# In Defence of the Importance of Human Rights for the Improvement of Access to Patented Medicines: *A Response to Thambisetty*

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## Abstract

*This article is a response to Siva Thambisetty, 'Improving Access to Patented Medicines: Are Human Rights Getting in the Way?'. Thambisetty argues that human rights law can pose an obstacle to improving access to patented medicines. In response, it will be argued that while she raises salient points regarding the institutional efficiency and practical implementation of both human rights norms and patent law reform, she misinterprets key elements of the international human rights law system. These misinterpretations cloud her arguments such that she does not fully recognise the utility of human rights law and dialogue in patent reform and the remedy of abuses. Her argument does not consider key principles of the international legal hierarchy and the clear intersections which allow for the oversight of the operation of laws within the State as well as the progression towards greater oversight of the activities of non-state actors such as pharmaceutical corporations. In response, it is argued that through the proper utilisation of international human rights law mechanisms and dialogue, current failings of patent law can be remedied, fostering instrumental changes in the international and domestic patent system, ensuring greater access to essential medicines.*

## Introduction

In two recent works both entitled *Improving Access to Patented Medicines: Are Human Rights Getting in the Way?,*[1] Siva Thambisetty outlines her thesis that patent law should be detached from international human rights law, allowing for internal reform, without the inhibitions which she argues derive from human rights dialogue and intervention.[2] She takes issue with an alleged "assumption that a hierarchisation of patent rights and human rights is possible, or that one system of rights can resolve the problems created by another system of law"[3] since "there is no direct, formalistic overlap"[4] between

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[1] Siva Thambisetty, 'Improving Access to Patented Medicines: Are Human Rights Getting in the Way?' (2018) 3 Law, Society, Economy Working Papers 1. ('Working Paper'); Siva Thambisetty, 'Improving Access to Patented Medicines: Are Human Rights Getting in the Way?' [2019] I.P.Q. 284. ('Article')

[2] Thambisetty, 'Working Paper'; Thambisetty, 'Article'.

[3] Thambisetty, 'Article' at 286.

[4] Thambisetty, 'Working Paper' at 5.

international human rights law and patent law. She argues further that the human rights' inability to deal with the inherent complexity of patent law "can frustrate the intellectual property/human rights interface."[5] She continues saying that "we should dissociate patent law from human rights to focus on more productive avenues of reform internal to patent law"[6] and "systematically retool… [patent law] to be a purposive and reflexive system of law that understands and participates in its own consequences".[7]

Her argument emanates from frustration with the persistence of patent law impacting individual access to medicine, raising salient points regarding the institutional efficiency and practical implementation of both human rights norms and patent law reform.[8] She makes clear her view is that patent rights should be limited to better ensure access to medicines, and on this point, I wholeheartedly concur. However, I fundamentally disagree with her thesis that human rights law poses an obstacle to the realisation of this goal. It is suggested that she misinterprets several key elements of the international human rights law system. Through these misinterpretations she fails to fully recognise the utility of international human rights law and dialogue in patent reform and remedy of human rights abuses.

In response, the importance of international human rights law in ensuring access to patented medicines will be highlighted. In the context of access to patented medicines, the 'right to health' is particularly important. Whilst stemming from several sources, the most prominent formulation is Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which outlines:

> "…the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".[9]

A full discussion of the 'right to health' and access to medicines is beyond the scope of this article. However, it is integral to understand that access to medicines is a core component of the right to health and is thus essential its full realisation under the ICESCR. Article 12(2)(d) further requires that States create:

> "…conditions which would assure to all medical service and medical attention in the event of sickness."[10]

This has been interpreted by the Committee on Economic, Social and Cultural Rights (CESCR) in General Comment 14 to include access to essential medicines as listed by the WHO.[11] How intellectual property law interacts with access to medicines is therefore of direct concern to international human rights law.

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[5] Thambisetty, 'Article' at 287.
[6] Thambisetty, 'Article'.
[7] Thambisetty, 'Working Paper'.
[8] Thambisetty, 'Article' at 287.
[9] International Covenant on Economic, Social and Cultural Rights (ICESCR) (1966), art.12(1).
[10] ICESCR, art.12(2)(d).
[11] Committee on Economic, Social and Cultural Rights (CESCR), *General Comment 14: The Right to the Highest Attainable Standard of Health (Art.12)*, (E/C.12/2000/4), p. [12](a).

