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Solidarity in Tension: Reconciling Intellectual Property Rights and the Right to Health in the Age of Pandemics

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Abstract

This article critically analyzes the changing and sometimes contentious interface between Intellectual Property Rights (IPR) and the Human Right to Health (HRH), particularly against the backdrop of health crises at the global level. With the COVID-19 pandemic having exposed fundamental inequities in access to vaccines, diagnostics, and treatments, tensions between private interests for innovation and public interests for health have emerged anew with particular intensity. At the core of this tension is a conflict between two normative regimes: one that values exclusive market-based rights and another that requires universal, accessible access as a fundamental human right. The growth of international human rights case law and the enforcement of IPR more strictly through agreements such as TRIPS has fuelled legal and ethical discourse on access to life-saving medical technologies.The essay examines the ways in which preventive solidarity i.e., the view that collective and prospective action is required to prevent future health emergencies can be used as a normative link between these fields. It evaluates legal tools like the Doha Declaration, TRIPS flexibilities like compulsory licensing, and the jurisprudence of high-profile cases like Novartis v. Union of India. In drawing from both global legal regimes and national constitutional assurances (particularly Article 21 and 47 of the Indian Constitution), the paper makes the case for an overhauled legal and ethical framework that respects innovation while instilling distributive justice. Finally, it advocates for a global IPR regimes rebalancing to incorporate solidarity-oriented mechanisms for equitable health governance in a time defined by pandemic vulnerability.

1. Introduction

The contemporary world is at a precarious juncture where the development of scientific advancement often runs into the dictates of human dignity and fair access to health. No place is the tension more tangible than in the strained affair between Intellectual Property Rights (IPR) and Human Right to Health (HRH). Long conceived of as mutually exclusive, the patent regimes and human rights regimes instantiate antithetical worldviews: IPR is a triumph of private monopoly and invention, whereas HRH is a celebration of collective access and social justice. The breakdown occasioned by the COVID-19 pandemic has made this compartmentalization impossible. The glaring disparities in vaccine allocation and treatment availability unmasked a systemic incapacity to harmonize profit-oriented patent regimes with the universalistic mandate of health as a human right.

This essay returns to this conflict from the perspective of solidarity, and specifically the new idea of preventive solidarity, that urges states and institutions to act in pre-emptive fashion as a community of

states to prevent global health catastrophes. Through the examination of the legal paths of IPR and HRH, particularly through TRIPS, the Doha Declaration, and General Comment No. 14, and Indian jurisprudence, this paper examines how solidarity can be a normative anchor. It argues that reconsidering the governance of IPR in light of health equity as its primary focus is necessary not only for justice, but for global health security. The intention is not to dilute innovation but to make a framework where scientific progress and distributive justice co-exist in a structurally integrated form.

The rights-duty relational paradigm seldom takes a more starkly dichotomous form than it does in any policy debate around Intellectual Property Rights and Human Right to health. While the former essentially revolves around proprietary concerns of private interests, individual or institutional, the latter is pivoted on universalistic and transcendental human rights principles of access to healthcare and embedded distributive justice priorities.

Conventionally Intellectual property rights (IPR) and Human Rights (HR) have both been independent fields of study in their own right and have witnessed tremendous growth and proliferation in recent times. Intellectual Property Protection has played a significant role in bringing about positive changes in a great number of diverse areas ranging from socio-cultural to science and technology.

However, they have also raised important questions about the widening technology gap between the rich and the poor people as well as between developing and developed nations, over protection of intellectual property leading to monopolistic pricing, issues of access and affordability. Health sector is one area where protection of intellectual property rights and protection of human rights to health have come face to face with each other and posed difficulties of striking the right balance.

2. IPR and HR: Parallel Universes

Human rights and IPR for a long time existed and operated as two parallel universes without cutting into each other. The reason for it was that the common elements necessary for establishing a correlation between them were not recognized or even conceptualized.

Another reason has been that the conflicting nature and character of these two domains between the two was traditionally given more emphasis than an exploration of the possibilities of finding commonalities between the two. The public sphere that is the state and as well as non-state actors pin their hopes on Human Rights while IPR is traditionally geared towards according profit centric rights which was conceived as a mechanism to promote Innovation and enterprise.

