### **NOTES AND COMMENTS**

# INTELLECTUAL PROPERTY AND HUMAN RIGHTS: FINDING A BALANCE BETWEEN PROTECTED RIGHTS AND PUBLIC INTEREST

#### **Abstract**

Intellectual Property Rights (IPRs) are considered as private rights. The governments of the day grant these rights to protect private interest of the creators and authors in respect of their intellectual creations like inventions, designs and literary works. By their very nature, IPRs can be enforced against other private individuals, even though the government also is bound by them, if not totally. The fundamental question that arises is if such private rights could be enforced to advance private interest at the cost of public interest? The 1948 Universal Declaration of Human Rights not only acknowledges the right of authors to protect moral and material interests resulting from any of their scientific, literary, or artistic works, but also emphasises the right to health, including public health, right to education, right to livelihood *etc.* Constitutionally also it is acknowledged that no right or freedom is absolute, and the State is empowered to curtail them in larger public interest through doctrines like *Eminent Domain.* However, the creators of the IP also claim that right to own, exploit and be acknowledged as creators, are their constitutionally guaranteed human rights.

In this paper, the authors propose to examine whether IPRs can be exercised as human rights or whether they are restrictions on human rights? In the wake of recent COVID-19 pandemic, where there is huge demand for vaccine to treat it, and the clinical trials are going on, the debate regarding right to life versus right to livelihood, compulsory licensing, use of Traditional Knowledge (TK) and Traditional Cultural Expressions (TCEs) for commercial purposes etc., has become significant. This paper seeks to review the jurisprudential foundations of public interest and private rights, relevant position under the international human rights and IPR regime, the position under national laws, and the judicial response to such controversies in select cases. Questions like unjust enrichment, use of powers granted to the governments to ensure a balance between the private or protected interests on one hand, and the public interest on the other hand are examined and certain useful suggestions are given to maintain the much-needed balance.

"Ultimately, intellectual property is a social product and has a social function. The end which intellectual property protection should serve is the objective of human well-being, to which international human rights instruments give legal expression...... To be consistent with obligations to respect international human rights, intellectual property regimes must promote and protect all human rights...."

United Nations Economic and Social Council, Human Rights and Intellectual Property: Statement by the UN Committee on Economic, Social and Cultural Rights [E/C.12/2001/15], Dec. 14, 2001, available at: https://www2.ohchr.org/english/bodies/cescr/docs/statements/E.C.12.2001.15HRIntelproperty.pdf (last visited May 2, 2022).

- excerpt from statement on 'Human Rights and Intellectual Property' by UNCESR (2001)

## I Nature of IPRs

INTELLECTUAL PROPERTY rights<sup>2</sup> are rights of exploitation in information.<sup>3</sup> Intellectual property<sup>4</sup> supports the aspirations of those who seek to achieve for right holders a control over the utilization of ideas or knowledge.<sup>5</sup> IP is a "general area of law that encompasses copyright, patents, designs, and trademarks, as well as a host of related rights." The World Intellectual Property Organization Convention defines "intellectual property" to include "rights relating to: literary, artistic and scientific works; performances of performing artists, phono- grams and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks, service marks and commercial names and designations; protection against unfair competition; and all other rights resulting from intellectual activity in the industrial, scientific, literary or artistic fields." The TRIPS Agreement<sup>8</sup> recognised eight different kinds of IPRs i.e., Copyright and Related Rights, Patents, Trademarks, Industrial Designs, Geographical Indications, Protection of Undisclosed Information, Layout-Designs (Topographies) of Integrated Circuits and protection of plant varieties.<sup>10</sup>

IP creates a legal means to appropriate knowledge.<sup>11</sup> IPRs are exclusive rights granted to makers of intellectual creations.<sup>12</sup> The protection of IP is based on both economic

- 2 Hereinafter referred to as "IPR".
- Peter Drahos, The Universality of Intellectual Property Rights: Origins and Development, in Intellectual Property and Human Rights 13–41, 14 (1999), available at: https://www.wipo.int/edocs/pubdocs/en/wipo\_pub\_762.pdf. (last visited on May, 20, 2022).
- 4 Hereinafter referred to as "IP".
- 5 Fritz Machlup and Edith Penrose, "The Patent Controversy in the Nineteenth Century" 10 J. Econ. Hist. 1–29 (1950).
- 6 Lionel Bently and Brad Sherman, Intellectual Property Law 1 (4th edn. 2014).
- 7 Convention Establishing the World Intellectual Property Organization, signed at Stockholm on July 14, 1967 and as amended on Sep. 28, 1979; The World Intellectual Property Organization is hereinafter referred to as "WIPO".
- 8 The Agreement on Trade-Related Aspects of Intellectual Property Rights, which entered into force on Jan. 1,1995.
- 9 Part-II, ss. 1–7 of TRIPS Agreement.
- 10 TRIPS Agreement: Art. 27 (3) (a); International Convention for the Protection of New Varieties of Plants ("UPOV Convention") was adopted on Dec. 2, 1961 and came into force on Aug. 10, 1968. It has been revised on Nov. 10, 1972, on Oct. 23, 1978, and on Mar. 19, 1991.
- 11 Laurence R. Helfer and Graeme W. Austin, Human Rights and Intellectual Property: Mapping the Global Interface 20 (1st edn. 2011).
- 12 Lida Ayoubi, "Intellectual Property and Human Rights", in Margaret Bedggood, Kris Gledhill, et. al., (eds), *International Human Rights Law in Aotearoa New Zealand* 977–1011, 979 (Thomson Reuters, 2017).

and moral reasons.<sup>13</sup> The rationale for IP protection has been that if a product involves substantial work, research and ingenuity, but could be replicated quickly, there is unlikely to be a sufficient financial incentive from society's point of view to commit resources for the invention.<sup>14</sup> Since the emergence of IPRs and in the course of their development, there has been a constant increase in their scope and the length of protection.<sup>15</sup> This shift can be compared to a new "enclosure movement" similar to the enclosure of common fields in 18<sup>th</sup> Century England.<sup>16</sup> The scope of this enclosure of knowledge-based or cultural goods is inconsistent with their nature and is unnecessary "since they do not deplete when shared."<sup>17</sup>

Unlike the tangible assets, the copyright and patent are designed to "grant an incomplete, porous control over the subject-matter: they are limited in time and scope." <sup>18</sup> IP fosters creativity and contributes to social progress, by allowing for specialization, generating revenue through commercial exchange. <sup>19</sup> However, there are distinctions between the property in tangible assets and the IP, due to rivalrous and non-rivalrous character of those assets, and the consequence of exclusive control over them. The tangible assets are categorized as rivalrous resources, whereas the nature of IP is non-rivalrous. <sup>20</sup> With

- 14 U.K. Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy Commission on Intellectual Property Rights 14 (2002), http://www.iprcommission.org/papers/pdfs/final\_report/CIPRfullfinal.pdf (last visited Aug 3, 2021).
- 15 Laurence Helfer, "Toward a Human Rights Framework for Intellectual Property", 40 U.C. Davis Law Rev. 971, 973 (2007).
- 16 James Boyle, "The Second Enclosure Movement and the Construction of the Public Domain", 66 Law Contemp. Probl. 33 (2003); See also Yochai Benkler, Free As the Air to Common Use: First Amendment Constraints on Enclosure of the Public Domain, 74 New York Univ. Law Rev. 354 (1999).
- 17 Sol Picciotto, "Defending the Public Interest in TRIPS and WTO" In Peter Drahos and Ruth Mayne (eds), Global Intellectual Property Rights: Knowledge, Access, and Development, 224 (2002), available at: http://books.google.com.br/books?id=ixJ-QgAACAAJ.
- 18 No time restriction applies to the property in physical assets and no right exists to make fair use of others' property, but on the contrary fair-use clauses are included in copyright; Cornides, *supra* note 13 at 148.
- 19 Using copyright lets artists and writers pursue their passions for creating art while also allowing producers to make a profit from the sale of their creations. Patents and Trademarks both have the potential to spur new research and development as well as enhance the quality of goods and services; Cornides, *supra* note 13 at 148.
- 20 Rivalrous resources are limited in quantity and their availability. Unless these resources belong to someone, they are vulnerable to being over-utilized and under-maintained. They tend to deteriorate or exhaust themselves if no property rights are attached to them. As a result, private ownership of tangible assets benefits society as a whole. When it comes to IP, it relies on knowledge which is not a finite resource, therefore it is non-rivalrous. Their value to society can only increase if they are utilised to their fullest potential. They cannot be over-exploited. Cornides, *supra* note 15 at 147; *See* also Helfer and Austin, *supra* note 11 at 20.

<sup>13</sup> Jakob Cornides, "Human Rights and Intellectual Property: Conflict or Convergence?", 7 J. World Intellect. Prop. 135–167, 145 (2004).

regard property in a tangible asset, the owner has power to exercise control over the particular asset that is limited in its scope an value; on the other hand there are restrictions over exclusive control in respect of intangible assets, because an exclusive right to profit from a specific creation or innovation might be more damaging for economic liberty than such control over a tangible asset.<sup>21</sup> The Constitutions of some countries consider IP under the right to property,<sup>22</sup> and others consider it an independent right,<sup>23</sup> which can increase the scope of constitutional clauses beyond the realm of patents and copyrights.<sup>24</sup>

The TRIPS Agreement drastically changed the normative contours of international IP law by obligating all member nations of the World Trade Organization (WTO) to adhere to certain minimal requirements of IP protection, including the requirement of recognition of patents in all fields of technology.<sup>25</sup> Under TRIPS, 164 States being members of the WTO are required to implement a set of basic minimum principles and standards for the protection and enforcement of IPRs. However, the nations across the globe are in various phases of economic development, based on different indicia like income, health and education. The disparities in income have doubled in the previous 40 years with the top 20 wealthiest nations now having an average income 37 times that of the 20 poorest countries.<sup>26</sup> Considering these deep inequalities, there has been a serious debate surrounding the globalising of IPRs and particularly States being permitted to have some choice in establishing the degree of IP protection in respect of pharmaceuticals.<sup>27</sup> The WIPO Development Agenda<sup>28</sup> also mandates for

- 21 Cornides, supra note 15 at 148.
- 22 Constitution of Armenia, Art. 60(7) (2015); Constitution of El Salvador, Art. 103(2) (1983); Constitution of Tunisia, Art. 41(2) (2014); UK Human Rights Act, Protocol 1 (1998); Constitution of Fiji, Art. 163 (2013); Constitution of Nepal, Art. 25 (2015).
- 23 Constitution of Azerbaijan, Art. 30 (2009); Constitution of Brazil, Art. 5(27) (1988); Constitution of Chile, Art. 19(25) (1981); Constitution of Colombia, Art. 61 (1991); Constitution of Panama, Art. 53 (1972).
- 24 Gabriele Spina Alì, "Intellectual Property and Human Rights: A Taxonomy of Their Interactions", 51 IIC Int. Rev. Intellect. Prop. Compet. Law 411–445, 421 (2020).
- 25 Ruth L. Okediji, "Intellectual Property in the Image of Human Rights: A Critical Review", in Framing Intellectual Property Law in the 21st Century: Integrating Incentives, Trade, Development, Culture, and Human Rights in Rochelle Cooper Dreyfuss & Elizabeth Siew-Kuan Ng (eds), 234–289, 243 (2018).
- 26 Global Intellectual Property Rights: Knowledge, Access, and Development, supra note 17 at 2.
- 27 TRIPS Agreement art. 7: provides that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."
- 28 WIPO, WIPO Development Agenda (2007), available at: https://www.wipo.int/edocs/pubdocs/en/general/1015/wipo\_pub\_l1015.pdf (last visited May 3, 2022).

the technology transfer, technical assistance, access to knowledge to be "development-oriented, demand-driven and transparent, taking into consideration the objectives and the unique requirements of developing nations."<sup>29</sup>

#### II Nexus between IPR and human rights - Theoretical context

Human rights are perpetual and non-assignable individual or group interests belonging to the realm of public law.<sup>30</sup> Human rights are fundamental rights, which are identified by the State and are inherently connected to human dignity. <sup>31</sup> The human rights involve obligations for both governments and individuals. Human rights law imposes three types of legal responsibilities, *viz.*, *first*, respect the right by not taking legal or policy actions that would infringe its specific provisions; *second*, protect the right and prevent other parties from violating its provisions through legislation and other measures; and *third*, develop constructive actions that enable, support individuals and communities in exercising their right.<sup>32</sup> In contrast, IP rights are not inalienable, but rather constructed in order to achieve collective purposes that are deemed useful.<sup>33</sup>

The foundations of IPRs may be traced to the Lockean 'labour-desert' or 'value added' theory under natural law, that considers property rights as proportionate to "the sacrifice actually incurred." The arguments surrounding the Utilitarian and Deontic IPR foundations have impacted the IP policy. However, the consequentialist approach focuses on how the IPRs affect others' duties and obligations, expanding the scope of IPRs as more than just an incentive to produce and develop. The IPRs also share the

<sup>29</sup> Jayashree Watal, The TRIPS Agreement and Developing Countries: Strong, Weak or Balanced Protection?, 1 J. World Intellect. Prop. 281–307 (2005).

<sup>30</sup> Ayoubi, *supra* note 12 at 983.