Structurally, this discussion follows the key elements of Thambisetty's argument. It begins by analysing the intersection of human rights and patent law, demonstrating how it fosters an environment of intersectionality which helps prevent extended harm to minority groups. It then critically examines the importance of human rights law and dialogue to the reform of patent law. Finally, it moves on to explore how the international human rights law system is essential in the implementation and reform of the TRIPS agreement in relation to access to medicines and patents. It ultimately concludes that Thambisetty's assessments are flawed. She does not fully consider the role of international human rights law and the importance of the intersection between human rights and the provision of essential medicines. By limiting the harm caused by patent law, whilst simultaneously providing a structural framework within which positive aspects of the existing international patent regulatory system can be utilised, human rights foster positive developments in ensuring access to essential medicines.

## The Intersection and Intersectionality of Patent Law and Human Rights Law

The first of Thambisetty's arguments is that "there is no direct, formalistic overlap"[12] between international human rights law and patent law and therefore, human rights are not a useful tool for patent reform.[13] This position is ignores two key areas of intersection: the first being a legal intersection in the form of a supervisory hierarchy and the second being from an subject-matter-interdependence and intersectional perspective.

### *The legal intersection*

Thambisetty's argument speaks to a view of human rights as an entirely separate and distinct regime which has little interaction with other categories of legal norms. She notes that the "two systems of law are like oil and water; the argument that one should prevail over the other is intellectually incoherent…"[14] However, this is a misinterpretation of the role of international human rights law. It acts as an oversight mechanism above the national regime, striving to ensure that individual rights are protected concretely and effectively.[15] It therefore operates in a supervisory capacity, external to the inner workings of domestic law. Therefore, the assumption that human rights *require*s some level of *direct* overlap is incorrect. The 'supervisory purpose' of human rights contradicts Thambisetty's assertion of a "a non-existent hierarchisation narrative"[16] within human rights dialogue concerning patents. As a matter of international law, States which are subject to international human rights law

[12] Thambisetty, 'Working Paper' at 5.
[13] Thambisetty, 'Working Paper' at 5.
[14] Thambisetty, 'Working Paper' at 5.
[15] Steven Wheatley, *The Idea of International Human Rights Law* (Oxford University Press 2019), p. 109.
[16] Thambisetty, 'Article' at 287.

have consented to the subversion of their national legal systems. Thus, to argue that one should not be subverted by the other is doctrinally incorrect.

Regarding the interplay between the TRIPS Agreement and international human rights law; whilst it is true that international law does not traditionally hold a hierarchical system between international norms[17] there is evidence of an emerging trend towards international human rights law superiority. As Cullet notes, the peremptory status of *some* human rights norms potentially indicates a progression towards a more *general* supremacy.[18] The UN Sub-Commission on Human Rights similarly stressed that intellectual property norms must be subordinate to human rights protection.[19] Thambisetty's position is therefore misjudged, given the present direction of international law towards the recognition of human rights supremacy.

Thambisetty argues further against a formalistic hierarchy, citing the argument that intellectual property is itself a human right.[20] Some, such as Hristova, support such a position, arguing that since patent property rights may be viewed as rights themselves, any conflict with opposing rights must be resolved via a process of balancing, rather than a fixed hierarchy.[21] However, the categorisation of intellectual property as a human right is flawed. States have generally elected to protect IP rights under domestic legislation and (non-human-rights-based) international agreements, rather than within instruments of human rights,[22] suggesting a rejection of this notion, something Thambisetty herself alludes to.[23] The alleged 'rights-holders' in these cases are corporate entities not natural persons. Significant debate exists surrounding their capacity to be held to, hold and subsequently assert *human* rights,[24] yet orthodoxy still asserts that *human* rights do not extend to corporate entities, as they are not *human*.

Similarly, the Committee on Economic, Social and Cultural Rights (CESCR) stresses that intellectual property rights should not be equated with human rights.[25] They make clear that the rights protected under Article 15 of the ICESCR and Article 27(2) of the Universal Declaration on Human Rights (UDHR)[26] pertaining to intellectual property are those of *moral* rights, not *economic* rights, which are protected under domestic law.[27] Thus, the economic interests of patent holders cannot claim the same