Therefore, the conflict between human rights and IPR can also be looked at as a conflict between public rights and the private rights and in so far as the stakeholders are concerned Sate and Civil society become advocates of a human centric approach whereas private organizations and entrepreneurs' dwell upon protection of IPRs.

These reasons therefore to a large extent precluded the mention of intellectual property rights in the human rights discourse. The intellectual property discourse also reciprocated the same sentiments and therefore references to human rights do not appear in the major intellectual property treaties such as the Paris and Berne Conventions. These treaties do refer to the protections granted to authors and inventors as "rights" but this notion of rights has a distinct economic and instrumental benefits or profit centric overtone[1]

[1] Laurence R. Helfer, "Human Rights and Intellectual Property: Conflict or Coexistence?", *available at*: https://scholarship.law.umn.edu/cgi/viewcontent.cgi?article=1399&context=mjlst.

In essence therefore the mutually exclusive existence of the two domains can be explained by the fact that both bodies of law were preoccupied with issues that concerned them directly and were therefore more important, and they were not perceived as either complimenting each other nor helping each other grow.

As a result of factors enunciated above, intellectual property and Human rights existed in silos for a considerable length of time despite the fact that the 1948 Universal Declaration of Human Rights itself recognizes the *authors' moral and material interests" in their "scientific, literary or artistic production[s]* as an essential fundamental liberty[2]

The neat compartmentalization discussed above however in due course showed signs of a breach. This was in a way a natural consequence of the expansion both human rights as well as the intellectual property regimes. While the human rights evolved from being circumscribed within a limited arena of first generation civil and political rights to gradually expanding and covering within their scope a whole range of second and third generation rights such as those related to economic, social and cultural rights that included within their ambit a plethora of rights such as health care, cultural heritage, healthy environment, natural resources to name a few.

The right to health consequently emerged as one of the most important areas of this extended new human rights discourse and was included in some of the important international human rights instruments which accorded a high priority to the right to health and incorporated them in their texts.

One of the earliest attempts to define health can be traced to the preamble of the 1946 World Health Organization (WHO) Constitution which defines health broadly as follows[3]

> [Health is] a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. "The Constitution defines the right to health as "the enjoyment of the highest attainable standard of health.

This definition of health and the subsequent elaboration of the right to health has been widely acknowledged as the pioneering attempt to envisage health as a fundamental and inalienable human right. It also enumerates some principles of this right as healthy child development; equitable dissemination of medical knowledge and its benefits; and government-provided social measures to ensure adequate health.

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Frank Grad commenting on the preamble of the WHO says that the preamble analyses the obligation of the states to contribute to the health of their citizens this Grad argues is not an imported obligation but is intrinsic to the fundamental right of every human being and observes[4]

> From the fundamental right to health of every human being, the Preamble moves to the health of all peoples, observing that this is fundamental to their attainment of peace and security, and depends on the fullest cooperation of individuals and states. The connection between health, peace and security is self-evident when diseases coupled with poverty and other social ills destabilize governments and societies. The Preamble notes that the

[2] Article 27(2) UDHR, *Available at*: http://www.un.org/en/udhrbook/pdf/udhr_booklet_en_web.pdf
[3] 3 *Available at*: http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf
[4] Frank.p.Grad: The Preamble of the Constitution of the World Health Organisation *Available at*: https://scielosp.org/pdf/bwho/v80n12/8012a13.pdf.

> achievement of any state in the promotion and protection of health is of value to all.

Similarly, the International Covenant on Economic, Social and Cultural Rights also recognizes this right as an important constituent of human right. Article 12 of the covenant exhorts the states to take steps to ensure the fullest availability of these rights. The Article states[5]

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

Apart from these two instruments mentioned above right to health is also mentioned in a number of other instruments such as the United Nations Committee on Economic, Social and Cultural Rights released General Comment No. 14[6] as well as in the Convention on Elimination of All Forms of Discrimination Against Women (CEDAW)[7] which also echoes the same sentiments in so far as it advocates protection of women from gender discrimination when it comes to receiving health services particularly with respect to reproductive and sexual rights.