<sup>31</sup> Philippe Cullet, "Human Rights and Intellectual Property Protection in the TRIPS Era", 29 Hum. Rights Q. 403–430, 404 (2013).

<sup>32</sup> Audrey R. Chapman, "The human rights implications of intellectual property protection", 5 J. Int. Econ. Law 861–882, 864 (2002).

<sup>33</sup> Paul Torremans, "Copyright (and other Intellectual Property Rights) as a Human Right", in Intellectual Property and Human Rights 221–254 (2015); See Caterina Sganga, Right to Culture and Copyright: Participation and Access, in Research Handbook on Human Rights and Intellectual Property Christophe Geiger ed., 560–578 (2015); See also Megan M. Carpenter, "Intellectual Property: A Human (not corporate) Right, in The Challenge of Human Rights: Past, Present and Future David Keane & Yvonnet McDermott eds., 312–330 (2012); See also Lea Shaver, The Right to Science and Culture, 1 Wis. L. Rev. 121–184 (2010), available at: https://www.aaas.org/sites/default/files/Shaver\_ScienceandCulture.pdf. (last visited on May 10, 2022).

<sup>34</sup> If you generate new works using existing public domain works and ideas, or if you make a major, industrially valuable advance to the existing pool of technological knowledge, then you get property as an acceptable reward. Barbara H. Fried, The Progressive Assault on Laissez Faire: Robert Hale and the First Law and Economics Movement 111 (1998); See generally Justin Hughes, "The Philosophy of Intellectual Property" 77 Geo. LJ 287 (1988).

<sup>35</sup> Shubha Ghosh, "Duty, Consequences and Intellectual Property" 10 Univ. St. Thomas Law J. 801–819 (2013).

natural law roots with traditional human rights theory.<sup>36</sup> The IPRs safeguard the interests of creators and inventors, encourage creativity, and facilitate the distribution of knowledge and cultural works. In doing so, IP is in line with human rights values such as the Universal Declaration of Human Right (UDHR).<sup>37</sup> Further, non-pecuniary nature and inalienability of moral rights afforded to authors, attribution given to the true and first inventors, replicates the fundamental structure of traditional human rights.<sup>38</sup> The State is laden with the responsibility to handle complicated issues arising out of the conflicting policy objectives like IP protection, public domain, and enforcement of human rights.<sup>39</sup>

Human rights and IPRS coexist or conflict with each other depending on different views of the jurists. The conflicting view proclaims that even if IPRs are not a direct cause of inequality, they may be used to justify existing ownership patterns without considering the validity of those patterns, and this perpetuates the current, highly unequal system. It argues that human rights provide a normatively sound basis for calling for restrictions on IPRs. The UN human rights system adopts this approach emphasising the supremacy of human rights responsibilities above economic agreements and strategies. Limiting and excluding some types of IPRs is considered the most effective way to balance IP with human rights. Human rights and other factors provide guidelines in framing the boundaries of what is covered by IPRs, as well as what is excluded from them.

<sup>36</sup> Daniel Gervais, "Human Rights and the Philosophical Foundations of Intellectual Property" in Research Handbook on Human Rights And Intellectual Property Christophe Geiger ed., 89–97 ( 2015).

<sup>37</sup> Universal Declaration of Human Rights, adopted 10 Dec. 1948, GA Res217A (III), 3 UN GAOR (Resolutions, part 1) at 71, UN Doc A/810(1948).

<sup>38</sup> Marina Alexandrovna Rozhkova, Difficulties of Differentiating between Intellectual Property Rights and Human Rights on the Basis of the Case-Law Research Report "Internet: Case-Law of the European Court of Human Rights" 7 J. Adv. Res. Law Econ. 1136–1141, 1137 (2016).

<sup>39</sup> Carlos Correa & Xavier Seuba eds., Intellectual Property and Development: Understanding the Interfaces, xx (2019).

<sup>40</sup> Cullet, supra note 31 at 406.

<sup>41</sup> Graeme W. Austin, "Connecting Intellectual Property and Human Rights in the Law School Syllabus", in *Across Intellectual Property: Eassays in Honour of Sam Ricketson* Graeme W. Austin *et al.* eds., 189–200 (2020); See Lisa Forman and Gillian Macnaughton, Moving Theory into Practice: Human Rights Impact Assessment of Intellectual Property Rights in Trade Agreements, 7 *J. Hum. Rights Pract.* 109–138 (2015), https://academic.oup.com/jhrp/article/7/1/109/2191146 (last visited Aug 3, 2021). See, e.g., Panel discussion, 9 Nov., 1998, Intellectual Property and Human Rights, WIPO, Geneva, Publication No 762(E) 1999; Sub-Commission Res 2000/7 at 1, stating that "actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights."

<sup>42</sup> Sub-Commission Res 2000/7, supra note 37.

<sup>43</sup> Okediji, supra note 25 at 254.

<sup>44</sup> Spina Alì, supra note 24 at 426.

It is considered by the co-existing view that human rights and intellectual property rights (IPRs) have the same goal, to specify the proper scope of private monopolistic power in order to create motivation for authors and inventions and also guarantee that the general public has equitable access to the products of their efforts.<sup>45</sup>IP law and human rights are considered as fundamentally compatible, but are seen to be in conflict about finding the proper equilibrium between access and incentives.<sup>46</sup> The conflict between IP and human rights is claimed to be illusory because IPRs, or some aspects of them, are considered fundamental human rights too, albeit of "weaker" weight than other rights.<sup>47</sup> As per this view, the IP systems' balance between innovation incentives and public access must give greater weight to promoting social and economic welfare.<sup>48</sup> It should be recognised that IPRs are also tools for achieving social goals and realising human rights, and the accessibility should not be restricted by a heavy focus on incentives.<sup>49</sup>

The way in which innovation, exclusive rights to fundamental research tools, and access to vital medicines are impacted by Patent trolls is one of the few examples of concerns about capacity of the patent system to deliver on the predetermined promise of public welfare. <sup>50</sup> It is critical to get away from the thinking that more number of issued patents is a good indicator of useful innovation for the general population, which ironically strengthens the contention that more private property denotes more public benefit, but in fact, there has been a steep fall in the quality of innovation and disclosures serving public interest. <sup>51</sup>

<sup>45</sup> Mpazi Sinjela, Human Rights and Intellectual Property Rights: Tensions and Convergences, ix (2007).

<sup>46</sup> Laurence R. Helfer, "Human Rights and Intellectual Property: Conflict or Co-Existence?", 22 Netherlands Q. Hum. Rights 167–179 (2004).

<sup>47</sup> Aurora Plomer, "The Human Rights Paradox: Intellectual Property Rights and Rights of Access to Science", 35 Hum. Rights Q. 143–175, 151 (2013).

<sup>48</sup> Helfer and Austin, supra note 11 at 74.

<sup>49</sup> Hans Morten Haugen, "Access Versus Incentives: Analysing Intellectual Property Policies in Four UN Specialized Agencies by Emphasizing the Role of the World Intellectual Property Organization and Human Rights", 13 J. World Intellect. Prop. 697–728, 716 (2010).

<sup>50</sup> James Bessen, "The Evidence Is In: Patent Trolls Do Hurt Innovation", Harvard Business Review (2014), https://hbr.org/2014/07/the-evidence-is-in-patent-trolls-do-hurt-innovation (last visited Sep 14, 2021); See Robert L. Stoll, Patent Trolls: Friend or Foe?, WIPO Magazine (2014), available at: https://www.wipo.int/wipo\_magazine/en/2014/02/article\_0007.html (last visited Sep 14, 2021).

<sup>51</sup> Srividhya Ragavan, "Correlative Obligation in Patent Law: The Role of Public Good in Defining the Limits of Patent Excusivity", 6 New York Univ. J. Intellect. Prop. Entertain. Law, 51 (2016); See Benjamin N. Roin, The Disclosure Function of the Patent System (or Lack Thereof), Harv. Law Rev. (2013); See also Sean B. Seymore, The Teaching Function of Patents, 85 Notre Dame Law Rev. 621–670 (2010).

According to Dinwoodie and Anette, "we must embrace pluralism in IP"<sup>52</sup> and if IP is conceived as a "IP Tree", human rights are the ground in which the roots of the tree are anchored and from which nourishment is derived; economic incentives are needed and must be monitored so as to determine the strength and structure of the trunk and its branches; culture and other forms of interaction with society stand for the climate and other environmental influences shaping the form and density of the foliage; trade corresponds to the forest management whose policy decides on mono-cropping, overharvesting, or sustainable and organic growth.<sup>53</sup>

### International legal perspectives - IPR and HR

The UDHR 1948<sup>54</sup> provides that "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." <sup>55</sup> Apart from identifying the right of authors, the UDHR ensures that "everyone has the right to own property" and "no one shall be arbitrarily deprived of his property." <sup>56</sup> The International Covenant on Civil and Political Rights 1966<sup>57</sup> provides for "the freedom to seek, receive and impart information and ideas of all kinds" <sup>58</sup> and the International Covenant on Social, Economic and Cultural Rights 1966<sup>59</sup> identifies the author's right "to benefit from the protection of the moral and material interest resulting from any scientific, literary or artistic production" and everyone's right "to enjoy the benefits of scientific progress and its applications." The European Convention on Human and Fundamental Freedoms 1950<sup>61</sup> emphasizes that "every natural or legal person is entitled to the peaceful enjoyment of his possessions and that State has the right to enforce such laws as it deems necessary to control the use of property in accordance with

<sup>52</sup> Graeme B. Dinwoodie and Annette Kur, "Framing the International Intellectual Property System", in Framing Intellectual Property Law in the 21st Century: Integrating Incentives, Trade, Development, Culture, and Human Rights, Rochelle Cooper Dreyfuss & Elizabeth Siew-Kuan Ng eds., 290–303, 293 (2018).

<sup>53</sup> Id. at 301.

<sup>54</sup> Available at: https://www.ohchr.org/en/udhr/documents/udhr\_translations/eng.pdf (last visited Mar. 3, 2021).

<sup>55</sup> UDHR, 1948, art 27.2.

<sup>56</sup> UDHR, 1948 art 17.

<sup>57</sup> Adopted by General Assembly Resolution 2200A (XXI) of Dec. 16, 1966, entry into force Mar. 23, 1976. Hereinafter referred to as "ICCPR"; https://www.ohchr.org/Documents/ProfessionalInterest/ccpr.pdf (last visited May 3, 2022).

<sup>58</sup> ICCPR, 1966, art 19.2.

<sup>59</sup> Adopted by General Assembly Resolution 2200A (XXI) of Dec. 16, 1966, entry into force 3 Jan. 1976. Hereinafter referred to as "ICESCR"; available at: https://www.ohchr.org/Documents/ ProfessionalInterest/cescr.pdf (last visited May 3, 2021).

<sup>60</sup> ICESCR, 1966, art. 15.1.

<sup>61</sup> Hereinafter referred to as "ECHFF"; available at: https://www.echr.coe.int/documents/convention\_eng.pdf (last visited Mar. 3 2021).

the general interest." <sup>62</sup> The American Convention on Human Rights 1969<sup>63</sup> stipulates that "everyone has the right to use and enjoyment of his property" and that "law may subordinate such use and enjoyment to the interest of society." <sup>64</sup> The African Charter on Human Rights and People's Rights 1981<sup>65</sup> provides that "The right to property shall be guaranteed. It may only be encroached upon in the interest of public need or in the general interest of the community." <sup>66</sup> Hence, the friction between the IPRs and the human rights guaranteed in these instruments is evident.

The Paris Convention 1883, recognizing industrial property rights like patents and trademarks, <sup>67</sup> and Berne Convention 1886, concerning copyright or property rights in literary and artistic works <sup>68</sup> were largely a matter of politics, rather than legal enforceability <sup>69</sup>. The WIPO <sup>70</sup> was established in 1967 to "encourage creative activity, to promote the protection of intellectual property throughout the world". <sup>71</sup>A modernised and fair patent system, according to WIPO, encourages ingenuity and intellectual activity, as well as investment in industrial applications and a conducive environment for knowledge transfer. <sup>72</sup>

- 62 Protocol of ECHFF, 1950, art. 1.
- 63 Hereinafter referred to as "ACHR"; available at: https://www.oas.org/dil/access\_to\_information\_ American\_Convention \_on\_Human\_Rights.pdf (last visited March 3, 2021).
- 64 ACHR, 1966, art. 21.1.
- 65 Hereinafter referred to as "ACHRPR"; available at: https://treaties.un.org/doc/Publication/UNTS/Volume%201520/volume-1520-I-26363-English.pdf (last visited Mar. 3 2022).
- 66 ACHRPR, 1981, art. 14.
- 67 Paris Convention for the Protection of Industrial Property, Mar 20, 1883 (last amended on Sep 28, 1979), *available at:* https://www.wipo.int/edocs/lexdocs/treaties/en/paris/trt\_paris\_001en.pdf (last visited Aug 14, 2021).
- 68 Berne Convention for the Protection of Literary and Artistic Works, Sep 9, 1886, (last amended on Sep 28, 1979), *available at:* https://www.wipo.int/edocs/lexdocs/treaties/en/berne/trt\_berne\_001en.pdf (last visited May14, 2022).
- 69 Helfer and Austin, supra note 11 at 24.
- 70 Hereinafter referred to as "WIPO".
- 71 Convention Establishing the World Intellectual Property Organization, 1967, *available at:* http://admin.theiguides.org/Media/Documents/WIPO%20Convention\_1.pdf (last visited May 14, 2022).
- 72 Audrey R Chapman, "A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science", 3 Wipo 127–68 (1999), available at: https://www.wipo.int/edocs/mdocs/tk/en/wipo\_unhchr\_ip\_pnl\_98/ wipo\_unhchr\_ip\_pnl\_98\_5.pdf (last visited May14, 2022).