[17] Philippe Cullet, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health' (2003) 79 International Affairs 139 at158.
[18] Cullet, 'Patents and Medicines' at 159.
[19] UN Sub-Commission on Human Rights, 'Intellectual Property and Human Rights' UNSCHR Res 2000/7 (17 August 2000).
[20] Thambisetty, 'Article' at 286.
[21] J. Pat. & Trademark Off. Soc 339.
[22] Wendy Gordon, 'Current Patent Laws Cannot Claim the Backing of Human Rights' in W Grosheide (ed), *Intellectual Property and Human Rights: A Paradox* (Edward Elgar 2010).
[23] Thambisetty, 'Article'.
[24] Turkuler Isiksel, 'The Rights of Man and the Rights of the Man-Made: Corporations and Human Rights' (2016) 38 Hums Rts Q 294.
[25] CESCR, *General Comment No.17: The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author* (2005) (E/C.12/GC/1712), p. [3].
[26] (Adopted 10 December 1948, UNGA Res 217).
[27] CESCR, *General Comment 17* at [4].

substantive weight as their moral counterparts.[28] The CESCR clearly expresses this superiority of human rights, noting that "intellectual property 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."[29] As such, where access to essential medicines are concerned, such balancing does not act as a barrier to the proper protection of the right to health. Intellectual property rights are economic policy made law. Human rights are inherent to everyone, fulfilled by law. The latter must always prevail over the former. Given this, whilst there is no intersection between the two laws in a formalistic sense, there is a clear supervisory and hierarchal intersection between the two, with human rights acting as a check on the outcomes of patent law.

*Practical intersection & intersectionality*

From the perspective of practical implementation, Thambisetty's position may hold more weight. As Cullet notes "[i]ntellectual property law and human rights law have largely evolved independently…"[30] As such, one might misinterpret independent evolution to prevent formal intersection. However, such *practical* intersections need not be formalistic. Indeed, the primary intersection between intellectual property law and international human rights law is subject-matter-interdependence. Both bodies of law directly affect how individuals can access essential medicines. As Cullet notes, "with the broadening scope of patents in areas related to basic needs such as health… the links between the two fields are becoming increasingly obvious and direct…"[31] Thus, the intersection rests where the negative impacts of patent law, such as its impact upon pricing and access to medicines, directly align with the protections and remedies of international human rights law.

An examination of the content of the 'right to health' reveals a clear intersection between the enshrined rights and the violations caused by exploitation of the position provided by patent protection. Key principles of the 'right to health' such as availability and accessibility[32] are flouted by excessive and exploitative price-rises by pharmaceutical companies,[33] allowed by their monopolistic patent-granted rights. Patent law has increasingly grown as a dominant force in economic development.[34] Owoeye and Owoeye note that this increased significance has positioned it as a major epicentre of human rights debate because of the inherent link between trade, the economy, and the fulfilment of essential human

[28] CESCR, *General Comment 17* at [4].
[29] CESCR, *General Comment 17* at [2].
[30] Cullet, 'Patents and Medicines' at 139.
[31] Cullet, 'Patents and Medicines' at 139.
[32] CESCR, *General Comment 14* at [12].
[33] For a detailed examination of the data see: Jing Luo, Aaron Kesselheim and Jerry Avorn, 'Out-of-Pocket Spending Among Commercially Insured Patients for Epinephrine Autoinjectors Between 2007 and 2014' (2017) 177 JAMA Internal Medicine 736.
[34] Olasupo Owoeye and Oluwabusayo Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage through a Health Rights Lens' [2018] 40 E.I.P.R. 49 at 50.

rights.[35] Indeed, there is a clear correlation between the strengthening of corporate patent rights and a stark decrease in pharmaceutical accessibility for those in poverty.[36]

It is clear therefore that there is an overlap between the negative impacts of patent law and the enshrined rights of international human rights law. As such, the removal of human rights dialogue from the debate would cause significant harm, especially to marginalised groups in low-income countries.[37] The imposition of the TRIPS agreement upon low-income countries has created significant problems for access to medicines,[38] and whilst the WTO has extended its application to the least developed countries (LDCs) until 2034,[39] this does not remedy the impact already felt in other nations, nor does it guarantee seamless transitions for those LDCs in a decade. This too speaks to the intersection between the two bodies of law. As General Comment 14 makes clear, there must be special protection for the right to access medicines for "vulnerable or marginalized sections of the population".[40] As an example, marginalised communities, such as LGBTQ+ and disabled groups, especially within low income and conservative countries, often suffer a pervasive barrier of discrimination.[41] As Mishra notes, in Uganda, the criminalisation of homosexuality severely limits the ability of LGBTQ+ individuals to access healthcare services.[42] The imposition of international intellectual property rules upon the nation-state, which in turn lead to a restriction of access to essential medicines, may only compound the levels of disadvantage faced by these individuals.[43] This is especially the case "where international rules on intellectual property dictate which goods and services will reach the population".[44] The benevolence of IP law cannot be presumed where it is placed in a malevolent context.