Both General Comments and CEDAW therefore serve as torchbearers of the global distributive aspects of human rights by advocating the expansion of healthcare to hitherto marginalized sections of the global society and especially for women belonging to poorer sections of the societies and inhabiting poorer or under developed geographies and therefore face a double discrimination by virtue of their gender and marginalization.

While the human rights discourse as clear from the above was giving an increasing prominence to health, the Intellectual Property domain with respect to health and healthcare was also expanding

and new innovations and technological developments ensured that societies had better access to health care, better living conditions and better resources at their disposal.

However, they also brought in the questions of access and affordability and therefore consciously and unconsciously created a divide based on economic affluence, social and cultural dominance and political power among others. In geopolitical terms they also resulted in creation of a divide between the developed world on the one hand and the developing world on the other. Innovators also were guilty many a time of utilizing the natural resources of the latter as well as indigenous know how of the primitive societies without passing the benefits to them and thereby directly impinging on their human rights.

The gradual but definite proliferation of the two legal domains engendered overlaps and therefore had the effect of a breaching of boundaries between the two. This also led to the establishment of an interface and interaction between them.

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[5] *Available at*: https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx

[6] *Available at:* https://www.refworld.org/pdfid/4538838d0.pdf (last visited April 1, 2020).

7 *Available at*: https://www.un.org/womenwatch/daw/cedaw/text/econvention.htm (last visited April 1, 2020).

It was the human rights community that first took notice of intellectual property law as laws which encroached upon their territory. "*Two events caused intellectual property to be placed on the agenda for human rights lawmaking. The first was an emphasis on the neglected rights of indigenous peoples. The second was the consequence of linking of intellectual property and trade through the TRIPS agreement which sought to strengthen the IPR regime often at the expense of human right considerations"*[8]
Audrey Chapman[9] talking about a human rights perspective in Intellectual Property and access to the benefits of science puts it quite succinctly.

> Commercialization has introduced market considerations into the conduct of science and changed its public character
> … Commercialization has also changed intellectual property from a means to provide incentives to researchers and inventors to a mechanism to encourage investment and protect the resources of investors.

The IPR-HR interaction is deliberated upon and discussed at various fora that are associated with governing or administering intellectual property and human rights regimes such as the World Intellectual Property Organization (WIPO), the U.N. Commission on Human Rights and the Sub-Commission on the Promotion and Protection of Human Rights, the World Trade Organization (WTO), the World Health Organization (WHO) to name a few. If an analysis is sought to be done regarding the subject matter of legal debates in these for a, two distinct conceptual paradigms regarding the human rights-intellectual property interaction shall emerge.
The first of these paradigms looks at human rights and intellectual property rights as being inherently contradictory and even at cross roads to each other. This kind of framework regards IPR and HR duality as a zero-sum game which implies that a strong IP regime essentially implies a weak HR protection regime and vice versa. This also acts under the presumption that these two are structurally inconsistent with each other and that. Intellectual property protection does not only undermine but is also incompatible with the entire gamut of human rights and responsibilities allied to it, especially in the area of economic, social, and cultural rights. A case in point is a resolution by the Office of the High Commissioner for Human Rights which recognizes the existence of such a conflict[10].

> …. Noting further that actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights in relation to, inter alia, impediments to the transfer of technology to developing countries….

The identification of these contradictions however also provides an impetus to the efforts to resolve the conflict and to harmonize the two regimes in a way that they become mutually complimentary.
The alternative paradigm of the human rights and intellectual property binary relationship endorses the viewpoint that both areas of law can find a common ground. Private monopoly rights and consequent incentives that authors and inventors deserve on account of their creativity coexist with the genuine requirements of the public to gain access to these innovations as a matter of right and not just charity. This

[8] *Supra* note 6.
[9]
[10] Audrey Chapman, "A Human Rights Perspective on Intellectual Property Scientific Progress, And Access to The Benefits Of Science"
available at:https://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_5.pdf
10 See, e.g., Intellectual Property Rights and Human Rights, Res. 2000/7.

school of thought therefore looks at striking a balance between these two legal domains, however to strike this balance is not as simple as it sounds.