Later, the World Trade Organization<sup>73</sup> was established and started functioning in 1995<sup>74</sup> and it also provided for the Agreement on Trade Related Aspects of IPRs<sup>75</sup> which requires the WTO members to provide processes and remedies under their domestic legislation to guarantee that IPRs may be successfully enforced by both foreign as well as national right holders.<sup>76</sup> TRIPS has profoundly altered the international IP landscape by providing safeguards against one country using its patent law to undermine the industrial policy of another, and can be regarded as "marriage of convenience" amidst international trade law and IP.<sup>77</sup>

The developing countries had signed TRIPS, as a bargain so that stronger protection of IP would give them better technology transfer and greater access to the market from developed countries, however that bargain never materialized. An approach based on human rights was omitted from the TRIPS since it was not seen as being conducive to free trade. The United Nations High Commissioner for Human Rights also observed that overall the TRIPS Agreement aims to promote innovation by providing commercial incentives, while human rights promotion and protection, such as in the ICESCR, are only authorised as exceptions that are subservient to the other provisions.

<sup>73</sup> Hereinafter referred to as "WTO".

<sup>74</sup> Agreement Establishing the World Trade Organization, Apr. 15, 1994, replacing the General Agreement on Tariffs and Trade, 1948, *available at:* https://www.wto.org/english/docs\_e/legal\_e/04-wto.pdf (last visited Aug 14, 2021).

<sup>75</sup> Hereinafter referred to as "TRIPS".

<sup>76</sup> Marney L Cheek, "The Limits of Informal Regulatory Cooperation in International Affairs: A Review of the Global Intellectual Property Regime", 33 Georg. Washingt. Int. Law Rev. 277–323 (2001). See Part-III of TRIPS Agreement, 1994, available at: https://www.wto.org/english/docs\_e/legal\_e/27-trips.pdf (last visited Aug 14, 2021).

<sup>77</sup> Elizabeth Siew-Kuan Ng and Albert Guangzhou Hu, "Flexibilities in the Implementation of TRIPS: An Analysis of Their Impact on Technological Innovation and Public Health in Asia", in Framing Intellectual Property Law in the 21st Century: Integrating Incentives, Trade, Development, Culture, and Human Rights Rochelle Cooper Dreyfuss and Elizabeth Siew-Kuan Ng eds., 115–153, 115, 119 (2018).

<sup>78</sup> Keith E. Maskus, Private Rights and Public Problems: The Global Economy of Intellectual Property in the 21st Century (2012).

<sup>79</sup> Klaus D. Beiter, Establishing Conformity Between TRIPS and Human Rights: Hierarchy in International Law, Human Rights Obligations of the WTO and Extraterritorial State Obligations Under the International Covenant on Economic, Social and Cultural Rights, in Hanns Ullrich et al. eds., TRIPS plus 20: From Trade Rules to Market Principles 445–505, 451 (2016).

<sup>80</sup> Report of the UN High Commissioner for Human Rights, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights (2001), UN Doc. E/CN.4/Sub.2/2001/13, para. 22, available at: https://digitallibrary.un.org/record/446005/files/E\_CN.4\_Sub.2\_2001\_13-EN.pdf (last visited May 14, 2022).

It can be seen that as regards patents, compulsory licensing,<sup>81</sup> government/public non-commercial use,<sup>82</sup> experimental/private non-commercial use,<sup>83</sup> parallel importation,<sup>84</sup> regulatory review exception,<sup>85</sup> and specific exclusions<sup>86</sup> are the flexibilities provided under TRIPS which allow for prominence of public interest and protection of human rights. TRIPS also allows limitations or exceptions to copyright<sup>87</sup> and trademark<sup>88</sup> protection. In contrast to TRIPS, which specifies minimal requirements for IPR protection, these clauses are ambiguous and give no advice targeted at ensuring an interpretation completely compliant with human rights standards.<sup>89</sup> 90

- 81 TRIPS, 1994, art. 31 reads: Compulsory licencing occurs when the public interest in increased access overrides the private interests of right holders to fully exploit their exclusive rights, and when an involuntary licence is granted between a "willing buyer" and an "unwilling seller." See Jerome H. Reichman & Catherine Hasenzahl, Non-voluntary Licensing of Patented Inventions Part I Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the United States of America, Part II The Canadian Experience, UNCTA/ICSTD Capacity Building Project on Intellectual Property and Sustainable Development, Geneva, Switz. (2003), available at: www.iprsonline.org/ictsd/docs/ReichmanBridgesYear6N7Oct2002.pdf and www.iprsonline.org/resources/docs/Reichman%20-%20Non-voluntary%20Licensing%20-%20Blue%205.pdf (last visited May 14, 2022).
- 82 *Id.*, art 31 reads: For national emergencies, other circumstances of extreme urgency or public non-commercial use or government use or anti-competitive practices, there is no need to try for a voluntary license. There is no need to seek a voluntary license for situations such as national crises, extreme urgency, public non-commercial usage, government use, or anti-competitive practices. *See available at:* https://www.wto.org/english/tratop\_e/trips\_e/factsheet\_pharm02\_e.htm (last visited Aug 14, 2021).
- 83 TRIPS, 1994, art. 30. Also referred to as "experimental use defense". It is a safe harbor provision which exempts, from patent infringement, scientific experimentation and research conducted without the consent of the patentee.
- 84 TRIPS, 1994, art. 6. Also referred to as "exhaustion of rights". It concerns the importation of genuine items that have been promoted in one country by the patent owner or its licensees and imported into another without the agreement of the patent owner or its licensees. The major reason for parallel importation is that the price in the country of exportation is lower than in the country of importation.
- 85 TRIPS, 1994 art 30: Also referred to as "Bolar" exception. It enables a prospective rival of the patent owner to conduct early work on the invention without the patent owner's consent in order to get regulatory clearance.
- 86 Id art., Inventions against morality or ordre public; Therapeutic, diagnostic and surgical methods for treatment of animals or humans; Animals and plants apart from micro-organisms; essentially biological processes for the production of plants or animals, other than nonbiological and microbiological processes.
- 87 TRIPS, 1994, Id art. 13.
- 88 TRIPS, 1994, Id art. 17.
- 89 Report of the UN High Commissioner for Human Rights, supra note 78 para. 23.
- 90 Antony Taubman, Hannu Wager and Jayashree Watal, A Handbook on the WTO TRIPS Agreement (2<sup>nd</sup> ed. 2020).

Subsequently, WTO adopted the Declaration on TRIPS Agreement and Public Health<sup>91</sup> which provided that the members have power to take action to provide access to medicines and preserve public health.<sup>92</sup> Later, in 2017 this culminated into a permanent TRIPS amendment improving access to affordable medicines for poor countries, originally adopted in 2003,<sup>93</sup> providing mechanism permitting WTO members that lack production capacity to import pharmaceutical products made under compulsory licensing.<sup>94</sup>

The connection between the Convention on Biological Diversity 1992<sup>95</sup> and the TRIPS regarding the protection of traditional knowledge<sup>96</sup> and folklore<sup>97</sup> <sup>98</sup> has been a complex issue on which the WTO members have diverging interpretations.<sup>99</sup> <sup>100</sup> The concern is about "granting of patents or other IPRs covering traditional knowledge to persons other than those

- 91 WTO, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2 (Nov 20, 2001), *available at:* www.wto.org/english/thewto\_e/minist\_e/min01\_e/mindecl\_trips\_e.pdf (last visited May 14, 2022); Hereinafter referred to as "Doha Declaration".
- 92 Doha Declaration, 2001, art.4.
- 93 See WTO, Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (TRIPS: Factsheet), available at: www.wto.org/english/tratop\_e/trips\_e/tripsfacsheet\_e.htm. See also WTO, WTO IP rules amended to ease poor countries' access to affordable medicines (January 23, 2017), available at: www.wto.org/english/news\_e/news17\_e/trip\_23 jan17\_e.htm; WTO, Amendment of the TRIPS Agreement (WT/L/641, Dec. 8, 2005), available at: www.wto.org/english/tratop\_e/trips\_e/wtl641\_e.htm.(last visited Aug 14, 2021).
- 94 TRIPS, 1994, art. 31 bis.
- 95 Entered into force on Dec 29, 1993. available at: https://www.cbd.int/doc/legal/cbd-en.pdf.(last visited Aug 14, 2021). Hereinafter referred to as "CBD".
- 96 Traditional knowledge means "knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"; Art. 8(j) of CBD, 1992.
- 97 Also known as "Traditional Cultural Expressions". Folklore are defined as "any forms, whether tangible and intangible, in which traditional culture and knowledge are expressed, appear or are manifested... which are: (aa) the products of creative intellectual activity, including individual and communal creativity; (bb) characteristic of a community's cultural and social identity and cultural heritage; and (cc) maintained, used or developed by such community, or by individuals having the right or responsibility to do so in accordance with the customary law and practices of that community." See WIPO, Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore: Twelfth Session, The Protection of Traditional Cultural Expressions/Expressions of Folklore: Revised Objectives and Principles, WIPO Doc. WIPO/GRTKF/IC/9/4, (Dec 6, 2007), available at: http://www.wipo.int/meetings/en/doc\_details.jsp?doc\_id=89833 (last visited Aug 14, 2022). 40 Sessions of the WIPO IGC have taken place till now.
- 98 Michael Jon Andersen, "Claiming the Glass Slipper: The Protection of Folklore as Traditional Knowledge", 1 J. Lan, Technol. Internet 148–164 (2010).
- 99 The Doha Declaration mandates the TRIPS Council to work on the issue of the relationship between the TRIPS and CBD, by review of art. 27.3(b).
- 100 Jane E. Anderson, Lan, Knowledge, Culture: The Production of Indigenous Knowledge in Intellectual Property Law 172–187 (2009).

indigenous peoples or communities who have originated and legitimately control the traditional knowledge" and it "being used without the authorization of the indigenous peoples or communities who have originated and legitimately control it and without proper sharing of the benefits that accrue from such use". There has been a focus on granting sui generis IPRs for traditional knowledge and its applications to the communities, because they may not fulfil the requirements of TRIPS regarding innovation or non-obviousness. The UN Declaration on the Rights of Indigenous Peoples 103 also identifies the rights of indigenous peoples. 104

The United Nations Convention on the Rights of Persons with Disabilities 2006<sup>105</sup> mandates for provision of accessibility of IP to the disabled. In furtherance of this objective, WIPO Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled 2013<sup>107</sup> makes it easier to produce and distribute accessible books for the visually impaired and blind people across the globe by establishing a uniform set of copyright limits and exceptions. <sup>108</sup>

## III Intersections of IPR and human rights

#### Right to health and access to medicines

IPR protection and laws recognizing right to health, overlap when it comes to medicines, establishing responsibilities that seem contradictory and incompatible. <sup>109</sup> TRIPS grants exclusive rights to patent holders and permits them to fix prices of patented drugs, <sup>110</sup>

- 101 WTO, The Protection of Traditional Knowledge and Folklore, IP/C/W/370/Rev.1, available at: https://www.wto.org/english/tratop\_e/trips\_e/ta\_docs\_e/4\_ipcw370rev1\_e.pdf (last visited May 14, 2022).
- 102 Rosemary J. Coombe, "Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity", 6 *Indiana J. Glob. Leg. Stud.* 59–115 (1998).
- 103 Adopted on Sep 13, 2007. Hereinafter referred to as "UNDRIP". *available at:* https://www.un.org/development/desa/indigenouspeoples/wp-content/uploads/sites/19/2018/11/UNDRIP\_E\_web.pdf (last visited Aug 14, 2021).
- 104 "...to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions." [Art.31 of UNDRIP, 2007]
- 105 Entered into force from May 3, 2008. Hereinafter referred to as "UNCRPD." available at: https://www.un.org/disabilities/documents/convention/convention\_accessible\_pdf.pdf (last visited Aug 14, 2021).
- 106 "States Parties shall take all appropriate steps, in accordance with international law, to ensure that laws protecting intellectual property rights do not constitute an unreasonable or discriminatory barrier to access by persons with disabilities to cultural materials" [Art. 30.3 of UNCRPD, 2006].
- 107 Came into force from Sep. 30, 2016, and hereinafter referred to as "Marrakesh Treaty"; available at: https://wipolex.wipo.int/en/text/301019.(last visited on May 14, 2022)
- 108 Marrakesh Treaty, 2013, art. 4-6.
- 109 Holger Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicines 175 (2009).
- 110 TRIPS, 1994, art. 33.