It is clear, therefore, that the impact of patent law on society must also be viewed from an intersectional perspective. To this end, human rights can be used as a tool of intersectionality,[45] allowing for the protection of indivisible human rights. Thambisetty's argument for purely internal reform is flawed since it is viewing the issue purely through the lens of patent law. The intersectional nature of the problem complicates simplistic, singular understandings of the nature of… disadvantage".[46] As such,

[35] Owoeye and Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage' at 50.
[36] Sandra Fredman, 'Poverty and Human Rights' in Dapo Akande and others (eds), *Human Rights and 21st Century Challenges: Povery, Conflict, and the Environment* (Oxford University Press 2020), p 229.
[37] Lipi Mishra, 'Medicine and Marginalization: How Intellectual Property Laws Provide a "Generic" Solution to a Grave Human Rights Problem' (2014) 2(6) Int Human Rights Int Working Papers Series, p .6.
[38] Owoeye and Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage' at 50.
[39] 'WTO Members Agree to Extend TRIPS Transition Period for LDCs until 1 July 2034' (*WHO*, 2021) <https://www.wto.org/english/news_e/news21_e/trip_30jun21_e.htm>.
[40] CESCR, 'General Comment No.14' at [12(b)].
[41] Mishra, 'Medicine and Marginalization' at 6.
[42] Mishra, 'Medicine and Marginalization' at 6.
[43] Mishra, 'Medicine and Marginalization' at 6.
[44] Mishra, 'Medicine and Marginalization' at 6.
[45] See: Colin Clark, Dee Matthew and Vicki Burns, 'Power, Privilege and Justice: Intersectionality as Human Rights?' (2018) 22 I.J.H.R. 108.
[46] Anastasia Vakulenko 'Gender and International Human Rights Law: The Intersectionality Agenda' in Sarah Joseph and Adam McBeth (ed), *Research Handbook on International Human Rights Law* (Edward Elgar 2010), p 196 at 197.

an intersectional approach to reform is needed specifically with the aid of international human rights law dialogue.

**The Importance of Human Rights Dialogue in Patent Law Reform**

Whilst the issue of access to medicines is multifaceted and complex, patent law both domestically and internationally plays a significant role. Multilateral standards provide for significant scope available to domestic authorities to shape their approaches towards patent regulation.[47] However, such scope has often contributed towards hardship in world's poorest communities with restricted access to vital medication. This is especially the case in relation to the impact on pricing, as reflected upon in the Doha Declaration.[48] Against this backdrop, the dialogues produced through international human rights, on both a domestic and international level, acts as a vital tool for the reform of patent law, contrasting the divergent domestic approaches to patent law with universal standards of rights protection.

Thambisetty argues that human rights dialogue can often focus on singular sites of harm, potentially frustrating the process of reform.[49] Matthews corroborates, noting instances where efforts of NGO's to collaborate alongside developing countries on issues of access to essential medicines have broken down when "the issues became increasingly technical and the rhetoric derived from framing the issue and language of human rights was no longer sufficient to hold the broader coalition together."[50] She thus argues, that human rights dialogue is no more than a "place-holder",[51] serving only to superficially foster change, whilst not sustaining the momentum required to create true legal reform. However, whilst some concessions must be made in this instance, the primary flaw pertains not to the *use* of human rights dialogue, but the *mode* of usage.

Where human rights dialogue is used superficially, without effective mechanisms of implementation and enforcement, there will be no momentum towards practical change. It is only when it is effectively utilised that this can be achieved. While human rights may not always be the perfect solution, as Cassel notes, "the fact that it has not triumphed everywhere does not mean that it serves no useful purpose anywhere".[52] Thambisetty's argument for the removal of *superficial* dialogue is therefore a defensible position. What should be rejected, however, is the notion that human rights as a *system* hold no place in the reform of patents.

*Creating a conceptual framework*

[47] WHO, WIPO and WTO, 'Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade' (2013), 54.
[48] Doha Declaration (2001), s.3.
[49] Thambisetty, 'Article'.
[50] Duncan Matthews, 'Public Health and Access to Medicines', *Intellectual Property, Human Rights and Development: The Roles of NGOs and Social Movements* (Edward Elgar 2011), p 42.
[51] Thambisetty, 'Article'.
[52] Douglass Cassel, 'Does International Human Rights Law Make a Difference?' (2001) 2 Chi, J. Int'l L. 121 at 122.