This is best reflected in an ECOSOC report which refers to article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) as well as article 27 of the Universal Declaration on Human Rights both of which essentially deal with the obligation of the State to 'respect, protect and fulfil people cultural rights and at the same time recognize the need to harmonize both public and private interests in intellectual property

The report states[11]

> "The starting point for a human rights analysis of TRIPS Agreement is article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the similarly worded article 27 of the Universal Declaration on Human Rights (the Universal Declaration) Article 15 of the Covenant obliges States parties to respect, protect and fulfil people's cultural rights. The article identifies a need to balance the protection of both public and private interests in intellectual
> property. On the one hand, article 15 recognizes the right of everyone to take part in cultural life and to enjoy the benefits of scientific progress and its applications. On the other hand, the same article recognizes 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 (emphasis added). Taking these two aspects of article 15 together, ICESCR could be said to bind States to design IP systems that strike a balance between promoting general public interests in accessing new knowledge as easily as possible and in protecting the interests of authors and inventors in such knowledge….
> Consequently, there is a degree of compatibility between article 15 and traditional IP systems. However, the question essentially is where to strike the right balance (emphasis added)."

3. Intellectual Property and Right to Health Dependencies and Divergences

Right to health has been considered as one of the most important human right in a number of international instruments. The constitution of the World Health Organization recognizes the right to health as follows[12]: The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

Article 25 of the Universal Declaration of Human Rights (UDHR) states[13]:

> Everyone has the right to a standard of living for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of

[11] *Available at*: https://documents-dds-ny.un.org/doc/UNDOC/GEN/G01/143/45/PDF/G0114345.pdf?OpenElement
[12] *Available at*: https://www.who.int/about/mission/en
[13] *Available at*: https://www.un.org/en/universal-declaration-human-rights/index.html (last visited March 3, 2018)

> unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

More recently addressing the International Coordinating Committee of National Institutions of Human Rights, Mary Robinson, the then UN High Commissioner for Human Rights observed[14]

> National Human Rights Institutions have the full range of human rights in the remit... An area which we have not touched on, and which I would like to mention here for further consideration is the right to health...

By virtue of its primal position among human rights it has also been recognized by the Constitution of India under the directive principle of state policy. Article 47 for example enjoins the state to raise the level of nutrition and standard of living and to improve public health.

Apart from international instruments and constitutional texts, the judiciary has also played a stellar role in establishing the Right to Health as among the most significant fundamental rights by bringing it within the ambit of Article 21 through judicial interpretation.

For example, in Vincent Panikurlangara v. Union of India, it was observed[15]:

> .... Maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society which the Constitution envisages. Attending to public health, in our opinion is, therefore of high priority - perhaps one at the top

in *State of Punjab* v. *Ram Lubhaya Bagga* the Supreme Court reiterated its stand the government and public authorities have a duty to focus on public health and observed as follows[16]:

> This Court has time and again emphasized to the Government and other authorities for focusing and giving priority to the health of its citizen, which not only makes one's life meaningful, improves one's efficiency, but in turn gives optimum output. Further to secure protection of one's life is one of the foremost obligations of the State. It is not merely a right enshrined under Article 21 but an obligation cast on the State to provide this both under Article 21 and under Article 47 of the Constitution. The obligation includes improvement of public health as its primary duty.

These cases are only illustrative and similar observations have been made by the Supreme Court in a number of other decisions. From the above discussion it is amply clear that right to health is firmly and undisputedly established as one of the most fundamental of human rights and sanctified not just in global instruments but also in the domestic jurisprudence including India.

However apart from the distinct human right facet health and health sector is also a potent market for a variety of entities ranging from health care service providers to pharmaceutical and allied sectors and therefore this is also an arena of innovation, discoveries and therefore a strong playground for Intellectual Property actors. It is therefore not surprising that in the health sector domain the questions of human rights vs intellectual property assume a significance unmatched by any other area.