and also allows members to preserve public health and nutrition.<sup>111</sup> As a minimal core obligation under the international human right to the highest attainable standard of health under ICESCR, States must make medicines cheap and readily available to the general public.<sup>112</sup> The Constitution of World Health Organization,<sup>113</sup> proclaims that "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 conditions."<sup>114</sup> The WHO Public Health, Innovation and IP Team is in-charge of fostering innovation in the discovery, production, development and delivery of vital health technologies<sup>115</sup>, and the WHO Intergovernmental Working Group on Public Heath, Innovation and IP<sup>116</sup> adopted the global strategy<sup>117</sup> carving out a strategic and central role to be played by WHO in the relationship.<sup>118</sup>

The need for provision of access to medicines has influenced negotiations between governments and pharmaceutical firms over the price of patented medicines and the

- 112 Lisa Forman, "An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law" 14 J. World Intellect. Prop. 155–175 (2011); See United Nations Economic and Social Council, supra note 1 para. 47.; See e.g., art. 12 of ICESCR, 1966.
- 113 The World Health Organization's constitution was approved during the International Health Conference in New York from 19 June to 22 July 1946, and was signed on July 22, 1946 by representatives of 61 States. (Off. Rec. WldHlth Org., 2, 100), and entered into force on Apr. 7, 1948, available at: https://www.who.int/governance/eb/who\_constitution\_en.pdf (last visited May 14, 2022); hereinafter referred to as "WHO".
- 114 Preamble of Constitution of WHO, 1946.
- 115 WHO | About PHI, available at: https://www.who.int/phi/about/en/ (last visited May 24, 2022).
- 116 A Group formed in response to the increasing burden of illnesses and disorders disproportionately affecting developing nations, particularly women and children, at the Fifty-Ninth World Health Assembly in Resolution WHA 59.24, May 2006
- 117 Adopted at the Sixty-first World Health Assembly Resolution WHA61.21, 2008 and finalized in Resolution WHA62.16, 2009. The strategy's objective is to foster fresh thinking about innovation and access to medicines, as well as to provide a more robust and sustainable foundation for vital health research and development focused on illnesses that disproportionately afflict developing nations. It comprises of 8 elements viz., "(1) Prioritizing research and development needs; (2) Promoting research and development; (3) Building and improving innovative capacity; (4) Transfer of technology; (5) Application and management of intellectual property to contribute to innovation and promote public health; (6) Improving delivery and access; (7) Promoting sustainable financing mechanisms; and (8) Establishing monitoring and reporting systems".
- 118 See WIPO, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2011).

<sup>111</sup> TRIPS, 1994, art. 8.

issuance of compulsory licenses<sup>119</sup> to produce generic drugs for domestic markets and for export to other eligible WTO member states.<sup>120</sup> The data exclusivity is also becoming a hurdle to public health, and globally, generic drugs have become necessary, not only to provide access to health, but also to promote innovation in poorer nations.<sup>121</sup>

The developments relating to compulsory licenses in Rwanda, <sup>122</sup> Canada, <sup>123</sup> Malaysia, <sup>124</sup> Thailand, <sup>125</sup> Indonesia, <sup>126</sup> and Brazil <sup>127</sup> are some of the noteworthy instances of convergence of IPRs and human rights, signifying the prominence given to public

- 119 "Under certain circumstances and conditions, a 'compulsory' or 'non-voluntary' license may be granted by a competent national authority to a third party allowing the exploitation of the patented invention during the patent term without the authorization of the patentee. A court or another competent authority grants a specific permission under a compulsory license authorization to a person or entity other than the right holder to produce, use, sell or import the patent-protected product, or use the patent-protected process." See WIPO Secretariat, WIPO Standing Committee on the Law of Patents: Draft Reference Document on the Exception Regarding Compulsory Licensing [SCP 30/3] (2019), available at: https://www.wipo.int/scp/en/meetings/session\_30/comments\_received.html, (last visited Aug 9, 2021).
- 120 Helfer and Austin, *supra* note 11 at 127; *See* Katrina Perehudoff and Ellen't Hoen, *Human Rights and Intellectual Property for Universal Access to New Essential Medicines, in Zaheer-Ud-Din Babar ed.*, Equitable Access to High-Cost Pharmaceuticals 67–87 (2018).
- 121 Srividhya Ragavan, The (Re)Newed Barrier to Access to Medication: Data Exclusivity, 51 *Akron Law Rev.* (2017).
- 122 Rwanda was the first nation to inform the WTO in 2003 that it wanted to import the generic HIV/AIDS cocktail medication Apo TriAvir from Canada in order to take advantage of the compulsory licencing rules. See George Tsai, "Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes under the WTO Doha Declaration", 49 V.A. J. Int. Law (2008).
- 123 The Canada's Access to Medicines Regime (CAMR) 2004 establishes the procedure for acquiring a compulsory license for export. See Ibid.
- 124 In 2003, to import generic versions of patented HIV antiretrovirals from India, Malaysia was the first Asian country to implement a compulsory license through Section 84 of the Malaysian Patents Act, 1983. See Raadhika Gupta, "Compulsory Licensing under TRIPS: How Far it Addresses Public Health Concerns in Developing Nations", 15 J. Intellect. Prop. Rights 357–363, 362 (2010).
- 125 Thailand's National Health Security Act of 2002 mandates that all citizens have universal access to basic medicines and that all AIDS patients have access to antiretrovirals since 2003. See Cynthia M Ho, "Patent Breaking or Balancing: Separating Strands of Fact from Fiction under Trips" 34 North Carolina J. Int. Law Commer. Regul. 371–469 (2009).
- 126 In 2004, Indonesia utilised compulsory licensing to choose a local company for the production of HIV antiviral drugs. See Gupta, supra note 124 at 362.
- 127 Brazil has made tremendous strides toward resolving public health issues by leveraging its compulsory licencing statute. Brazil enacted [Industrial] Property Law number 9.279, me.f. May 15, 1997 embedding the compulsory licensing statutes and began an intensive anti-AIDS program in 1983. Brazil has utilised the prospect of granting a compulsory license to bargain for a cheaper price with pharmaceutical corporations. See Robert Bird and Daniel R. Cahoy, "The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach", 45 Am. Bus. Law J. 283–330 (2008); Vera Zolotaryova, "Are We There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication" 33 Brooklyn J. Int. Law (2008).

interests over protected rights. Patents can also create obstacles for developing country vaccine manufacturers to enter into the vaccine market. There is a need to find an effective patent system that encourages desirable innovation without placing an undue burden on society. 129

### Right to food and food security

The UDHR provides that "everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food..." and also the ICESCR recognizes the right of everyone to adequate food and makes States Parties responsible for taking steps and implementing particular programmes in conjunction with international cooperation to ensure that no one remains hungry. There is food security when everyone has access to enough safe and nutritious food to fulfil their dietary needs and food choices at all times so they may lead active and healthy lives. In protecting traditional knowledge, recognizing farmers' rights and the rights of source countries, the impact of IP upon food security and access to essential medicines can be found. This right is closely associated with the IPRs governing plant genetic resources.

The PGR disputes<sup>136</sup> include three different kinds of agricultural and food-related plant genetic material: (a) found in its natural or "raw" state *-in situ*; (b) stored in global seed banks– *ex situ*; and (c) that have been "worked" through human invention (new plant varieties, isolated plant genes, or genetically modified plants).<sup>137</sup> TRIPS Agreement and the International Convention for the Protection of New Varieties of Plants 1961<sup>138</sup> regulate IP protection for plant-related innovations. The UPOV confers

- 130 UDHR, 1948, art. 25.
- 131 ICESCR, 1966, art. 11.1.
- 132 ICESCR, 1966, art. 11.2.
- 133 FAO, Report of the World Food Summit 1996, available at: http://www.fao.org/3/w3613e/w3613e00.htm (last visited May 14, 2022).
- 134 Michael Blakeney, Intellectual Property Rights and Food Security 6 (2009).
- 135 Hereinafter referred to as "PGR".
- 136 Also known as "Seed Wars".
- 137 Keith Aoki, Seed Wars: Controversies and Cases on Plant Genetic Resources and Intellectual Property (2008); *Helfer And Austin, supra* note 11 at 379.
- 138 Revised in in 1972, 1978, and 1991. *available at:* https://www.upov.int/edocs/pubdocs/en/upov\_pub\_221.pdf (last visited May 14, 2022). A plant variety is eligible for protection if it is new; distinct from other varieties by virtue of its qualitative and quantitative characteristics; uniform with regard to the specific features of its sexual reproduction or vegetative propagation; and stable, such that the variety's essential characteristics persist even after repeated reproduction or propagation; hereinafter referred to as "UPOV".

<sup>128</sup> Subhashini Chandrasekharan *et al.*, "Intellectual property rights and challenges for development of affordable human papillomavirus, rotavirus and pneumococcal vaccines: Patent landscaping and perspectives of developing country vaccine manufacturers" 33 *Vaccine* 6366–6370 (2015).

<sup>129</sup> Ragavan, supra note 53 at 49; See WIPO Secretariat, supra note 121; See also Jayashree Watal & Rong Dai, Product Patents and Access to Innovative Medicines in a Post-TRIPS Era (2019).

upon the breeder, exclusive rights of reproducing the protected variety, conditioning it for propagation, importing and exporting the variety, and stocking it for any of these purposes. However, UPOV provides private non-commercial exception, tesearch exception, breeder's exemption, farmer's privilege and compulsory licensing in public interest as limitations to the exclusive rights of breeder. States or other unregulated entities may violate the right to food, as a result, it's critical to make sure that IPRs benefit rural farmers, stimulate innovation, and share information in order to combat poverty and malnutrition.

### Right to traditional knowledge and prevention of biopiracy

Another aspect concerning public rights is prevention of biopiracy,<sup>147</sup> which involves claim of IPRs in unimproved PGRs and misuse of traditional knowledge.<sup>148</sup> The CBD imposes a duty on third parties using PGRs to fairly and equally share the benefits with the relevant nation or community of origin. It would constitute a biopirate, if the entity claiming legal protection did not pay back fairly to those from whom the access was obtained for raw materials. Also, getting their informed consent would be a condition for grant of protection under UPOV and it is referred to as bioprospecting, but such sharing provision is absent in the TRIPS.<sup>149</sup> The biopiracy

- 139 UPOV, 1991, art. 14.
- 140 Subsistence farmers are allowed to consume protected seeds and other propagating material for their own use. See art.15(1)(i) of UPOV, 1991.
- 141 It is permissible to conduct research and testing on protected varieties for scientific objectives that do not result in commercial exploitation. *See* art.15(1)(ii) of UPOV, 1991.
- 142 Breeders have the right to use protected varieties to develop new variations that are not fundamentally derivatives of protected varieties. See arts.14(5) and 15 of UPOV, 1991.
- 143 Farmers may propagate using the product of the crop acquired by growing a protected variety on their own land holding. See art.15(2) of UPOV, 1991.
- 144 Allows for the restriction of breeders' exclusive rights in the public interest, subject to the breeder receiving equitable recompense. *See* Art. 17 of UPOV, 1991.
- 145 See generally Laurence R Helfer, FAO Legislative Study- Intellectual property rights in plant varieties: International legal regimes and policy options for national governments (2004).
- 146 See Jeannette Mwangi, "Trips and Agricultural Biotechnology: Implications for the Right to Food in Africa" in Mpazi Sinjela ed., Human Rights and Intellectual Property Rights: Tensions and Convergences 241–287 (2007).
- 147 "Act by which a commercial entity seeks to obtain IPRs over biological resources, including plant varieties, that are seen as belonging to developing states or indigenous communities." See Helfer, supra note 145 at 20.
- 148 See generally Carlos M. Correa, Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options 172 (2000).
- 149 Sayan Bhattacharya, "Bioprospecting, Biopiracy and Food Security in India: The Emerging Sides of Neoliberalism", 23 *Int. Lett. Soc. Humanist. Sci.* 49–56 (2014), *available at:* www.scipress.com/ILSHS.23.49 (last visited Aug 19, 2021).

as per Daniel F. Robinson<sup>150</sup> may categorized as patent-based biopiracy<sup>151</sup> non-patent biopiracy<sup>152</sup> and misappropriation.<sup>153</sup> Some significant cases of medicine biopiracy relate to Tepezcohuite, <sup>154</sup> Neem, <sup>155</sup> Hoodia Cactus, <sup>156</sup> Jamun, <sup>157</sup> Turmeric, <sup>158</sup>