An example of the importance of rights dialogue is its ability to establish a conceptual framework within which actions, inactions and notions of inherent rights are conceived. Indeed, the 'right to health' as it is understood under international human rights law provides the framework within which all other actors including individuals can conceive of the contents and scope of the rights such that they may be effectively protected, enforced and respected. Taking this further, Cassel rightly identifies that:

> "International articulation of rights norms has reshaped domestic dialogues... [and] facilitates international and transnational processes that reinforce, stimulate, and monitor these domestic dialogues…"[53]

Human rights are "a common standard of achievement for all peoples and all nations."[54] The standards of human rights are a benchmark for the conduct of not only states, but "all peoples",[55] including non-state actors such as pharmaceutical companies.[56] Without human rights law and discourse, there is no benchmark against which the activities of actors such as pharmaceutical companies can be judged. The impact of this rights framework can be seen in action through health-rights dialogue,[57] which has been utilised to "promote public health and protect against the undue evergreening of patents in developing countries".[58] Furthermore, by creating defined standards of behaviour human rights dialogue can create a flexible approach that allows for an appropriate balance between intellectual property rights and access to medicine.[59] Indeed, as Patterson and London make clear, the dialogue and arguments derived from human rights law provide states with "a framework on which they can formulate laws and policies that integrate public health objectives and human rights standards."[60] It is this human rights-based approach, they argue, which provided for an effective response to the HIV/AIDS crisis.[61]

This framework provides the potential for intersectional approaches to medical access. Despite Thambisetty's desire for an internalised process of reform, she acknowledges that access to medicines cannot be viewed as a sole issue of patent law, with other factors such as public healthcare and private insurance also playing pivotal roles.[62] As such, conceptualising types of medicinal access issues holistically is vital. To this end, Thambisetty rightly highlights an issue in rights implementation, that focus is often drawn too narrowly towards "specific sites of harm".[63] However, whilst international human rights law does have focal points, this does not preclude the existence of a more dispersed system. International human rights law creates a framework within which we can conceive a multitude

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[53] Cassel, 'Does International Human Rights Law Make a Difference?' at 122.
[54] Universal Declaration on Human Rights (UNGA Res.217, 1948), Preamble.
[55] UDHR, Preamble.
[56] John Ruggie, 'Guiding Principles on Business and Human Rights' (UNHCR, 2011).
[57] See: Sofia Gruskin, Edward J Mills and Daniel Tarantola, 'History, Principles, and Practice of Health and Human Rights' (2007) 370 Lancet 449.
[58] Owoeye and Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage' at 49.
[59] ibid.
[60] David Patterson and Leslie London, 'International Law, Human Rights and HIV / AIDS' (2002) 80 Bull W.H.O. 964, 967.
[61] Patterson and London, 'International Law, Human Rights and HIV / AIDS' at 967.
[62] Thambisetty, 'Article' at 288–289.
[63] Thambisetty, 'Article' at 287.

of different methodologies and methods for the protection of and implementation of health rights. International organisations such as the United Nations and World Health Organisation (WHO), alongside specifically mandated treaty bodies such as the Committee on Economic, Social and Cultural Rights (CESCR), create a system of interconnected mechanisms of enforcement which aim to span the entirety of the scope of the 'right to health', including, but crucially not limited to, issues of patents. In this way, human rights provide a holistic approach to a multifaceted problem, while allowing for a specific focus on salient cases which aid in increasing awareness of specific rights issues. Therefore, by removing this system of interconnected mechanisms, Thambisetty's approach may narrow this focus to the detriment of both rights protection and patent reform.

*Oversight and enforcement mechanisms*

A critical issue within medical-patent reform is the proper means by which abuses should be managed. Thambisetty argues for a focus upon the "institutional processes that allow key actors in the system to step back from what they are doing to ask whether what they are doing procedurally is what they are supposed to be doing substantively."[64] Such a process seems reckless. Key actors such as corporations have used the freedom given them by the law to cause severe rights abuses.[65] To allow them to self-regulate without sufficient oversight seems counterintuitive at best. The benefit of international human rights law is that it can be used to function as an oversight mechanism whilst permissive technicalities within the body of patent law are scrutinised.

