legislatures as fora to voice opposition to and to obstruct domestic implementation of the global body's measures. The prerequisites to invoke this strategy are the capacity of the

[26] Ruth Grant and Robert Keohane (2004), "Accountability and Abuses of Power in World Politics", *IILJ Working Paper 2004/7*, 14, [Online: web] Accessed 15 Nov. 2014, URL: http://iilj.org/papers/2004/2004.7%20Grant%20 Keohane.pdf.

[27] Richard B. Stewart (2006), "The Global Regulatory Challenge to U.S. Administrative Law", *N.Y.U. Journal of International Law & Policy*, 37: 695.

[28] *Bayer Corporation vs. Natco Pharma Ltd*., Order No. 45/2013 (Intellectual Property Appellate Board, Chennai).

[29] *Novartis AG vs. UOI & ors.*, MIPR 2013 (1) 0313 (SC).

[30] Gopakumar G. Nair and Andreya Fernandes (2014), "Patent Policies and Provisions Relating to Pharmaceuticals in India", *Journal of Intellectual Property Rights*, 19: 7.

[31] "IPR Policy Soon", *The Hindu*, 08 Sept. 2014, [Online: web] Accessed 15 Nov. 2014, URL: http://www.thehindu.com/business/Industry/govt-to-come-out-with-ipr-policy-sitharaman/article6391438.ece. in pursuance thereof, a National IPR Policy has been drafted; *National IPR Policy*, 19 Dec. 2014, [Online: web] Accessed 15 May 2015, URL: http://dipp.nic.in/English/Schemes/Intellectual_Property_Rights/IPR_Policy_24December2014.pdf.

disregarded to effectively organize and advocate and that they have receptive domestic fora.[32] This strategy may be of little use when the distributed administrations consist of private actors that certify compliance with global standards, unless certain well disposed international organizations or governments are members or financial supporters of the global standard setting regime; otherwise private certifying entities will have little incentive to consider those disregarded in the establishment of the standards.[33]

The third strategy envisages the creation of new global regimes to fill regulatory and structural gaps. Rather than using 'voice' to try to change the practices of existing regimes, these initiatives reflect an 'exit' strategy.[34] And for reasons similar with respect to the existing global regulatory bodies, these new found regimes are susceptible to corruption and undemocratization. This strategy is particularly apt for dealing with structural disregard resulting from gaps in existing global regulatory programs where the other strategies canvassed here are of little avail. In the current context, this strategy appears to be an alternative that could be explored.

A fourth strategy for the disregarded is to reform the governance of existing decision-making mechanisms and arrangements of global regulatory authorities so as to secure greater regard by global regulatory authorities of the interests and concerns of the disregarded. Such governance tools might include deliberative decision making, accountability mechanisms, market and reputational mechanisms, transparency and disclosure provisions, non-decisional participation, and reason giving.[35] These mechanisms, if implemented, find a broadened range of actors covered, extending to the private actors, such as NGOs or firms, and to states. Some of these mechanisms do find place within the scheme of TRIPS, as elucidated hereinafter.

The nuances of imperialistic global regulation and need and modes to imbibe elements of holistically conceived GAL therein having been perused, it would be pertinent to substantiate positively the Third World argument that the human right of access to essential

[32] *Supra* note 17. For example, certain Latin American NGOs and human-rights advocates for local citizens' rights to essential medicines have successfully lobbied to limit domestic authorities' recognition and enforcement of pharmaceutical companies' intellectual property rights.
[33] *Supra* note 6.
[34] *Ibid.*
[35] Some of these tools find mention in the three pillars of the Aarhus Convention, which are (1) public access to information, (2) public participation in decision making, and (3) availability to the public of administrative or legal review procedures; Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters, Art. 1, July 25, 1998, 38 ILM 517 (1999).

medicines have been made subservient to the trade related intellectual property regime under WTO and that the balance ought to be restored immediately.