- 150 See Daniel F. Robinson, Confronting Biopiracy: Challenges, Cases and International Debates (2010).
- 151 The patenting of innovations that are based on biological resources and/or traditional knowledge that have been taken without the consent of other nations, indigenous or local people, and without benefit-sharing with these groups. See Id. at 21.
- 152 IP control through plant variety protection or misleading trademarks based on biological resources and/or traditional knowledge, which were derived illegally from other countries or indigenous or local communities without adequate authorization and benefit-sharing. See Id. at 21.
- 153 Illegal exploitation of biological resources and/or traditional knowledge without sufficient benefit-sharing from other nations, indigenous people or local communities. See Id. at 21.
- 154 The Tepezcohuite (Mimosa tenuiflora) of Chiapas, Mexico is Thorny tree with skin-healing qualities that may also be used to cure burns, and analgesic, anti-inflammatory, anti-bacterial, epidermal regeneration properties are all found in it. Using the powdered bark, Leon Rouqe, an ex-Chiapa, received a U.S. Patent in 1989 (US 4,883,663) and later in 1992, a US patent (US 5,122,374) was granted for use of its extracts in pharmaceutical compositions. See Patents on life: the final assault on the commons, available at: https://www.grain.org/fr/entries/53-of-patents-pi-ates#p41 (last visited June 14, 2022).
- 155 The Neem (Azadirachta indica) is an Indian medicinal plant, having remarkable properties present in bark, leaves, flowers and seeds for treating human and animal diseases. Robert Larson, obtained US Patent (5,124,349 and 4,556,562) for pesticides based on Neem and transferred the rights to W R Grace and Co. Eventually, in May 2000, a combination of individuals and organisations succeeded in overturning the patent. However, there are still several patents in Neem. See available at: https://neemfoundation.org/about-neem/patent-on-neem/ (last visited May 22, 2022). See also Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, available at: http://www.tkdl.res.in/tkdl/langdefault/Common/Biopiracy.asp?GL=Eng (last visited May14, 2022).
- 156 Hoodia (Trichocaulon) is a succulent cactus used by the San people of South Africa, for sustenance and medicinal purposes. Hoodia's appetite-suppressing ingredient (P57) was patented by the South African Council of Scientific and Industrial Research (CSIR) in 1995 and licenced to the British Biotech Company 'Phytopharm' in 1997. In 1998, Pfizer paid Phytopharm \$ 32 million for the rights to develop and sell P57, a possible weight-loss medication and treatment for obesity. There was a breakthrough deal in March 2002 that gave the San a share in the future revenues. See Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, supra note 138
- 157 Jamun (blackberry) is used in the treatment of diabetes as common knowledge in India. In 1999 US patent (5,900,240) was granted to Cromak Research Inc., for a mixture of Jamun (blackberry), Karela (bitter gourd), Gumar and Brinjal, to treat diabetes. See Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, supra note 140.
- 158 Turmeric (curcuma longa) is a traditional Indian medication used to heal sprains and inflammations. It was granted US Patent (5,401,504) in the year 1993 to the Medical Centre of University of Mississippi over processing use of turmeric for healing of wounds. Later upon challenge by Indian Government the USPTO cancelled the patent in the year 1997. See Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, supra note 138.

Ayahuasca, <sup>159</sup> Quinoa, <sup>160</sup> which clearly portray that it limits indigenous usage and overrides the fundamental rights of local communities to exploit natural resources when patents are granted; and attempt in USA to patent certain known rice-lines of Basmati Rice<sup>161</sup> is an example of biopiracy. The principles of proprietarian IPRs, state sovereignty, community rights and common heritage of mankind are intricately linked to the problem of biopiracy. <sup>162</sup> The difference in wealth between traditional knowledge holders and those who benefitted underscore the necessity of preventing abuse and attributing rights to the indigenous communities. <sup>163</sup>

It is critical to limit the detrimental impact of patents on PGRs by making a clear difference between patentable inventions and non-patentable discoveries. A thorough examination of novelty and inventive step must be provided, and use-bound protection covering only the function of the gene specified in the claim must be allowed. Also, a broad research and breeding exemption should be stipulated, including for the commercialization of a new plant variety derived from the protected material. Farmers must be allowed to save and re-use saved seeds, and the interface between patent and PVP must be addressed through compulsory licences. <sup>164</sup>

- 159 Ayahuasca (Banisteriopsiscaapi Mort.) is a drink used by Shamans of the Amazon basin in religious and therapeutic ceremonies to diagnose and treat sickness, to connect with spirits, and to divine the future. In 1986 US citizen Loren Miller claimed to have discovered a new variety in Ecuador, and the Plant Medicine Corporation was granted US patent (05751) on it. Later, the USPTO revoked the patent in 1999 upon challenge by Indigenous Organisations of the Amazon Basin. However, the inventor was subsequently successful in convincing the USPTO and the original claims were reconfirmed and the patent rights restored to the innovator in 2001. See Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, supra note 140.
- 160 Quinoa (Chenopodium quinoa Willd.) is a necessary part of the diet of Quechua and Aymara people in the Andes. In 1994, US patent (5,304,718) was granted to two professors from Colorado State University for Apelawa, a traditional quinoa variety. In, 1998 Andean farmers forced the University to surrender its US patent on 'Apelawa' quinoa. See Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, supra note 138.
- 161 Basmati rice (Oryza sativa Linn.) that has long grains and a distinctive flavour and taste, is mostly grown in Punjab, Western India, and Pakistan, and it is a popular export from India. In 1997, Texas based RiceTec Inc. obtained US Patent (5,663,484) for a new plant variety that is a cross between Basmati rice and American long-grain rice. However, the patent claims that stated to have characteristics similar to Indian Basmati rice, and would restrict Indian exports to US, were withdrawn on pressure from India. Also, the trademark "Texmati" was successfully opposed before the UK Trade Mark Registry. See Patents on Life, supra note 139; Bio-piracy of Traditional Knowledge, supra note 138.
- 162 Bhattacharya, supra note 149 at 55.
- 163 Srividhya Ragavan, Protection of Traditional Knowledge, 2 Minnesota Intellect. Prop. Rev. 1–60, 58 (2001).
- 164 See Carlos M Correa, TRIPS-Related Patent Flexibilities and Food Security: Options For Developing Countries Policy Guide (2012), available at: https://quno.org/sites/default/files/resources/ENGLISH\_TRIPS-Related Patent Flexibilities and Food Security\_CORREA.pdf (last visited April 20, 2022); See also Claudio Chiarolla, "Right to food and intellectual property protection for plant genetic resources", in Christophe Geiger ed., Research Handbook on Human Rights and Intellectual Property 521–543 (2015).

# Right to development

The Right to Development is a human right identified by the United Nations. <sup>165</sup> The African Charter on Human and Peoples' Rights, <sup>166</sup> Arab Charter on Human Rights, <sup>167</sup> Rio Declaration on Environment and Development, <sup>168</sup> Vienna Declaration and Programme of Action, <sup>169</sup> UN Millennium Declaration, <sup>170</sup> Monterrey Consensus, <sup>171</sup> World Summit Outcome Document, <sup>172</sup> Declaration on the Rights of Indigenous Peoples, <sup>173</sup> UN Sustainable Development Goals 2030, <sup>174</sup> are some of the significant international instruments which also recognize this right.

IP is a public policy instrument that encourages technological progress by providing the motivation, and is beneficial to human well-being. Thus, it has crucial linkages

- 165 "The Right to Development is an inalienable human right by virtue of which every human person and all peoples are entitled to participate in, contribute to, and enjoy economic, social, cultural and political development, in which all human rights and fundamental freedoms can be fully realized." See UN Declaration on the Right to Development, adopted on Dec. 4, 1986, UN Doc. A/RES/41/128, available at: https://www.ohchr.org/Documents/ProfessionalInterest/rtd.pdf (last visited May 14, 2022).
- 166 Also known as 'Banjul Charter'. Adopted 27 June 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 21, 1986; available at: https://www.achpr.org/public/Document/file/English/banjul\_charter.pdf (last visited May, 14 2022).
- 167 Adopted by the Council of the League of Arab States on May 22, 2004, entered into force Mar. 15, 2008, *available at:* http://hrlibrary.umn.edu/instree/loas2005.html (last visited Aug 14 2021)
- 168 Adopted at United Nations Conference on Environment and Development (UNCED) from 3 to 14 June 1992; *available at:* https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A\_CONF.151\_26\_Vol.I\_Declaration.pdf (last visited Aug 14 2021).
- 169 Adopted by the World Conference on Human Rights in Vienna on June 25, 1993; available at https://www.ohchr.org/Documents/ProfessionalInterest/vienna.pdf (last visited Aug 14 2021)
- 170 United Nations Millennium Declaration, UN General Assembly resolution 55/2 of Sep. 8, 2000; available at: https://www.ohchr.org/EN/ProfessionalInterest/Pages/Millennium.aspx (last visited May, 14 2022).
- 171 Monterrey Consensus of the United Nations International Conference on Financing for Development, adopted on 22 March 2002; *available at:* https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A\_CONF.198\_11.pdf (last visited Aug 14 2021)
- 172 Adopted by the UN General Assembly on Sep.16, 2005; available at https://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A\_RES\_60\_1.pdf (last visited June 14, 2022).
- 173 United Nations Declaration on the Rights of Indigenous People, UN General Assembly resolution 61/ 295 of 13 September 2007, available at: https://documents-dds-ny.un.org/doc/UNDOC/GEN/ N06/512/07/PDF/ N0651207.pdf (last visited June 14 2022).
- 174 Transforming our world: the 2030 Agenda for Sustainable Development, UN General Assembly resolution A/Res/70/1 of Sep. 25, 2015, available at: https://www.un.org/ga/search/view\_doc.asp?symbol=A/RES/70/1&Lang=E (last visited June 14 2022).

with the right to development.<sup>175</sup> The report of the UN Human Rights Council (UNHRC), points out at some of the significant implications between IPRs and right to development.<sup>176</sup> The Doha Declaration on TRIPS and Public Health have made a significant contribution to the fulfilment of the right to development through IPRs. Also, the goal of self-determination of Indigenous peoples<sup>177</sup> by recognition and protection of traditional knowledge shall also not be lost sight of, in the quest for development.<sup>178</sup>

# Right to access materials for education and freedom of expression

Exclusive rights in artistic and literary works are granted by the copyright law to authors, preventing competition from copyists, and ensuring that royalties or revenue generated by such works goes to the authors in the belief that this will encourage authors to invest in new creativity and additional effort. <sup>179</sup> Nevertheless, copyright's ultimate aim is to benefit the society, and granting exclusive monopoly rights without suitable limits might hamper rather than encourage creativity. Justice Oliver Wendell Holmes in *Abrams* 

- 175 Ahmed Abdel-Latif, "The right to development: What implications for the multilateral intellectual property framework?" in Christophe Geiger ed., Research Handbook on Human Rights and Intellectual Property 605–626 (2015).
- 176 "(i) access to the public goods technology that is important for the enjoyment of many human rights can be restricted, e.g. essential medicines may be unavailable or priced out of reach; (ii) in certain contexts, intellectual property rights may discourage innovation and supply of public goods that are important for enjoyment of human rights by raising the costs of research and development that require licensing patented technologies, e.g. numerous costly licenses were required in developing 'Golden rice' and negotiated; (iii) distribution of intellectual property rights ownership is highly skewed, with the overwhelming majority of intellectual property rights being held by a few leading technologically-developed countries leaving developing countries at a disadvantage; (iv) the distribution of innovation is highly skewed as the intellectual property rights system provides incentives for innovations that produce market returns and is of little use in stimulating investment in poor peoples' technology needs such as medicines for malaria; (v) intellectual property rights systems conceptualized in an industrialized country context does not provide for the rights of protection of traditional knowledge and community owned resources; and (vi) tight intellectual property rights systems reduce opportunities for technology transfer for developing countries to 'catch up' with the technological environment of the developed countries." See Human Rights Council, Technical mission in order to review the WIPO Development Agenda from the perspective of its contribution to the realization of the right to development, para.13, 19 Nov 2009, available at https://www2.ohchr.org/english/ issues/development/right/docs/A-HRC-15-WG2-TF-CRP1.pdf (last visited Aug 14 2021).
- 177 See UNDRIP, 2007, art. 3 and 31.
- 178 Susy, "Using Intellectual Property Rules to support the Self-Determination Goals of Indigenous Peoples" in Christophe Geiger ed., Research Handbook on Human Rights and Intellectual Property 627–640 (2015).
- 179 Christopher Jon Sprigman, "Copyright and Creative Incentives: What Do(n't) We Know?", in Rochelle Cooper Dreyfuss and Elizabeth Siew-Kuan Ng eds., Framing Intellectual Property Law in the 21st Century: Integrating Incentives, Trade, Development, Culture, and Human Rights 32–61 (2018).

v. United States<sup>180</sup> observed that "the ultimate good desired is better reached by free trade in ideas—that the best test of truth is the power of the thought to get itself accepted in the competition of the market" and marked it to be a commitment of the United States Constitution.<sup>181</sup> The human right to freedom of expression also finds mention in various international instruments.<sup>182</sup>

The UDHR states that "education shall be directed to the full development of the human personality", 183 the ICESCR provides that "education shall be directed to the full development of the human personality and the sense of its dignity, and shall strengthen the respect for human rights and fundamental freedoms" 184 and the UN Convention on the Rights of the Child 1989 185 emphasizes on role of education in "the development of the child's personality, talents and mental and physical abilities to their fullest potential." The Statute of Anne 1710 186 which is considered as the first copyright statute is titled as "An Act for the Encouragement of Learning, by vesting the Copies of Printed Books in the Authors or purchasers of such Copies, during the Times therein mentioned" which signifies that the emphasis was on encouraging learning. Therefore, conflicts occur when educational resources with copyrighted content are essential for fulfilling the right to education.