Thambisetty does not consider the potential of new avenues of business and corporate human rights accountability emerging in academia and the UN, including the drafting of a new treaty of business and human rights.[66] These emerging and existing oversight mechanisms within international human rights law are specifically designed to limit abuses or failings of the state and increasingly powerful non-state actors. It is clear, therefore, that contrary to Thambisetty's position, the utilisation of human rights enforcement mechanisms is set to *increase* rather than *decrease*.

Practically, human rights may function as a useful tool in the reform of specific deficiencies within the patent system. Regarding the granting of patents, Thambisetty herself highlights that the assessment of the inventive step and industrial application requirements do not involve an assessment of the potential impact or social utility which an invention might hold.[67] Therefore, tackling the issue of the abuse of patents is subverted at the very heart of granting patents. In this sense, Thambisetty is correct in her judgment that technocratic procedure may inhibit the achievement of furthering access to medicines

[64] Thambisetty, 'Article' at 287.ibid 287.
[65] For examples of corporate human rights violations and contemporary reporting on business and human rights issues generally see: Business and Human Rights Resource Centre, https://www.business-humanrights.org/en/.
[66] Surya Deva and David Bilchitz (eds), *Building A Treaty on Business and Human Rights* (Cambridge University Press 2017); Olivier De Schutter, 'Towards a New Treaty on Business and Human Rights' (2016) 1 B.H.R.J. 41.
[67] Thambisetty, 'Article' at 296.

since there is an inherent disconnect between practice and theory. As she notes, "[t]he social utility of individual patents and evaluation of the quid pro quo of the monopoly versus social benefit in any individual case requires a radical retooling of patent law".[68] It is argued that this exposes a clear prerogative for human rights to act as a check on those harms which result from a lack of internal oversight within the patent granting system. Furthermore, if we are to consider the so-called "retooling"[69] of the patent granting system, it would be detrimental to inhibit reference to the established human rights framework, to rigorously evaluate the extent to which any developed measures align with the rights and needs of those they are designed to help. Indeed, as shall be analysed in the following section, this can be applied to the international TRIPS system and patent law reform more generally.

## Human Rights and the TRIPS Agreement

### *The implementation of TRIPS flexibilities*

The TRIPS agreement sets up minimum standards for state parties in the protection of intellectual property rights.[70] Its impact, however, has been to strengthen the power of rights-holders at the expense of individual access to medicines, often of those in poverty[71] or minority groups[72]. Contained within the agreement, however, are a series of 'flexibilities' that seek to dampen the potential negative impacts the agreement might have. They allow states a certain level of discretion in the implementation of the agreement to better fulfil their international obligations. These include flexibilities regarding "patentable subject matter; provisions relating to exceptions to patent rights; provisions relating to data protection; and provisions relating to abuse of rights, competition and the control of anti-competitive practices."[73]

*Prima facie,* the TRIPS agreement has sufficient safeguards to protect individual access to medicines. Indeed, Mishra argues that the flexibilities built into the agreement can, in the right circumstances, make it a constructive "agent for change".[74] Illustrative of this is the potential for unauthorised usage of patented medicines by the government.[75] This can be utilised to open up access to essential medicines since, where national laws permit, a State may use a patented medicine for "public non-commercial use"[76] without the consent of the patent holder.[77] Article 8 further provides for states to "adopt measures

[68] Thambisetty, 'Article' at 296.ibid.
[69] Thambisetty, 'Article' at 296.ibid.
[70] Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), art.1.
[71] Stephen M Rose and Stephanie Hatzenbuehler, 'Embodying Social Class: The Link between Poverty, Income Inequality and Health' (2009) 52 Int. Social Work 459.
[72] See: Owoeye and Owoeye, 'Intellectual Property, Access to Medicines and Universal Health Coverage', and Mishra, 'Medicine and Marginalization'.
[73] Sisule F Musungu, Susan Villanueva and Roxanna Blasetti, 'Utilizing Trips Flexibilities For Public Health Protection Through South - South Regional Framework' [2004] South Bulletin 1, 11–12.
[74] Mishra, 'Medicine and Marginalization' at 36.
[75] TRIPS, art.31(b).
[76] TIPRS, art.31(b).
[77] TRIPS, art.31(b).

necessary to protect public health"[78] providing significant scope for states to limit pharmaceutical companies ability to financially inhibit access to medicines. However, whilst these options are available, there is a distinction between what a state *may* do and what they *actually* do.[79]