[14] *Available at*: http://shodhganga.inflibnet.ac.in/bitstream/10603/128256/19/13_chapter%206.pdf (last visited March 03, 2020)
[15] (1987) 2 SCC 165, para 16
[16] (1998) 4 SCC 117, para 6.

4. TRIPS and the Right to Health Contours of a Synergy

The Agreement on Trade related aspects of Intellectual Property (TRIPS)[17] was adopted in 1994 with an aim to strengthen the IPR regime. The adoption of TRIPS at the same time gave rise to acrimonious debates about their potential and often negative impact on Human Rights.

It is also important to understand that TRIPS is not just limited to the medical field but covers all areas concerning intellectual property, however its effect on the healthcare and on health as a right is arguably the most profound since it directly relates to issues of accessibility and affordability in countries of the developing world.

TRIPS obligated the countries to make suitable changes to their respective legislations in order to bring about a certain uniformity in the IPR protection regime. WTO members were obligated to implement TRIPS provisions within specified timeframes This impacted the developing and underdeveloped countries the most because of the highly technological nature of patents etc. and therefore brought to fore the faceoff between the developed and the developing world on the question of granting patents particularly in those areas of technologies that directly impact human life on a mass scale, health related technologies being the most important.

The Sub-Commission on the promotion and protection of human rights recognized this dichotomy and remarked as follows[18]:

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

India is an example of how TRIPS jeopardized the abilities of the developing nations to protect public health. India was obligated to make suitable legislations to conform to the TRIPS agreement by 2005 and it therefore passed the Patent Amendment Act in 2005 to fulfil its obligations. Prior to this act, India allowed for the manufacture of generic versions of many drugs. After TRIPS agreement came into force India had to implement a globally harmonized product patent regime in the pharmaceutical sector. This however had far reaching implication for access and availability to medicines in India. Patents enforce monopoly rights and tend to increase prices and consequently restrict availability and affordability.

The problem between TRIPS and Human Rights does not only relate to access to medicines alone, it also extends to traditional knowledge and technology transfer. Traditional communities use their traditional knowledge to make medicines. Sometimes giant pharmaceutical companies commercialize this knowledge without even paying royalty or acknowledging the source. Developing countries have serious concerns about protecting traditional knowledge owned by the traditional communities in their countries. Furthermore, one of the main purposes of TRIPS is to facilitate transfer of technology to foster development in developing and least developed countries. However, multinational companies are not always willing to co-operate. Developing countries have voiced their concerns against the effects of IP system on health, traditional knowledge and technology

[17] https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm
[18] Intellectual property rights and human rights, Sub-Commission on Human Rights resolution 2000/7. *Available at*: https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/E-CN_4-SUB_2-RES-2000-7_Eng.pdf (

The above analysis of the Indian context gives a fair idea of the problems faced by the developing world since they have the same impact on all such countries.

This conflict was nevertheless identified largely due to the strong reservations places by the developing and the least developed countries and attempts were made to resolved inconsistencies while remaining within the core parameters of the agreement. A few representative provisions in this regard are worth mentioning[19].

Article 7 of the TRIPS agreement seeks to balance the rights of producers and users in a manner conducive to `social and economic welfare. Article 8 (1) specifically mentions that members may formulate their domestic policies and adopt measures necessary to protect among other things public health and nutrition. Article 27 (2) and (3) also provide a leeway to members to exclude certain subject matters from patentability certain inventions for protecting human life and health as well as certain diagnostic, therapeutic and surgical methods for the treatment of humans or animals. In addition, other articles also provide for aspects such as public non-commercial use during emergencies (Art 31), technical cooperation (Art 40, 67) etc[20].