Lord Denning in the case of *Hubbard v. Vosper*<sup>187</sup> for copyright infringement expounded on the meaning of fair dealing as an exception and observed that, "It is impossible to define what is 'fair dealing'. It must be a question of degree. You must first consider the number and extent of the quotations and extracts.... then you must consider the use made of them.... Next, you must consider the proportions...other considerations may come into mind also. But, after all is said and done, it is a matter of impression." The fair dealing or fair use doctrine<sup>188</sup> which is

- 180 250 U.S. 616 (1919)
- 181 Helfer and Austin, supra note 11 at 223.
- 182 UDHR, art. 19.
- 183 UDHR, art. 26(2).
- 184 ICESCR, 1966, art. 13(1).
- 185 Hereinafter referred to as "UNCRC".
- 186 8 Ann., c. 19 (Eng.); available at: https://case.edu/affil/sce/authorship/statueofanne.pdf (last visited June 14 2022).
- 187 [1972] 2 Q.B. 84
- 188 Whether or not there is a "fair use" of a piece of work is determined by weighing four factors: (1) its purpose and character; (2) its nature as a work protected by copyrights; (3) the amount and substantiality of the use relative to the copyrighted work; and (4) its effect on the copyrighted work's potential market or value. Usage for transformative purposes such as criticism, comment, news reporting or parody, as well as non-profit educational use, teaching (including multiple copies for classroom use), scholarship or research is permitted. See David Tan, "Taking the Mickey out of Disney: A Cultural Approach to the Transformative Use Doctrine in Copyright Law, in Framing Intellectual Property Law" in Rochelle Cooper Dreyfuss and Elizabeth Siew-Kuan Ng eds., The 21st Century: Integrating Incentives, Trade, Development, Culture, and Human Rights 171–209 (2018).

provided under the Berne Convention<sup>189</sup> and also the TRIPS,<sup>190</sup> allows for the reproduction, use of copyrighted works and is the main method for balancing the "inherent conflict" between copyright protection and freedom of speech/expression.<sup>191</sup> The question of permissible copying of copyrighted education material as fair use, for teaching/course packs, has been a matter of contention across the world<sup>192</sup> and for educational activities, exceptions and limitations have been provided under the copyright law in different national legal systems.<sup>193</sup>

Further, the Marrakesh Treaty promotes disability rights by inhibiting copyright, and advances the right to read for people with print disabilities, allowing them to receive, make and use accessible copies of works, shifting the international copyright law towards inclusion.<sup>194</sup> There is a need to expand and refine the understanding of proper

- 190 TRIPS, 1994, art. 13
- 191 Tan, supra note 188.
- 192 See Folsom v. Marsh, 9 F. Cas. 342 (C.C.D. Mass. 1841); Addison-Wesley Publishing Company v. Brown, 223 F. Supp. 219 (E.D.N.Y. 1963); New York Times Co. v. Roxbury Data Interface, Inc., 434 F. Supp. 217 (D.N.J.1977); Marcus v. Rowley, 695 F.2d 1171 (9th Cir. 1983); Harper & Row, Publishers, Inc. v. Nation Enterprises, 471 U.S. 539 (1985); Weissmann v. Freeman, 868 F.2d 1313 (2d Cir. 1989); Basic Books Inc. v. Kinko's Graphics Corp., 758 F. Supp. 1522 (S.D.N.Y. 1991); Campbell v. Acuff-Rose Music, 510 U.S. 569 (1994); American Geophysical Union v. Texaco Inc., 60 F.3d 913 (2nd Cir. 1994); Princeton University Press v. Michigan Document Services Inc., 99 F.3d 1381 (6th Cir. 1996); CCH Canadian Ltd. v. Law Soc'y of Upper Can., [2004] S.C.R. 339 (Can.); Alberta (Education) v. Canadian Copyright Licensing Agency (Access Copyright), [2012] 2 S.C.R. 345 (Can.); Cambridge University Press v. Becker, 863. F.Supp.2d 1190 (N.D.Ga., 2012); Cambridge University Press et al. v. Patton et al., 769 F.3d 1232 (11th Cir. Ga. 2014); Authors Guild, Inc. v. Hathi Trust, 755 F.3d 87 (2d Cir. 2014); Authors Guild v. Google, Inc., 804 F. 3d 202 (2d Cir. 2015); The Chancellor, Masters & Scholars of the University of Oxford v. Rameshwari Photocopy Services, 2016 SCC OnLine Del 5128.
- 193 See Daniel Seng, WIPO Standing Committee on Copyright and Related Rights: Study on Copyright Limitations and Exceptions for Educational Activities [SCCR/33/6] (2016), https://www.wipo.int/edocs/mdocs/copyright/en/sccr\_33/sccr\_33\_6.pdf (last visited Aug 14, 2021); Daniel Seng, WIPO Standing Committee on Copyright and Related Rights: Updated Study and Additional Analysis of Study on Copyright Limitations and Exceptions for Educational Activities [SCCR/35/5 REV.] (2017), available at: https://www.wipo.int/edocs/mdocs/copyright/en/sccr\_35/sccr\_35\_5\_rev.pdf (last visited May 2, 2022); Daniel Seng, Limitations and Exceptions in Copyright Law for Educational Activities: An Asia-Pacific Analysis, in Regional Seminar for the Asia Pacific Group on Libraries, Archives, Museums, and Educational and Research Institutions in the Field of Copyright (2019), available at: https://www.wipo.int/edocs/mdocs/copyright/en/wipo\_reg\_cr\_sin\_19/wipo\_reg\_cr\_sin\_19\_education.pdf (last visited Aug 14, 2021); Muhammad Masum Billah & Saleh Albarashdi, Free Use of Copyrighted Materials in Education and Research and the Limit of Such Use, 17 Chicago-Kent J. Intellect. Prop. 422–448 (2018).
- 194 Paul Harpur, "The Weakening of the Exception Paradigm: The World Intellectual Property Organization Changes Path with the Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired, or Otherwise Print Disabled" in Discrimination, Copyright and Equality: Opening the e-Book for the Print-Disabled 64–92 (2017).

<sup>189</sup> Berne Convention 1886 in its Appendix enables developing countries to have bulk access to some types of copyrighted works including educational resources.

relationship between instrumentalist and deontic copyright justifications, in order to articulately appreciate public interest, without just focusing on narrow private interests. 195

#### Position in India

The Indian Constitution through its various provisions, particularly the *Directive Principles of State Policy*, <sup>196</sup> ordains India to be a Welfare State <sup>197</sup> and the *fundamental rights* <sup>198</sup> guarantee to the citizens basic, inalienable rights even against the State, with an enforceable machinery manned by the Supreme Court <sup>199</sup> and high courts <sup>200</sup> of the country. Apart from the express fundamental rights guaranteed under the Constitution, <sup>201</sup> the right to health, <sup>202</sup> right to food, <sup>203</sup> right to development *etc.*, have been considered as a part of the right to life, by way of interpretation confirming to international law. <sup>204</sup> The State is laden with responsibility to enhance the living standards, nutrition levels, and improve public health. <sup>205</sup> In addition, most of the Directive Principles of State Policy are incorporated into fundamental rights, by the Supreme Court of India through judicial activism <sup>206</sup>. It is the Human Rights Act of 1993, fundamental rights and directive principles that constitute the backbone of India's legislative framework for safeguarding human rights. Apart from this, public interest

- 195 Sprigman, supra note 179 at 61.
- 196 Part-IV of Constitution of India, 1950.
- 197 The government in which the State plays a critical role in protecting and promoting the economic and social well-being of its citizens, based on the principles of equal opportunity and fair distribution of wealth.
- 198 Part-III of Constitution of India, 1950.
- 199 Constitution of India, 1950, art.32.
- 200 Constitution of India, 1950, art. 226.
- 201 Right to Equality (arts.14-18); Right to Freedom (art.19); Right to Life and Personal Liberty (art.21); Right to Education (art.21A); Right against Exploitation (art.23-24); Right to Freedom of Religion (arts.25-28); Right to Cultural and Educational Rights (arts.29-30); and Right to Constitutional Remedies (art.32).
- 202 Bandhua Mukti Morcha v. Union of India, AIR 1984 SC 802; State of Punjab v. Mohinder Singh Chawla (1997) 2 SCC 83; State of Punjab v. Ram Lubhaya Bagga (1998) 4 SCC 117;
- 203 Shantistar Builders v. Narayan Khimalal Totame (1990) 1 SCC 520
- 204 People's Union for Civil Liberties v. Union of India (1997) 1 SCC 301; ESC Ltd. v. Subhash Chandra Bose (1992) 1 SCC 441.
- 205 Constitution of India, 1950, art.47.
- 206 Municipal Council, Ratlam v. Vardhichand 1980 Cri LJ 1075; Olga Tellis v. Bombay Municipal Corporation, AIR 1986 SC 180; Rakesh Chandra Narayan v. State of Bihar, AIR 1989 SC 348; CESC Ltd. v. Subash Chandra Bose, AIR 1992 SC 573; J.P. Unnikrishnan v. State of Andhra Pradesh (1993) 1 SCC 645; R.Rajagopal v. State of Tamil Nadu (1994) 6 SCC 632; Consumer Education Research Centre v. Union of India (Asbestosis case), AIR 1995 SC 922; Virender Gaur v. State of Haryana, (1995) 2 SCC 577; Paschim Banga Khet Mazdoor Samiti v. State of W.B. (1996) 4 SCC 37; Dalmia Cement (Bharat) Ltd. v. Union of India, (1996) 10 SCC 104; Bandhua Mukti Morcha v. Union of India (1997) 10 SCC 549.

and human rights are protected in numerous additional statues, including Indian legislations on IPRs.<sup>207</sup> The National IPR Policy 2016<sup>208</sup> also has an objective as "To have strong and effective IPR laws, which balance the interests of rights owners with larger public interest." <sup>209</sup>

The Justice Rajagopal Ayyangar Committee Report<sup>210</sup> has laid down the foundation for the formulation of the Patents Act 1970<sup>211</sup> in India, by giving priorities to public interests and also promotion of patent literacy. There are general principles under the Patents Act that apply to patentable innovations in India.<sup>212</sup> According to it, patents are issued not only to provide a monopolistic right to the patentees for import of the patented item,<sup>213</sup> but also to make advantages of the patented product affordable to the general population.<sup>214</sup> The technical knowledge must benefit both users and producers in a manner that promotes social and economic well-being and retains a good balance between the rights and obligations.<sup>215</sup> It also emphasizes that patents do not obstruct protection of public health and nutrition, and should be used as an instrument to advance public interest, particularly in areas critical to India's socioeconomic and technological advancement.<sup>216</sup> The Central Government reserves the authority to take appropriate measures to protect public health, even after the grant of patent<sup>217</sup> and also prevent patent rights from being misused by the patentee through the use of methods that restrict commerce or impede the transfer of technology across borders.218

<sup>207</sup> The Copyright Act 1957; The Patents Act, 1970 (as amended in 2005); The Trade Marks Act 1999; The Designs Act, 2000; The Geographical Indications of Goods (Registration and Protection) Act, 1999; The Semiconductor Integrated Circuits Layout Design Act, 2000; The Protection of Plant Varieties and Farmers' Right Act, 2001.

<sup>208</sup> Government of India, National Intellectual Property Rights Policy/: Creative India; Innovative India (2016), available at: https://dipp.gov.in/sites/default/files/national-IPR-Policy2016-14October2020.pdf (last visited Aug 14, 2021).

<sup>209</sup> Objective 3 of National IPR Policy (2016).

<sup>210</sup> N. Rajagopala Ayyangar, Report on the Revision of the Patents Law (1959), available at: http://www.ipindia.nic.in/writereaddata/Portal/Images/pdf/1959-\_Justice\_N\_R\_Ayyangar\_committee\_report.pdf (last visited June 14, 2022).

<sup>211</sup> Hereinafter referred to as "Patents Act".

<sup>212</sup> Patents Act, art. 83.

<sup>213</sup> Id., s. 83(a).

<sup>214</sup> Id., s. 83(g).

<sup>215</sup> Id., s. 83(c).

<sup>216</sup> Id., s. 83(d).

<sup>217</sup> Id., s. 83(e).

<sup>218</sup> Id., s. 83(f).

<sup>219</sup> See Chapter-XVI of Patents Act [Ss.82-94].