III. Trade Related Intellectual Property Regime under WTO and the Right of Access to Essential Medicines: A Case of Skewed Balance

III.I. Access to Essential Medicines: The Human Rights Approach

As Bruno Simma and Philip Alston have queried, in underlying the significance of the right to health, 'whether a theory human rights law which… finds no place for a right of access to primary health care is not flawed in terms both of the theory of human rights and of United Nations doctrine?'[36] The right to health is primarily codified under Article 12 of the International Covenant on Economic, Social and Cultural Rights, which asserts that states must recognize 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.'[37] The right of access to essential medicine is conceptualized as a sub-component of the broader right to adequate health,[38] rests on four pillars: availability; accessibility; cultural acceptability; and quality.[39] States' endeavour to ensure availability of medicines could include, for example, making use of compulsory license flexibilities in the TRIPS to ensure sufficient quantities of medicines within their countries, and supporting research and development of drugs to address diseases that place a particular burden on developing countries.[40] On the issue of accessibility of medicines, states must ensure access in geographic, physical and economic terms and without discrimination. Cultural acceptability calls on states to support the proper use of traditional medicines and the

[36] Bruno Simma and Philip Alston (1992), "The Sources of Human Rights Law: Custom, Jus Cogens and General Principles", *Australian Yearbook of International Law,* 12: 82.
[37] International Covenant on Economic, Social, and Cultural Rights, 1966, Article 12, [Online: web] Accessed 15 November 2014, URL: http://www2.ohchr.org/english/law/pdf/cescr.pdf.
[38] U.N. Special Rapporteur on the Right of Everyone to the Highest Attainable Standard of Physical and Mental Health, *Addendum: Mission to the World Trade Organization*, Paragraph 18, U.N. Doc. E/CM.4/2004/49/Add.1 (Mar. 1, 2004).
[39] ECOSOC, Committee on Economic, Social & Cultural Rights, *General Comment No. 14: The right to the highest attainable standard of health (Art. 12)*, Paragraph 12, U.N. Doc. E/C.12/2000/4 (August 11, 2000), [Online: web] Accessed 15 November 2014, URL: http://www.unhcr.org/refworld/pdfid/4538838d0.pdf.
[40] U.N. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 61st Sess., UN Doc. A/61/338 (2006) Paragraph 47.

integration of those medicines into national programs; and ensure compliance with medical ethics so that clinical trials are carried out with informed consent.[41] Finally, states must ensure that medicines are of good quality.[42]

It has been urged both on the part of states and international organizations, such as the WTO and the World Intellectual Property Organization (WIPO), to take account of states' human rights obligations when negotiating, signing and implementing international agreements.[43] Further, it has been suggested that powerful states must refrain from exerting their influence in a manner that undermines the ability of weaker states to fulfill their economic, social and cultural rights obligations.[44] Perceiving that the primary component of the Transnational Capitalist Class is constituted by the transnational firms, in 2008, the Special Rapporteur on the right to health issued human rights guidelines addressed directly to pharmaceutical companies calling on them, *inter alia*, to respect the right of countries to use to the fullest extent possible the flexibility afforded by TRIPS; make and respect a public commitment not to lobby for more demanding IP protections than those required by TRIPS;[45] and respect the Doha Declaration on the TRIPS Agreement and Public Health (2001).[46] A further cue might be taken from the evolution of the 'Protect, Respect, Remedy' framework, a set of obligations which, if fully embraced, would impose some international human rights obligations directly on businesses.[47]

Thus, there is no dearth in emphasizing the importance of granting cognition to the human right of access, albeit via soft law. The basic contours of the human right of access to