These TRIPS provisions mentioned above even though significant, however remained splinter provisions spread across various articles and were open to multiple interpretations which were sought to be used by the patent holders particularly by the big Multinational enterprises in their favour and to the detriment of consumers and end users. To address these ambiguities and bring about certainly in interpretation the WTO members in 2001 adopted a special Declaration at the WTO Ministerial Conference in Doha to allay ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The Doha declaration on TRIPS Agreement and Public Health also attempted to address the enormity of the public health concerns afflicting the developing and LCD countries of the world and called for a wider consensus to remedy these problems. Paragraphs 4,5 and 6 are particularly significant in this respect. Paragraph 4 of the declaration states[21]:

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose"

Doha declaration was therefore one of the most significant attempts to harmonize the contradictions between intellectual property and human rights ecosystems. The ministerial conference acknowledged that intellectual property protection is indeed important to encourage innovation and development of medicine and health related technologies however at the same time issues such as the high prices of medicines, non-transfer of technology made both access and affordability extremely difficult for poorer countries and poorer populations. Special provisions therefore were sought to be incorporated for poorer economies

[19] For details see AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, particularly Articles 1,3,4,5,6 7,8, 27, 30,31,39,40,41,67,73.
Available at: http://www.tripsagreement.net/trips_files/documents/TRIPS_E.pdf

[20] See, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm for an elaboration of these articles.

[21] *Available at*: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.

including transfer of technologies from developed to least developed countries particularly those who lacked manufacturing capacities.

The conference therefore made certain adaptations to mitigate the challenges brought about by the TRIPS regime. It provided for certain options to the national governments to address public health needs which is also termed as flexibilities that are mentioned in paragraph 5 of the declaration[22].

5. Flexibilities: Incorporation of a Human Rights Element into IPR

Flexibilities can be construed as special or limited exceptions to the otherwise stringent IPR protection mechanisms granted to the rights holder under TRIPS and have a distinct human rights aspect to them. The only condition is that they should not hinder normal exploitation of the patent or unreasonably prejudice the legitimate interest of the right holder.

Developing countries can use these flexibilities to mitigate problems particularly in the health care domain like access to medicines, checking high prices, and ensuring availability.

These flexibilities have been incorporated in paragraphs 4,5 and 6 of the Declaration and provide for compulsory licensing, national emergencies and exhaustion with an aim to introduce certain flexibility as per country specific requirements

Article 66.1 of the TRIPS agreement[23] also refers to flexibilities and provides the rationale as follows:

> "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5……...The Council for TRIPS shall, upon duly motivated request by a least-developed country member, accord extensions of this period."

There are many flexibilities envisaged throughout the TRIPS agreement but some of the most important ones particularly in the context of the human right to health are as follows.

- **Compulsory Licensing:** A compulsory license is issued by a government authority or a court to make certain use of a patented invention without the consent of the patent holder. This mechanism is generally present. in most patent laws, is recognized as a permissible option or flexibility under the TRIPS Agreement, and has been used by a number of WTO members in the pharmaceutical field. Compulsory licensing is subject to the following considerations[24]
  - authorization of such use must be considered on its individual merits
  - scope and duration of such use without the patent holder's authorization must be limited to the authorized purposes.
  - authorization of such use must be predominantly for the supply of the domestic market of the Member authorizing such use.

[22] Article 5 recognizes these flexibilities and states "Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include".
The paragraph subsequently lists compulsory licensing, emergency and public health crises such as HIV/AIDS, tuberculosis, malaria as well as national exhaustion as flexibilities to circumvent IPR wherever required without diluting its basic principles.

[23] *Available at*: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

[24] Flexibilities In The Trips Agreement And Its Impact on National Intellectual Property Policy.
Available at: http://www.belipo.bz/wp-content/uploads/2011/12/TRIPS-FLEXIBILITIES.pdf

- adequate remuneration must be paid to the patent holder, based on the economic value of the license
- decisions relating to the authorization of, and remuneration for such use, must be subject to judicial or other independent review in the Member authorizing such use.

However, TRIPS rules originally restricted compulsory licenses to serve mainly the domestic market (Article 31f)[25] and it was therefore of little use to countries which did not have sufficient manufacturing infrastructure domestically.

The DOHA Ministerial conference and the subsequent declaration on the TRIPS agreement and Public Health recognized that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could find it difficult to make use of the compulsory licensing flexibility and instructed the TRIPS Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002. This came to be known as the 'Paragraph 6 issue[26]' because it was contained in the paragraph 6 of the declaration.