Grant of compulsory license is provided for under the Patents Act.<sup>219</sup> After three (3) years from grant of patent, anybody can obtain a compulsory licence from the Controller, regardless of whether they already possess the licence for that Patent, if: "(i) the reasonable requirements of the public with respect to the patented invention have not been satisfied; or (ii) the patented invention is not available to the public at a reasonably affordable price; or (iii) the patented invention is not worked in the territory of India."<sup>220</sup> The Controller may also suo motu issue compulsory license, in cases of "national emergency" or "extreme urgency" or "public non-commercial use" without adhering to the standard process for issuing compulsory licence.<sup>221</sup> Also the patent may be granted subject to conditions that "the patented process, machine, apparatus or other article may be used, imported or made by or on behalf of the Government for its own use"<sup>222</sup> or for experiment, research or teaching by any person,<sup>223</sup> and the government can import it for its use or for distributing it to any hospital or medical institution, taking into consideration the public service.<sup>224</sup>

Generic versions of patented medicines are widely produced and exported from India. *Natco Pharma*, a domestic company was granted the first compulsory license in India, against the multinational pharmaceutical company *Bayer*, in respect of Sorafenib Tosylate drug with *Nexavar* brand name for treating liver and kidney cancer, to allow for affordable access.<sup>225</sup> <sup>226</sup> The Patents Act also prohibits the granting of patents for those inventions that do not enhance the drug's known efficacy,<sup>227</sup> in order to avoid *evergreening*<sup>228</sup> of patent and ensure access to health care access. The Supreme Court in

- 220 Patents Act, s. 84.
- 221 Patents Act, s. 92.
- 222 Patents Act, s. 83(1) and (2).
- 223 Patents Act, s. 83(3).
- 224 Patents Act, s. 83(4).
- 225 Bayer had priced Nexavar at Rs.2,80,428/- per month's course for a patient, whereas Natco planned to sell its generic version named Sorafenat, for just Rs.8,800/- per year, and noting that Bayer's fees was unaffordable to the Indian people, the Controller issued compulsory license vide Order, Dt: 09-03-2012. The Order was challenged in Bayer Corporation v. Union of India, [MANU/IC/0016/2013: MIPR 2013 (2) 97] before the IPAB Chennai, but the same was rejected vide Order, Dt: 04-03-2013 and a further challenge before the High Court of Bombay in Bayer Corporation v. Union of India, [MANU/MH/0986/2014: AIR 2014 Bom 178] was also dismissed vide Order, Dt: 15-07-2014.
- 226 See Feroz Ali, "Nexavar: The First-Market Initiated Compulsory Licence 9 NUJS Law Rev. 229–257 (2016); See also K D Raju, Compulsory v. Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries, 22 J. Intellect. Prop. Rights 23–31 (2017).
- 227 Patents Act, s. 3(d).
- 228 Pharmaceutical companies' practise of obtaining new patents for modest reformulations/ iterations of a patented medicine that do not significantly improve its medicinal efficacy in order to covertly extend the life of the patent. The major strategies employed for evergreening of pharmaceutical drugs are "enantiomers, combination drugs, new medical uses, new formulations, metabolites, new routes of administration and polymorphs of existing drugs". See Say Yed Hesameddin Tafreshi, "Anti pharmaceutical patent ever-greening law: Global need in support of public health", 24 J. Intellect. Prop. Rights 103–112 (2019).

the landmark *Novartis* case,<sup>229</sup> struck down a mere improvement in a patented drug *Gleevec* for the treatment of chronic myelogenous leukaemia and certain gastrointestinal cancer, as non-patentable, which secured increased affordable generic drug production.<sup>230</sup> Patents may be revoked by the government if they are used in a way that harms the state or is generally harmful to the public, or against the interests of the general public.<sup>231</sup>

The exceptions to use of a copyrighted work are given in the Copyrights Act, 1957<sup>232</sup> including fair dealing<sup>233</sup> which generally have the objective of providing access to knowledge and public interest as the parameters. The Copyright Act also allows for "the adaptation, reproduction, issue of copies or communication to the public of any work in a format accessible to persons with disability'<sup>234</sup> and also permits for "grant of compulsory licence for benefit of disabled.'<sup>235</sup> Apart from this, the Biological Diversity Act 2002 and the Protection of Plant Varieties and Farmers' Right Act 2001along with the Patents Act, guarantee protection of public interest by avoiding biopiracy, mandating disclosure of place/country of origin and safeguarding farmer's rights. The case BT Cotton of Monsanto as depicted in Monsanto Technology LLC v. Nuziveedu Seeds Ltd., <sup>236</sup> reflect broad ramifications of the problem.

In 2001 the Traditional Knowledge Digital Library<sup>237</sup> was initiated in India.<sup>238</sup> The TKDL protects "Indian traditional medicinal knowledge and prevent its misappropriation at International Patent Offices."<sup>239</sup> In 2018, India has also made a request to the PCT Minimum

- 229 Novartis v. Union of India, 2013 (6) SCC 1
- 230 See Niloufer Sohrabji and Kaitlyn Maloney, "Section 3(d) and Pharmaceutical Patents in India", 25 J. Intellect. Prop. Rights 65–73 (2019).
- 231 Patents Act, s. 66.
- 232 As amended in 2012; Hereinafter referred to as "Copyright Act".
- 233 It allows the use of copyrighted works for "private/personal use, research, criticism or review, reporting of current events, reproduction for judicial proceedings, reproduction for teaching, performance in course of activities of educational institution, etc." [S. 52 of Copyright Act].
- 234 Copyright Act, s. 52(zb).
- 235 Copyright Act, s. 31B.
- 236 AIR 2019 SC 559: MANU/SC/0027/2019
- 237 Hereinafter referred to as "TKDL".
- 238 It is a partnership between the Council of Scientific and Industrial Research (CSIR), Ministry of Science and Technology, and the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Ministry of Health and Family Welfare, of India; and is being implemented at the CSIR. It contains about 1250 formulations selected from various classical texts of Indian Systems of Medicine such as Ayurveda, Unani, Siddha and Sowa Rigpa.
- 239 The access of TKDL is available to 13 Patent Offices (EPO, USPTO, UK, IPO, Rospatent of Russia, Japan, Canada, Germany, Spain, Australia, Peru, Chile and Malaysia), under TKDL Access (Non-disclosure) Agreement. The TKDL Access Agreement is unique in nature and has built-in non-disclosure provisions to shield India's interests against any exploitation. See, available at: http://www.tkdl.res.in/tkdl/LangDefault/Common/Home.asp (last visited June 14, 2022).

Documentation Task Force<sup>240</sup> to add TKDL to PCT documentation for ensuring TK prior art is not patented and the Indian indigenous populations benefit from it, the same is under deliberation.<sup>241</sup> The Geographical Indications of Goods (Registration and Protection) Act, 1999<sup>242</sup> promotes rural development by advancing commercial and economic interest, enriching cultural, traditional and environment stewardship, through granting legal protection by way of Geographical Indication<sup>243</sup> for marketing products and services at global level.<sup>244</sup>

# IV COVID-19: IPR and human rights

Globally, 233,136,147 confirmed cases of COVID-19, including 4,771,408 deaths, have been reported to WHO up to September 30, 2021.<sup>245</sup> In spite of much research being done around COVID19, there has been development of a few vaccines<sup>246</sup> and medicines,<sup>247</sup> which however have not been proved to be totally effective in preventing the disease and treating the patients, but the lack of universal focus on developing

- 240 WIPO, Meeting of International Authorities under the Patent Cooperation Treaty (PCT) | PCT Minimum Documentation Task Force: Status Report [PCT/MIA/26/8] (2019), https://www.wipo.int/edocs/mdocs/pct/en/pct\_mia\_26/pct\_mia\_26\_8.pdf (last visited June 17, 2022).
- 241 WIPO, Meeting of International Authorities under the Patent Cooperation Treaty (PCT) | PCT Minimum Documentation Task Force: Status Report [PCT/MLA/27/11] (2020), https://www.wipo.int/edocs/mdocs/pct/en/pct\_mia\_27/pct\_mia\_27\_11.pdf (last visited Sep 17, 2021).
- 242 Hereinafter referred to as "GI Act".
- 243 In India there are 370 registered GIs as up to April, 2020 and the authorized users are association of persons, association of producers, organization or any authority representing the interest of the producers. The GI Act defines producer in relation to goods as "any person who if such goods are agricultural goods, produces the goods and includes the person who processes or packages such goods; if such goods are natural goods, exploits the goods; and if such goods are handicraft or industrial goods, makes or manufactures the goods and includes any person who trades or deals in such production, exploitation, making or manufacturing, as the case may be, of the goods" [S.2(1)(k)]. See The Geographical Indications of Goods (Registration and Protection) Act, 1999 No.48 of 1999, http://www.ipindia.nic.in/act-1999.htm (last visited Sep 17, 2021).
- 244 Naresh Kumar Vats, "Geographical Indication-The Factors of Rural Development and Strengthening Economy" 21 J. Intellect. Prop. Rights 347–354, 347 (2016).
- 245 WHO Coronavirus (COVID-19) Dashboard, *available at:* https://covid19.who.int/ (last visited Oct 1, 2021).
- 246 See COVID-19 vaccines, World Health Organization (2021), available at: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines (last visited June 10, 2022); See also World Health Organization, Status of COVID-19 Vaccines within WHO EUL/PQ evaluation process [Guidance Document] (2021).
- 247 See World Health Organization, WHO Living guideline: Drugs to prevent COVID-19 (2021), available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-prophylaxes-2021-1 (last visited June 10, 2022); See also Coronavirus (COVID-19) | Drugs | FDA, U.S. Food & Drug Administration (2021), https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs (last visited Aug 29, 2021); See available at: also J. Stewart, COVID-19: Prevention & Investigational Treatments Drugs.com (2021), available at: https://www.drugs.com/condition/covid-19.html (last visited Aug 29, 2021).

alternative medicines using traditional knowledge and traditional medicinal practices for the same is quite striking. Though, there are a number of claimants who reportedly developed such alternatives, very few claims have proved to be genuine, and some of these have been in use due to public acceptance, providing successful relief to patients and partial endorsement of their effect by regulatory bodies. For instance, the medicine made with herbal concoction based on the ayurvedic/ naturopathic medicine and ancient Indian traditional knowledge by one Bonigi Anandaiah in the Krishnapatnam area of Nellore District in Andhra Pradesh State of India, gained huge popularity and was administered to more than 80,000 people in a few weeks by May 2021. However, distribution of medicine was then halted by the Andhra Pradesh Government in the end of May, 2021. and later granted permission for administration withholding the permission with respect to the eye drops. Anandaiah has also filed a writ petition directing the Andhra Pradesh Government not to interfere and disturb the activities of his trade and permit him to continue his pro-bono services to the

- 249 See Fraudulent Coronavirus Disease 2019 (COVID-19) Products | FDA, U. S. Food and Drug Administration (2021), available at: https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products (last visited May 10, 2022).
- 250 Timothy Caulfield, Misinformation, alternative medicine and the coronavirus | Folio, Folio (2020), available at: https://www.ualberta.ca/folio/2020/03/commentary—misinformation-alternative-medicine-and-the-coronavirus.html (last visited May 10, 2022).
- 251 B. Anandaiah code-named his medicines as 'P' for clearing infection in the lungs, 'F' for clearing poisonous substances from the body, 'L' to activate the liver and 'K' for critical cases; See Curious case of Anandaiah potion: All you need to know about Krishnapatnam medicine being touted as "Covid cure" SCIENCE News, June 1, 2021, available at: https://www.indiatoday.in/science/story/anandaiah-covid19-ayurvedic-medicine-vaccine-andhrapradesh-1809413-2021-06-01 (last visited Sep 29, 2021); See also Krishnapatnam Anandaiah Corona medicine for Covid treatment: All you need to know | Vijayawada News Times of India, June 4, 2021, available at: https://timesofindia.indiatimes.com/city/vijayawada/krishnapatnam-ayurvedic-medicine-for-covid-treatment-all-you-need-to-know/articleshow/83228584.cms (last visited Sep 29, 2021).
- 252 The 'P', 'L', 'F' category of medicines are granted permission with clarification that there is no harm in use of the herbal paste, and also that there is no evidence about the medicine being able to reduce the effects of COVID-19 and also that it may be a health supplement. See Paul Oommen, Andhra clears Anandaiah's herbal medicine, but says it's not a cure for COVID-19, May 31, 2021, available at: https://www.thenewsminute.com/article/andhra-government-gives-greenlight-anandaiah-s-herbal-medicine-covid-149829 (last visited May 20, 2022).
- 253 The permission to the eye drops is subject to receipt of the reports from Indian Institute of Chemical Technology and LV Prasad Eye Institute. See Andhra Pradesh Govt. nod for 'Anandaiah preparation', excluding eye drops The Hindu, June 1, 2021, available at: https://www.thehindu.com/news/national/andhra-pradesh/andhra-pradesh-government-permits-usage-of-anandaiah-herbal-medicine-for-covid-patients/article34689680.ece (last visited June 10, 2022).
- 254 See, W.P. No.10806/2021 filed on 27-05-2021 before the High Court of Andhra Pradesh.

<sup>248</sup> See Vibhu Paudyal et al., Complementary and alternative medicines use in COVID-19: A global perspective on practice, policy and research, Research in Social and Administrative Pharmacy (2021), available at: /pmc/articles/PMC8116135/ (last visited May 28, 2022).

public, and the same is pending. Though, the medical fraternity in general refused to accept the efficacy of such medicine, the Central Council for Research in Ayurvedic Sciences (CCRAS), Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) Department of Andhra Pradesh allowed the usage of herbal medicine after conducting tests on the samples. This episode makes it clear that the major pharma companies in India and abroad, may not extend a helping hand to the alternative medicines, probably due to the high economic stakes involved.

Another issue is the opacity behind the joint research collaboration between Government of India and the pharmaceutical companies which developed COVID vaccines. Particularly, the patent issues, terms of ownership rights, pricing and marketing rights regarding the vaccines so developed, have a bearing on the human rights like right toaccess to medicines and public health. The partnership between Bharat Biotech and Government of India for the preparation of the Covaxin vaccine<sup>255</sup> is not clear as to the extent of public funding<sup>256</sup>, and also there are questions as to conflict of interest relating to financial, political nature appearing to influence the research output.<sup>257</sup>

The position of international travel has also been affected due to the COVID-19 situation, and some countries have come with a vaccine passport system.<sup>258</sup> However, there has been opposition to this system on the grounds that *firstly*, while vaccination supplies are still limited, it is morally dubious to provide preference to those who were fortunate to get early access; *secondly*, racial minorities and low-income groups will likely continue to have lower vaccination rates even if supply restrictions improve, and it may lead to invidious discrimination; *thirdly*, the extent of protection offered by immunisation is unknown especially against novel strains, and it is uncertain that people who have had vaccinations may spread viruses to others; *fourthly*, incentives favouring

<sup>255</sup> COVAXIN is India's indigenous COVID-19 vaccine by Bharat Biotech, developed in partnership with the Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV). See COVAXIN - India's First Indigenous Covid-19 Vaccine | Bharat Biotech, available at: https://www.bharatbiotech.com/covaxin.html (last visited May 20, 2022).