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[41] *Supra* note 39, Paragraph 12(c); *Supra* note 40, Paragraph 50.
[42] *Supra* note 39, Paragraph 12(d); *Supra* note 40, Paragraph 51.
[43] ECOSOC, Sub-Commission on the Promotion & Protection Of Human Rights, *Intellectual Property Rights and Human Rights*, Res. 2000/7, U.N. Doc. E/CN.4/Sub.2/RES/2000/7 (Aug. 17 2000); Commission on Human Rights, *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*, Resn 2004/26 (April 16, 2004) paragraph 10 (b).
[44] *Supra* note 40, Paragraph 64.
[45] U.N. Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines*, UN Doc. A/63/263 (Aug. 11, 2008) (prepared by Paul Hunt) paragraph 26.
[46] *Id.* at paragraph 27.
[47] UNHRC, 8th Session, Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, 'Protect, Respect and Remedy: A Framework for Business and Human Rights' (Apr. 7, 2008) A/HRC/8/5, [Online: web] Accessed 15 November 2014, URL: http://www.reports-and-materials.org/Ruggie-report-7-Apr-2008.pdf; adopted via UNHRC, 17th Session, Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, 'Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy", (Mar. 21, 2011) U.N. Doc. A/HRC/17/31, [Online: web] Accessed 15 November 2014, URL: http://www.businesshumanrights.org/media/documents/ruggie/ruggie-guidingprinciples-21-mar-2011.pdf, Paragraph 6, Annex Paragraph 11.

essential medicines thus noted, it would be appropriate to assess the TRIPS mechanism, a distributed paraphernalia of the WTO apparatus, for the quantum of compliance with the human rights approach, and for the degree of abidance to the GAL principles.

III.II. Perusal of the Scheme of Eponymous TRIPS Agreement: Straying away from the Human Rights Vision

By linking trade and IP rights in the TRIPS, the WTO has introduced a new mechanism for regulating public health. The fulfilment of the aims enshrined in Article 27 of the Agreement requires extensive legal adjustments particularly for the newly industrializing and developing countries, and thus substantial effort on their part.[48] This international system for the protection of IP has been harshly criticized from the perspective of the urgent need for life-saving pharmaceuticals in the fight against life-threatening epidemics.[49] The problem revolves especially around the interpretation of Article 31, which allows compulsory licensing and government use of a patent without the authorization of its owner only under a number of conditions, thereby aiming at protecting the interests of the patent-holder. Such grant cannot be exclusive,[50] and it must, as a general rule, be granted predominantly to supply the domestic market.[51]

The requirement that the compulsory license be used 'predominantly' to supply the domestic market limits the ability of countries that cannot produce pharmaceutical products nationally to cater to the health of their populace. Considering the health situation in a large number of developing countries, in which large parts of the population are infected with life-threatening and largely preventable epidemics, substantial resistance to the TRIPS regime has developed among the group of newly industrialized and developing WTO members. To assuage this plight, the Doha Declaration on the TRIPS Agreement and Public Health was adopted in 2001,[52] wherein the WTO members stressed the importance of implementing and

[48] Frank Schorkopf and Christian Walter (2003), "Elements of Constitutionalization: Multilevel Structures of Human Rights Protection in General International and WTO Law", *German Law Journal*, 4: 1359.
[49] *Ibid.*
[50] Article 31 (d).
[51] Article 31 (f).
[52] Declaration on the TRIPS agreement and public health, adopted on 14 November 2001, [Online: web] Accessed 15 November 2014, URL: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

interpreting the TRIPS in a way that supports public health by promoting both access to existing medicines and the creation of new medicines. The exemptions on pharmaceutical patent protection for the least developed countries was extended, further work was assigned to the TRIPS Council to establish a means of providing additional flexibility, so that countries unable to produce pharmaceuticals domestically can obtain generic supplies of patented drugs from other countries. Adducing a solution to the paragraph 6 issue, the TRIPS Council provided special permission (an interim waiver) to deviate from the obligation in Article 31, allowing countries producing generic copies of patented products under compulsory licenses to export the products to eligible importing countries.[53] However, the obstacles created by the TRIPS have not been fully dismantled: there still exist a plethora of impediments. The regime of TRIPS-Plus agreements imposing the requirements of data exclusivity; seizure of consignments of generic drugs in transit, the possible threat from a voluntary patent pooling system to destroy the existing compulsory licence regime; [54] and the substantiated claim that some Indian drug manufacturers cut corners and make substandard drugs for markets with non-existent, under-developed or emerging regulatory oversight[55] deter the effective export of generic drugs to countries with no manufacturing capacity.