Pursuant to this an amendment to the TRIPS agreement added a new Article 31 bis (1)[27] which introduced a compulsory license for exports which provided for the export of a pharmaceutical product to developing or least developed countries to meet their public health requirements when they lack domestic infrastructure to manufacture the said drugs subject to certain conditions.

Another flexibility in the form of parallel imports was therefore envisaged.

Exhaustion and Parallel Imports: Exhaustion or the first sale doctrine postulates that once a good is sold to another party with the authorization of the IP owner, the IP right is exhausted with respect to that good and subsequent transactions like sale, renting, lending can't be controlled by the first or original right holder. Three kinds of exhaustion principles have been envisages depending on the scope and geographical extent of their applicability namely national, regional and international. The wider the exhaustion the more advantageous it is for the consumers and the user country. Therefore, the developing and least developed countries advocate international exhaustion while the developed or producer countries are votaries of a narrower national exhaustion principle. Parallel imports are directly linked to the principle of exhaustion and involves the import and resale in a country without the consent of the right holder, of a protected product which was put on the market of the exporting country by the right holder or in another legitimate manner. Along with the doctrines of exhaustion of rights, parallel importation allows protected goods to be imported at a cheaper price from a foreign market.

In the context of health care, it is of huge benefit to countries which have insufficient or no manufacturing capacities in the pharmaceutical sector. One of the best specimens of the effective use of such flexibilities has been in the case of HIV/AIDS where anti-retroviral medication has transformed HIV/AIDS into a clinically manageable condition. However, for a long time despite the proven efficacy of anti-retroviral

[25] Article 31(f) stipulates that generic drug produced under compulsory licensing "must be authorised predominantly for the supply of the domestic market of the Member authorising such use". Doha Declaration, Paragraph 6: WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under TRIPS.

[26] Para 6 of the Declaration on the TRIPS agreement and public health states: We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

[27] See, Article 31 bis (1) TRIPS agreement.

treatment donors as well as international organizations often choose to focus on prevention, at the expense of treating the disease owing to a very high cost of such treatment

The proven success of anti-retroviral medications in prolonging life expectancy and increasing productivity was to a large extent nullified due to issues of accessibility and had a detrimental impact on the political, social, and economic systems of countries ravaged by the pandemic. The culprit was stringent intellectual property rights regime which acted as a major impediment to increased access to affordable anti-retroviral drugs.

Certain countries like India however have brought in the public health angle and given primacy to human rights aspect by adopting a relaxed regime by condoning and even encouraging generic manufacturers and parallel imports which has ensured availability of these drugs at a significantly lower prices and increases access to anti-retroviral treatment. Cipla for example sold generic drugs which were far cheaper than the upscale patented versions and literally transformed the fight against AIDS.

Poorer countries of Asia and Africa also indirectly benefited through parallel imports. Indian example has shown that instead of poverty, the true impediment to access is unaffordability. The MNCs were arguing that poverty and ineffective administration of healthcare services are the real obstacles.

These flexibilities however have been naturally resented by the rights holders with include pharmaceutical companies who argue that such policy spaces actually work as disincentives to innovation and infusion of funds for further research and development. There has also been an attempt to secure patents by series of incremental inventions as well as by blocking manufacturers of generic drugs by dragging them to courts. The judiciary world over including India therefore has become a participant to this IPR-HR debate and through landmark decisions added new dimensions to the debate.

6. Novartis judgement: The Game Changer

The Novartis judgement[28] is an example of how judiciary in India has looked at this often-dichotomous relationship and given primacy to human rights when pressing questions of human right to health is involved. This judgement in particular sought to promote public good and accessibility while discouraging negativities such greenwashing, monopolistic pricing and innovation with.

The issue was concerning the patent application of in 1997 by Novartis, a Switzerland based company manufactured a drug Gilvec and got it patented in several jurisdictions including US. Novartis applied for patent in India which was taken up for consideration in 2005 when India became party to TRIPS. It was denied by the patent office relying on section 3(d) of Patent Act 2005 stating that the drug does not demonstrate any known therapeutic efficacy[29].