Many states have often struggled to fully utilise these flexibilities, especially in the public health context due to the ambiguous nature of the provisions[80] combined with the practical inability of some nations to tackle the abuse of patents.[81] External pressure from exporting nations have historically resulted in the avoidance of the use of flexibilities,[82] alongside other tactics such as restricting parallel importation.[83] Progress has been made in this area, with some trade agreements acknowledging the importance of health in relation to the exercise of the flexibilities, drawing directly upon the rights-based commitments made in the Doha Declaration.[84] Human rights law and dialogue, in particular a rights-based approach to health, has arguably contributed towards this shift. Indeed, the WHO, WTO and WIPO have collectively acknowledged that TRIPs flexibilities in regard to health are directly underpinned by a human rights-based policy position.[85] By bringing human rights dialogue to the fore, and reaffirming their obligations under the right to health,[86] substantial political pressure can be exerted upon both states and non-state actors, fully opening possibilities for developing nations to freely utilise the flexibilities.[87]

What is needed is not a step back from rights-based dialogues, as Thambisetty advocates,[88] but an overhaul of the powers and systems which influence the development of domestic and international norms, such that the goals of human rights are put at the fore of international trade, decision-making and dialogue. To effectively employ and reform the system of flexibilities, one must have regard to the ongoing development of international human rights law and its requirements. Indeed, through a reimagining of the international legal system, giving greater normative weight to human rights and their requisite enforcement mechanisms, such as the newly emerging UN draft treaty,[89] those forces which restrict the proper utilisation of the TRIPS flexibilities can be limited effectively.

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[78] TRIPS Art.8.
[79] James Love, 'Access to Medicine and Compliance with the WTO TRIPS Accord: Models for State Practice in Developing Countries' in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002), p. 75.
[80] Monirul Azam, *Intellectual Property and Public Health in the Developing World* (Open Book Publishers 2016), p. 16.
[81] Musungu, Villanueva and Blasetti, 'Utilizing TRIPs Flexibilities for Public Health Protection' at 32.
[82] Kevin Outterson, 'Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?' (2008) 34 Am. J. L. & Med 279 at 282.
[83] Duncan Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' [2005] E.I.P.R. 420 at 426.
[84] See for example: Economic Partnership between the CARIFORUM States (2019), art.147(B).
[85] WHO, WIPO and WTO, 'Promoting Access to Medical Technologies and Innovation', 41.
[86] Katrina Perehudoff and Ellen 't Hoen, 'Human Rights and Intellectual Property for Universal Access to New Essential Medicines', *Equitable Access to High-Cost Pharmaceuticals* (Academic Press 2018).
[87] Perehudoff and 't Hoen, 'Universal Access to New Essential Medicines' at 67.
[88] Thambisetty, 'Article'.
[89] OEIGWG, Third Revised Draft (2021) 'Legally Binding Instrument to Regulate, In International Human Rights Law, The Activities of Transnational Corporations and Other Business Enterprises' < https://www.ohchr.org/Documents/HRBodies/HRCouncil/WGTransCorp/Session6/LBI3rdDRAFT.pdf>.

*Rebalancing power*

The utility of international human rights law dialogue extends further into resetting the balance of power between patent rights holders, individual human rights holders and the state. Adopting a rights-based approach to health allows not only for greater structure and aid to developing countries but furthermore, allows for individuals to strongly assert their rights through an increase in awareness and state-backed power. Instances of the constitutional adoption of economic and social rights have also proved to be an effective tool in the limitation of TRIPS-related harms.[90] As Okediji reports, in *Asero Ochieng v. Attorney-General,*[91] the Kenyan High Court overturned a "TRIPS-driven"[92] anti-counterfeiting law which would have limited access to generic medicines, which the Statute sought to outlaw.[93] The Court relied heavily on the State's obligations under Article 12 of the ICESCR to protect the 'right to health'.[94] It demonstrates a clear ability for human rights norms to act as a barrier to the imposition of harmful intellectual property measures which might otherwise impact access to medicines. Okediji notes that this represents a clear limitation on the power of patent-holders and further demonstrates "the power of economic, social, and cultural rights to transform a general principle into a clear legal entitlement for citizens limiting the state's power to simply effectuate laws without regard for its welfare effect".[95] The UN Conference on Trade and Development (UNCTAD) has subsequently stated that the Kenyan legislation went beyond the minimum standards required under the TRIPS agreement.[96] Nonetheless, the case is still demonstrative of how international human rights law can be effectively utilised to remedy the impact of IP-related harms more broadly.