Despite favouring strong patent protection in member jurisdictions, apparently there are implicit and explicit exceptions contained in TRIPS Article 8, 27, 30, 31, and 73 that if used effectively could provide developing countries with ammunition to combat some of their lack of access problems.[56] However, the use of the word "necessary" under Article 8 indicates that the government does not have complete discretion to use these measures, but that its use is subject to review by the WTO,[57] and the Article is limited to such measures 'consistent with the provisions' of TRIPS. The flexibility under Article 27 does not provide developing countries with a clear answer on how to provide better access to lifesaving drugs because the denial of patentability of a lifesaving drug would be accompanied by denial of any commercial exploitation of the drug within that country including the domestic manufacture

[53] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Decision of the General Council of 30 August 2003, [Online: web] Accessed 15 November 2014, URL: https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.
[54] Laura Chung (2010), "Use of Paragraph 6 System for Access to Medicine", *North Carolina Journal of International Law & Commercial Regulation*, 36: 137.
[55] Roger Bate *et. al.* (2014), "Poor Quality Drugs and Global Trade: A Pilot Study", NBER Working Paper No. 20469, [Online: web] Accessed 15 November 2014, URL: http://www.nber.org/papers/w20469.
[56] Wesley A. Cann, Jr. (2004), "On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries For Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism", *University of Pennsylvania Journal of International Economic Law*, 25: 755.
[57] *Ibid*.

of generic versions or compulsory licensing of the drug for a profit. Further, in order for a government to make effective use of a compulsory license for domestic production under TRIPS Article 31, it must have a reasonably sophisticated pharmaceutical industry to produce medicine and it must have a manufacturer with sufficient manufacturing capacity to create economies of scale to keep the costs down and the price of the medicine affordable.[58] Pursuant to these strict compulsory license requirements under Article 31 (f), developing countries and least developed countries cannot obtain drugs through importation at an affordable price in the quantity and quality required. Thus, even within the scope of provisions apparently conducive to promoting access, options lurk at the behest of the institution to meander the same.

A primary perusal reveals that certain administrative safeguards have indeed been incorporated in the TRIPS text, particularly in relation to procedures for the enforcement of IP rights.[59] Article 41, for example, provides that such procedures shall be fair and equitable; that they shall be written, reasoned and only based on evidence in terms of which both parties have had a right to be heard; and that there shall be a possibility for review. Articles 41-2, 49 and 62 impose regulatory due process requirements for acquisition and enforcement of intellectual property rights, including a right to review. Articles 54-58 stipulate a number of notification and review requirements, particularly where customs authorities refuse to release goods suspected of violating the Agreement. Article 62 deals with procedures for the acquisition of IP rights, including reasonable time-limits and a right to review, while Article 63 contains a general transparency requirement. However, it should always be borne in mind that administrative law itself is a 'Western' construct, developed in a particular setting and it inherently structurally biased towards certain interests.[60] When operationalized in the trade regulatory context, any such structural biases could serve to entrench the already dominant position of Western corporations. The afore noted procedural administrative safeguards explicitly appertain to the distorted discourse on IP rights by the Global North, adducing a further reason to pen down the Third World perspective, imbibing the same with substantive as well as procedural elements of GAL.

[58] Markus Nolff (2004), "Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the Decision of the WTO Regarding its Implementation: An "Expeditious Solution"?", *Journal of Patent and Trademark Office Society*, 86: 291.
[59] Richard B. Stewart and Michelle Ratton San Chez Badin (2009), "The World Trade Organization And Global Administrative Law", *IILJ Working Paper 2009/7* (Global Administrative Law Series).
[60] C. Harlow (2006), "Global Administrative Law: The Quest for Principles and Values", *European Journal of International Law,* 17: 187.