Novartis filed a writ petition in Madras High Court challenging the refusal by the patent office and also section 3(d) of the Patents Act on the ground that it was not in conformity with TRIPS agreement and that it was also violative of Article 14. of the Indian constitution. The petitions were refused on jurisdictional grounds but mainly also on the ground that section 3(d) is not arbitrary since the its purpose was to ensure affordable access to life saving drugs to people.

The case then came to the Supreme Court as a Special Leave Petition. The Supreme Court also refused patent and among other things held that the purpose of the said section was to prevent evergreening of patents and also reiterated that objective of the said Act was to ensure affordable access to life saving drugs to people which was also the constitutional objective.

[28] *Novartis AG* V. *Union of India,* (2013) 6 SCC 1.
[29] See, Patents Act 2005, *Available at:* https://ipindia.gov.in/writereaddata/Portal/IPOAct/1_69_1_patent_2005.pdf

On the issue of novelty and inventive step also the Court held applied the test of therapeutic efficacy which needs to be clearly proved. The Court however decided that the drug Novartis seeks to patent is the modification of a known drug and it did not differ significantly as far as properties enhancing efficacy are concerned.

The Supreme Court also held that the true intention to enact section 3(d) was to prevent the concept of evergreening and thus if the invention does not fulfil the test of Section 3(d), it cannot be granted a patent. The court further specified that this case should not be interpreted to mean that Section 3(d) bars all incremental inventions. It is with regard to the field of medicine especially in cases of life-saving drugs, great care and caution needs to be taken so as to protect the right to life of the masses. Patent was therefore refused with respect to this product

This judgement therefore came as a huge relief because it accorded prime consideration to public policy and public health issues, discouraged efforts to "evergreen" patents and enabled Indian companies to continue producing generic version of drugs to ensure affordable access.

The judgement garnered widespread support from international organizations and advocacy groups like Médecins Sans Frontières, WHO, etc. who welcomed the decision against evergreening of pharmaceutical patents and for keeping human rights considerations while rendering the decisions.

Conclusion

The COVID-19 pandemic was a turning point, one that exposed the weak seams of an international health architecture that values innovation but all too often excludes access. The conflict between patent exclusivity and public health demands is not a legal abstraction—it materializes in concrete suffering, postponed treatments, and avoidable deaths, particularly in the Global South. While global tools like TRIPS leave room for some flexibilities, and declarations like Doha seek to address conflicts, these are usually in fragmented and underused forms. Judicial activism in India, particularly in the Novartis judgment, is a positive antidote by showing that constitutional morality and universal solidarity can steer patent law to more compassionate directions.

But more deep-seated change is required. Instituting the notion of preventive solidarity into international IPR systems involves transcending charity and exception, and toward a cooperative rights-based approach to health governance. This involves enforcing more stringent criteria on patentability, empowering local production through flexibilities, and reshaping the function of IPR as a tool of public interest, not corporate fortress. Finally, health equity needs to be recognized as not a divergence from innovation, but as a prerequisite to its legitimacy. If solidarity is to become more than rhetoric, it needs to inform the architecture of public policy and international law, and most importantly, in the post-pandemic era.

Right to health, its non-discriminatory and affordable access has been embedded and prominently highlighted in numerous human rights instruments something which has played a significant role in forcing a rethink about their reconciliation with the essentially private nature of rights bestowed by Intellectual property. In the domain of healthcare there has been some success, however there remains a pressing need to do more for giving the human rights including the right to health by evolving a stricter patentability regime by allowing only genuine innovations and filtering out frivolous ones.

Many experts are also of the view that strict patent requirement instead of a relaxed requirement of incremental invention would actually encourage innovation as the pharmaceutical companies would have to invest more in R&D to come up with new cures rather than rearrange and repackage known compounds and to keep patenting them forever. This is particularly useful for countries like India given the extent of

poverty and lack of availability of affordable medicines in the country.

However, this alone is not sufficient and the redistributive processes will also need to be strengthened in order to reduce gaps of all kinds geographical, economical, educational, age and gender in availability and affordability of healthcare to all. This can be achieved only with the essential recognition that IP rights are in the ultimate analysis themselves human rights. This will enable a cohesive and mutually beneficial integration of the legal norms that surround the two regimes and further harmonize the IPR-HR interface.