Subsequent international instruments have clearly drawn influence from human rights dialogue, such as the Doha Declaration which reaffirms that states must prioritise the health of individuals over patent rights.[97] As London points out, the very existence of the negotiations surrounding Doha show how human rights frameworks provide a platform for the intervention and aid of NGOs towards developing countries in relation to intellectual property.[98] Indeed, despite the declaratory (and thus non-binding) nature of the instrument, the Doha Declaration made a significant impact. As Yu highlights, it was integral in the amendment of the TRIPS agreement via Article *31bis* which allows for the import of generic medicines where internal manufacturing capacity is insufficient.[99] This reform came about only

[90] Ruth L Okediji, 'Does Intellectual Property Need Human Rights?' (2018) 51 N.Y.U. J. Int'l Law & Pol. 1 at 52.
[91] *Asero Ochieng v. Attorney-General* (2010) K.L.R. (H.C.K.) (Kenya)..
[92] Okediji, 'Does Intellectual Property Need Human Rights?' at 52. The law in question was the Anti-Counterfeiting Act 2008.
[93] Okediji, 'Does Intellectual Property Need Human Rights?' at 52.
[94] *Asero* (2010).
[95] Okediji, 'Does Intellectual Property Need Human Rights?' at 54.
[96] UNCTAD-UNIDO, *TRIPS Flexibilities and Anti-Counterfeit Legislation in Kenya and the East African Community: Implications for Generic Producers* (2016) (UNCTAD/DIAE/PCB/2015/6), 19.
[97] Doha Declaration on the TRIPS Agreement and Public Health ( November 2001) (WT/MIN(01)/DEC/2).
[98] Leslie London, 'What Is a Human-Rights Based Approach to Health and Does It Matter?' (2008) 10 Health & Human Rights 65 at 72.
[99] Peter Yu, 'Challenges to the Development of a Human Rights Framework for Intellectual Property' in Paul Torremans (ed), *Intellectual Property Law and Human Rights* (Kluwer 2020), p. 40.

as a result of the impact of human rights dialogue. As Yu notes, "[h]ad the human rights-related activities not raised concerns and provided the needed counterbalancing language, the Doha Declaration that sparked off a number of changes to the international intellectual property system might not have been adopted".[100] The utility of human rights dialogue in the reformation of IP law is thus clear. As Mishra notes, effective reforms "can be realized with a little push from human rights principles that place a greater premium on ideas such as the right to health".[101] Thus, the sense of shared human identity provided by international human rights law dialogue exposes potential and existing abuses, reducing their acceptability and impunity.

Protection however must not only cover abuses by the state since pharmaceutical production is driven by the private sector. The TRIPS agreement is heavily balanced in favour of patent-rights-holders. As Cullet notes, "[i]ntellectual property rights in the TRIPS Agreement are seen mainly as a vehicle to foster international trade and not as a moral recognition for scientific or technological prowess…"[102] Such a business-centric perspective is perhaps not surprising given that it was "the brainchild of an industry coalition of developed nations"[103] including the CEO of the pharmaceutical company Pfizer acting as chair of the Intellectual Property Rights Committee, created to push for greater patent protection.[104] It is therefore argued that internal reform is unlikely to be effective without a strong foundation of human rights dialogue, informing positive actions, to curb the pull of corporate self-interest. Human rights can prove an effective tool in rebalancing power to give greater political and legal weight to the rights of individuals to access essential medicines through emerging mechanisms of non-state actor accountability (as noted above) as well as freeing up the powers of the state to utilise the flexibilities of the TRIPS agreement.

## Conclusion

In sum, Thambisetty's argument does not consider key principles of international legal hierarchy and clear intersections allowing for the oversight of both the operation of laws within the State as well as the progression towards greater oversight of the activities of non-state actors such as pharmaceutical corporations. It has been argued that through the proper utilisation of international human rights law mechanisms and dialogue, the failings of patent law can be remedied, alongside fostering instrumental changes in the international and domestic patent system, to ensure greater access to essential medicines for individuals. Through an effective implementation of international human rights law mechanisms in tandem with a systematic overhaul of international and domestic patent law, a seismic refocusing of

[100] Yu, 'Challenges to the Development of a Human Rights Framework for Intellectual Property' at 40.
[101] Mishra, 'Medicine and Marginalization' at 36.
[102] Cullet, 'Patents and Medicines' at 144.
[103] Azam, 'Intellectual Property and Public Health in the Developing World' at 9.
[104] Azam, 'Intellectual Property and Public Health in the Developing World' at 9.

priorities will follow, such that the needs of individuals are prioritised over the economic interests of pharmaceutical companies and the state.