III.III. Obstacles to and Deficits in Voicing the Discontents against the Trend of Upward Harmonization

The trend of 'upward harmonization' of IP rights endorsed under the WTO Regime, under the pretext of strengthening IP rights the world over, has confronted severe discontents since it has acted as an impediment in the realization of the human right to access of essential medicines. While the supporters of upward harmonization argue that it will have positive effects on trade, foreign direct investment,[61] and global innovation, the opponents vehemently contend that such harmonization could ossify the imperfect IP system of the North and impede development.[62]

The TRIPS contains detailed, comprehensive substantive rules and is linked to the WTO's comparatively hard-edged dispute settlement system in which treaty bargains are enforced through mandatory adjudication backed up by the threat of retaliatory sanctions.[63] Thus, where human rights obligations come into conflict with WTO obligations, the pressure to adhere to WTO rules is far stronger than is the pressure to uphold human rights; countries may be punished for failing to follow WTO rules but not for ignoring the recommendations of U.N. human rights treaty bodies. Violating human rights may lead to swift condemnation by civil society groups, but these protests do not generate the same level of pressure as is imposed by the market and domestic financial actors to stay the course with economic policy rules. A reconfiguration of the balance is ardently called for in the TRIPS-enshrined IP protection law because since the inception of TRIPS, it has been heavily tilted towards trade facilitation, and not the human right; and that too in terms derogatory to the weaker class resulting in undue unjustified disregard.

Negotiations over intellectual property moved to the WTO because WIPO was viewed as hostile to raising domestic levels of intellectual property protection, and because the WTO

[61] Such claims are largely unsubstantiated; and it has been proved that innovation do thrive even in the absence of patent protections. Michele Boldrin and David Levine (2005), *Against Intellectual Monopoly*, [Online: web] Accessed 15 November 2014, URL: http://levine.sscnet.ucla.edu/general/intellectual/against.htm.

[62] Jerome H. Reichman and Rochelle Cocker Dreyfuss (2007), "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty", *Duke Law Journal*, 57: 85.

[63] Laurence R. Helfer (2006), "Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking", *Yale Journal of International Law*, 29:1.

provided a way to pay off developing countries for accepting stronger obligations.[64] In case of faulty implementation of imposed obligation, WIPO can only bark, whereas, WTO can actually bite.[65]

Instead of using trade as a lens through which to filter the scope of international obligations imposed by the eponymous TRIPS, the Appellate Body and the panels have largely subsumed the international IP system as a whole within the trade apparatus. Rule of law could still be ushered in via the dispute settlement mechanism. The dispute resolution is only applicable to IP by virtue of its nexus to trade. The dispute settlement board could enable the states to better tailor their IP laws to local interests if it focuses its attention on the extent to which challenged actions specifically encumber or distort trade.[66] But this would require imbuing the substantive provisions of the covered agreement with elements of GAL. The WTO's dispute settlement mechanism ought to give both sides an opportunity to voice their concerns, and enable a panel to make an educated decision about what kind of approach best serves the developing nation's goals.[67] If trade-relatedness were made a criterion for determining TRIPS compatibility, nations would have more room to adapt their laws to domestic needs and to make them responsive to local changes in circumstances.[68] Whatsoever, the trade-relatedness of patented essential pharmaceutical drugs can never be disputed, rendering this alternative of reconceptualizing the role of dispute settlement mechanism infelicitous in this context.

The realization of this right is often plagued by certain obstacles stemming from the very basic legitimacy deficit accorded to economic and social rights in contrast to the civil and political rights in the current globalization discourse; accrual of primacy to the human right without enforceability leading to a severe accountability deficit; and finally capacity deficit in terms of the civil society's inability and disinclination to play an active role and lack of judicial and legislative support to translate and implement human rights obligations. The ultimate consequence is that the weaker class succumbs to global pressure.

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[64] *Supra* note 62.
[65] *Supra* note 12.
[66] Susy Frankel (2006), "WTO Application of 'the Customary Rules of Interpretation of Public International Law' to Intellectual Property", *Vanderbilt Journal of International Law,* 46: 365.
[67] Andrea M. Curti (2001), "The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS", *American Journal of Law and Medicine*, 27: 469-485.
[68] Graeme B. Dinwoodie and Rochelle C. Dreyfuss (2009-1010), "Designing A Global Intellectual Property System Responsive to Change: The WTO, WIPO, and Beyond", *Houston Law Review,* 46: 1187.

Even when domestic actors succeed in incorporating human rights elements into agreements, domestic implementation may fall far short of expectations due to structural impediments and institutional problems. India's experience exemplifies such a quagmire. When India signed TRIPS in 1995, the country's large generic drug manufacturing sector and active civil society were already alert to the possible implications for the right to health and access to essential medicines.[69] Despite intense domestic and international advocacy, and a relatively successful campaign to incorporate public health flexibilities into national implementing legislation, research has shown that it has been difficult to make use of the existing legal flexibilities.

Thus enunciated, it is picturesquely clear that there are significant obstacles to implementing the rights-based approach to intellectual property and access to medicines. These obstacles emerge in the context of both horizontal and vertical fragmentation in the realm of international law. Horizontally, states' human rights obligations may not cohere with their financial commitments, despite calls for such coherence by numerous human rights actors. Vertically, competing international norms may lead to one overshadowing another, and more often than not human rights norms fall prey to financial lucre in the global arena. Such fragmentation, nevertheless, should not compromise the implementation GAL within the institutional rubric. But the very contents and objects of GAL need to be reconceptualized within the WTO TRIPS Agreement Framework, to competently utilize it as an instrument for resistance.

IV. Compensating Strategies to Facilitate the Effective Use of Existing Flexibilities

As an alternative, three compensating strategies have been conjured to facilitate the effective use of TRIPS flexibilities,[70] responding to the transnationalized pressures that TRIPS implementation sets up. Via the strategy of 'fragmentation' the ability of unique local legal requirements to introduce friction into transnational circuits of influence has been identified. The introduction by South African government of the Medicines and Related

[69] *Supra* note 18.
[70] *Ibid.*

Substances Control Amendment Act in 1997 to promote the availability of HIV/AIDS drugs via parallel imports and compulsory licensing under TRIPS could be cited as an example of this strategy. Although litigation ensued and the nation was placed in 'Section 301 Watch List' by the US Trade Representative, ultimately the 'well-organized grassroots campaign' led to the realization certain 'necessary flexibility to meet the health needs of developing countries' is inherent in the TRIPS.[71]

The second strategy of 'mimicry' shall work these transnational circuits against the grain by legitimating local law with reference to the law of high protection countries while reinscribing the meaning of those texts and precedents. Here, 'recipient' countries model and legitimate their local law with reference to the law of 'dominant' countries. But rather than adopt wholesale the meanings of these provisions, these texts are revised or reinscribed. Mimicry is legal transplantation with a difference, and may include strategic citation of legal precedents from other jurisdictions.[72] For example, the adoption of Section 3 (d) in the Indian legislation, a specific and unique local provision, does offer administrative officials and judges some insulation from the influence of transnational legal culture. This strategy has the potential of utilizing the loopholes in taking note of the local concerns, whilst subscribing to the international imposition at large.

The third strategy of 'counter-harmonization' would seek to rewrite these transnational circuits by creating an alternative model of patent law that is coordinated among developing countries. At a time when the BRICS Bank has seen the light of the day, why can't we envisage an alliance or coalition, partial or full, amongst these nations towards an IP regime that balances the interests of fair trade and human right? However, a note of caution must be struck. Where a coalition of weak bargainers obtains a negotiating gain that requires high levels of rule complexity to implement, it reduces its chances of successfully realizing that gain.[73] There must exist a strategy for countering forum shifting by a powerful losing state that is aimed at recapturing that gain.[74] Although there have been evidence in the recent past that India could provide a pole for the endeavour of counter-harmonization, after the Novartis decision, its subsequent listing in 'priority watch list' was followed by threats of possible

[71] Haochen Sun (2004), "The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health", *European Journal of International Law*, 15 (1): 123.
[72] *Supra* note 18.
[73] Peter Drahos (2007), "Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines", *Liverpool Law Review*, 28: 11.
[74] *Ibid.*

'domino effect' to nations intending to follow suit.[75] This strategy has striking resemblance with the third normative administrative framework to address the issue of unjustified disregard, dealt with in Part II of this Essay.

V. Concluding Remarks

Of all forms of inequality, injustice in health care is the most shocking and inhumane.[76] Such injustice is vehemently perpetrated under the IP regulatory framework endorsed by the distributed paraphernalia of the WTO via TRIPS, wherein the right of the impoverished populace of the developing and the least developed countries to access patented essential drugs is unjustifiably disregarded, and the interest of the transnational pharmaceutical corporations unduly advanced. To contend that elements of GAL which is only procedurally sound ought to inform such regulation is, however, oblivious of the history of colonization and the ongoing neo-colonization. It is indisputable that GAL is today being shaped by a transnational capitalist class that seeks to legitimize unequal laws and institutions and deploy it to its advantage. It is imperative, therefore, to reconceptualize GAL to inform the substantive aspects of the covered agreements of the WTO as well. Such reconceptualization ought to pay heed to the diminished bargaining power and curtailed national policy space of the developing and the least developed states. It is submitted that such holistically conceived GAL would serve as a tool of resistance and harbinger of change.

The trend of imposition of the obligation of 'upward harmonization' strikes at the root of the self-reliant utilitarian patent vision. The rationale adduced pro strong patent regime appear baseless and unsubstantiated, and tend to promote a 'culture of consumerism'.[77] The implicit and explicit exceptions contained in the TRIPS and the successors thereto to the strong patent protection advocated are reduced to mere sophistry if their intricacies are perused; the subjective elements are always left to be decided upon by the WTO. They do not, by themselves, provide ample ammunition to the weaker states to combat the lack of

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75 USTR, *2014 Special 301 Report*, [Online: web] Accessed 15 November 2014, URL: https://ustr.gov/sites/default/files/USTR%202014%20Special%20301%20Report%20to%20Congress%20FINAL.pdf.

76 Martin Luther King Jr., Presentation at the Second National Convention of the Medical Committee for Human Rights, Chicago, March 25, 1966.

77 B.S. Chimni (1993), "The Philosophy of Patents: Strong Regime Unjustified", *Journal of Scientific and Industrial Research*, 52: 234-239.

access problems. One option to redress the situation lies in amending TRIPS to consider the needs of the developing countries. However, this option might lead to the recurrence of history: the negotiations might once again meander in favour of the developed, as it happened whilst intending to amend the Paris Convention.

The other option is to utilize the available normative frameworks to address the issue of unjustified disregard and resorting to the compensating strategies. Undertaking strong steps locally against the imposition of global imperialist standards as evidenced in the *Bayer* and *Novartis* judgments, the proactive stand taken by the civil society groups, contestation and resistance to implementation of global norms and decisions by distributed administration including domestic administrative agencies is required. There are conditions in which administrative law principles can serve as instruments of change. These conditions include the design of appropriate participatory structures of administrative bodies, the presence of social movements and non-governmental organizations that support the causes of ordinary citizens, and the existence of a right to information- access laws that can be used to compel the transparency and accountability of administrative bodies. The compensating strategies have ample potential to be translated into effective tools of resistance in the long run, providing an articulate voice to socialist utilitarian concerns. Envisaging new global regimes, an exit strategy that utilizes the mode of counter-harmonization, might be an option worthy to be explored in this regard. However, a coalition amongst the weaker powers requires exercise of abundant caution to be effective.

Nevertheless, any or all of the aforesaid strategies to address unjustified disregard and the relevant administrative bodies thereof ought to be informed by the elements of a holistically conceived GAL, adopting a progressive substantive international law regime with a strong human rights dimension. Also, an open institutional culture must be fostered within concerned agencies so that dialogue between stakeholders is institutionalized and deliberative democracy in administration is promoted.