<sup>256</sup> R Ramakumar, Covid-19 vaccine: Who owns the IP rights to Bharat Biotech's publicly funded Covaxin? (2021), available at: https://scroll.in/article/993257/why-its-vital-for-indians-to-know-who-owns-intellectual-property-rights-to-bharat-biotechs-covaxin (last visited Apr. 25, 2022).

<sup>257</sup> ICMR Should Do a Better Job of Managing Its Conflicts of Interest - The Wire Science, (2021), available at: https://science.thewire.in/health/icmr-better-manage-covaxin-conflicts-of-interest/ (last visited June 20, 2022).

<sup>258</sup> Some organisations and corporations are creating their own digital health pass schemes. The International Air Transport Association, a trade association representing 290 airlines, promotes its Travel Pass app as a method for travellers to maintain proof of vaccination against COVID-19. Several nations, including the European Union, the United Kingdom, France, Australia, Israel, China, and Bahrain, have also developed some sort of COVID-19 passport; See What Is a Vaccine Passport? (2021) available at: https://www.webmd.com/vaccines/covid-19-vaccine/vaccine-passport-covid (last visited May 20, 2022).

the vaccinated are likely to hurt those who have ethical or religious concerns about vaccination; and *lastly* there is a lack of consensus in accurately certifying vaccination.<sup>259</sup>

For instance, the system of Green pass/EU COVID Vaccination Passport/EU Digital COVID Certificate (EUDCC) recognizes only four vaccines *i.e.*, Moderna, Comirnaty (BioNTech, Pfizer), Janssen (Johnson and Johnson)and Vaxzevria (formerly COVID-19 Vaccine AstraZeneca, Oxford), to the exclusion of all other vaccines even though they are approved by WHO, leading to discrimination against mostly the Asian and African countries. Here, the double standard of EU in respect of Oxford-AstraZeneca produced vaccines and the same vaccines produced elsewhere is clearly exhibited. Also, the Covishield made available in 91 African countries under an EU initiative, is excluded in Europe for Green Pass, high to travel in EU. Also, the Government of India has taken a position to consider the vaccine made in India by considering the CoWin certificate for EUDCC<sup>262</sup> otherwise warned reciprocal action, and also some EU nations have accepted Covishield vaccine of India in order to get Green Pass. In another incident, the UK Government had given recognition to AstraZeneca Covishield of India from September 22, 2021<sup>264</sup> but the vaccine certification from India was not on

<sup>259</sup> Mark A. Hall and David M. Studdert, "Vaccine Passport" Certification — Policy and Ethical Considerations" 385 N. Engl. J. Med. e32 (2021), available at: https://www.nejm.org/doi/full/10.1056/NEJMp2104289 (last visited Sep 29, 2021).

<sup>260</sup> All Details on EU COVID-19 Vaccine Passport Revealed: Here's What You Need to Know - SchengenVisaInfo.com, (2021), available at: https://www.schengenvisainfo.com/news/all-details-on-eu-covid-19-passport-revealed-heres-what-you-need-to-know/ (last visited May 20, 2022).

<sup>261</sup> The African Union consisting of 55 member states gave a statement that "non-recognition of Covishield vaccine, endangers the equitable treatment of persons having received their vaccines in countries profiting from the EU-supported COVAX Facility"; Kampala, African Union criticises EU decision to not approve Covishield for Covid-19 certificate - World News (2021), available at: https://www.indiatoday.in/world/story/african-union-eu-decision-covishield-covid-19-certificate-1820958-2021-06-30 (last visited June 10, 2022).

<sup>262</sup> Suhasini Haidar, *India tonghens stand on EU COVID passport - The Hindu* (2021), *available at:* https://www.thehindu.com/news/national/india-toughens-stand-on-eu-covid-passport/article35066572.ece (last visited June 10, 2022).

<sup>263</sup> Covishield has been accepted by Austria, Germany, Slovenia, Greece, Iceland, Ireland, Spain, and Switzerland; See These European countries to give "green pass" to people from India vaccinated with Covishield vaccine, (2021), available at: https://www.livemint.com/news/india/these-european-countries-to-give-green-pass-to-people-from-india-vaccinated-with-covishield-vaccine-11625120734262.html (last visited June 10, 2022).

<sup>264</sup> Pfizer BioNTech, Moderna, Janssen (J&J), Oxford AstraZeneca (including the formulations AstraZeneca Covishield, AstraZeneca Vaxzevria, and Moderna Takeda) are now recognised by the UK government for international travel; Saurabh Sinha, UK Covishield Vaccine: UK recognises Covishield; no quarantine relief for Indian travellers | World News - Times of India (2021), available at: https://timesofindia.indiatimes.com/world/uk/uk-accepts-covishield-but-indians-to-quarantine/articleshow/86421378.cms (last visited May 20, 2022).

the list of 18 approved countries<sup>265</sup> wherein the vaccination received from a "relevant public health body" of those countries would be considered "fully vaccinated"; but when entering the UK, Indian travellers even though fully vaccinated would be classified "non-vaccinated" and were to be quarantined for 10 days, since the certification from all nations must fulfil a "minimum criteria."<sup>266</sup> Considering this as a clear discrimination, the Government of India condemned the non-recognition of its vaccine certification and threatened reciprocal measures if the vaccinated travellers from India are treated unfairly.<sup>267</sup> probably as a result of the same, from October 11, 2021 India's vaccine certificate has been recognised and quarantine is not required for Indian travellers fully vaccinated with Covishield.<sup>268</sup>

A passport requirement for foreign travel is not appropriate, according to the WHO, due to unequal access and a lack of strong data on prevention viral transmission after the vaccination. <sup>269</sup>Exempting incoming travellers who are fully vaccinated, *i.e.*, who have received the last recommended dose of a COVID vaccine listed by WHO for emergency use or approved by a stringent regulatory authority at least two weeks before travelling, from SARS-CoV-2 testing and/or quarantine requirements may be considered by the countries. In order to prevent vaccination recipients from experiencing further anxiety, countries should progress toward mutual recognition of immunisation certificates. <sup>270</sup>

- 265 Apart from the United States of America and Europe, the United Kingdom has approved inbound vaccinations from the following 18 countries: Australia, Malaysia, Bahrain, Saudi Arabia, Brunei, Antigua and Barbuda, UAE, Canada, Israel, Japan, South Korea, Dominica, Kuwait, New Zealand, Qatar, Singapore, Taiwan and Barbados; See Covishield row with UK: Both sides engage in talks to clear out differences | India News India TV, (2021), available at: https://www.indiatvnews.com/news/india/uk-10-day-quarantine-rule-vaccinated-india-discriminatory-latest-coronavirus-update-736019 (last visited May 20, 2022).
- 266 UK travel rules: Talks on to resolve travel norms row, but vaccine certification must meet 'minimum criteria', says UK | India Today News, (2021), available at: https://www.indiatoday.in/ coronavirus-outbreak/story/uk-travel-rules-india-vaccine-certification-meet-minimum-criteria-1856125-2021-09-23 (last visited Apr. 1, 2022).
- 267 Soutik Biswas, Covishield: UK recognises Covid jab after India outcry BBC News (2021), available at: https://www.bbc.com/news/world-asia-india-58647433 (last visited Oct 1, 2021).
- 268 Poulomi Ghosh, "New travel rules in UK from October 11. What changes for Indians?" | Latest News India - Hindustan Times (2021), available at: https://www.hindustantimes.com/india-news/new-travel-rules-in-uk-from-october-11-what-changes-for-indians-101633884218398.html (last visited June 10, 2022).
- 269 Neetu Chandra Sharma, WHO panel advises against use of vaccination passports for global travel (2021), available at: https://www.livemint.com/news/world/who-panel-advises-against-use-of-vaccination-passports-for-global-travel-11626725107261.html (last visited May 10, 2022).
- 270 PT Jyothi Datta, Vaccine passports and certificates should not become 'licence to travel', say experts The Hindu BusinessLine (2021), available at: https://www.thehindubusinessline.com/news/vaccine-passports-and-certificates-should-not-become-licence-to-travel-say-experts/article36682177.ece (last visited June 10, 2022).

#### **V** Conclusion

The new pandemic, COVID-19, has pushed the never-ending argument over IP and human rights to the fore, and this time, it is about providing access to the medicine and vaccination needed to fight it through compulsory licensing and other measures. Patenting an innovation creates an artificial scarcity that allows the vaccine or drug's value to be preserved, controlled, and even enhanced after the invention has been produced. The innovation processes are driven by scarcity and the resulting deprivation, also as a result of inadequate investments in capacity building and a refusal to transfer technology, scarcity thrives. It gives the patent owner complete control over the product's manufacturing process through the use of highly restrictive licence agreements.<sup>271</sup>It must be noted that the UN Human Rights Council's 2016 Resolution, urges countries to work together to develop approaches and models that support the dissociating of cost of new research and development from the prices of vaccines, medicines and diagnostics for diseases that primarily affect developing countries, in order to ensure their long-term accessibility, affordability and availability, so as to guarantee that all those in need get medical treatment.<sup>272</sup>

COVID-19 was announced to be a public health emergency of international concern (PHEIC) on January, 30, 2020 and was declared as a pandemic on March, 11, 2020 by the WHO, and the COVID-19 Technology Access Pool (C-TAP) was launched by it on May 29, 2020.<sup>273</sup> The Gavi, Coalition for Epidemic Preparedness Innovations (CEPI), and WHO are leading a global campaign called 'COVID-19 Vaccines Global Access (COVAX)'to provide equitable access to COVID-19 vaccinations.<sup>274</sup> Also WIPO's global PATENTSCOPE database inducted a COVID-19 search function, that supports

<sup>271</sup> Siva Thambisetty, "Vaccines and patents: how self-interest and artificial scarcity weaken human solidarity", *LSE British Politics and Policy* (2021), *available at*: https://blogs.lse.ac.uk/politicsandpolicy/vaccines-and-patents/ (last visited June 10, 2022).

<sup>272</sup> UN Human Rights Council, Access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health | A/HRC/RES/32/15 (2016).

<sup>273</sup> The C-TAP is designed to expedite the development of goods necessary to combat COVID-19, as well as the scaling up of production and the reduction of barriers to access, in order to make products worldwide available. 18 generic pharmaceutical companies have taken an open pledge to join the Medicines Patent Pool and take collective action against COVID-19. The World Health Organization (WHO), in collaboration with a group of other global health actors, private sector partners, and other stakeholders, has launched the Access to COVID-19 Tools (ACT) Accelerator, a collaboration aimed at accelerating the development, production, and equitable global access to new COVID-19 essential health technologies; *See* Covid-19 Technology Access Pool, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool (last visited May 20, 2022).

<sup>274</sup> COVAX, *available at:* https://www.who.int/initiatives/act-accelerator/covax (last visited May 3, 2022).

searching of COVID-19 related patent information through predefined search strings, 275 and similar tools, databases have been established by several national patent offices. When it comes to COVID-19, the developed nations have prioritised containment of the virus and innovation, in contrast, the developing countries must focus not only on containment of the virus but also on the availability and affordability of its treatment. 276 Like, compulsory licensing for importing generic lopinavir/ritonavir was issued by the Israeli government;<sup>277</sup> and Canada;<sup>278</sup> Chile,<sup>279</sup> and Ecuador<sup>280</sup>also provide for the legal framework to issue compulsory licenses.<sup>281</sup> However, maximizing innovation incentives must be considered for encouraging large-scale investments to be made in the development of a vaccine especially in the innovation stage, and then later after a successful vaccine is made, there may be need to support access with policy measures.<sup>282</sup> Francis Gurry, the then Director General of WIPO also emphasizes that, "given the drastic impact of COVID-19 crisis on human health and welfare and on economic production and economic welfare, the world needs to deploy all available innovation strategies, incentives and systems in the pursuit of vaccines, treatments and cures." This situation is reflecting the global north-south divide and their diverse priorities.

South Africa and India have represented to the TRIPS Council in October 2020, for a waiver of protections under WTO rules relating to copyrights, patents, undisclosed

- 276 Hilary Wong, "The case for compulsory licensing during COVID-19" 10 J. Glob. Health 1-5, 1 (2020).
- 277 On March 24, 2020, a Compulsory License was given since AbbVie's Kaletra was unable to meet demand, and generic alternatives are being supplied from India. Additionally, AbbVie has stated that it would not pursue its patent due to the pandemic.
- 278 COVID-19 Emergency Response Act, S.C. 2020, C-13 (Can.), modified the Canadian Patent Act to expedite the process of awarding a compulsory licence on public health grounds, with compensation to be negotiated afterwards.
- 279 The Chilean Chamber of Deputies' Resolution for Compulsory Licensing of Coronavirus Patents says that the corona pandemic provides adequate basis for granting compulsory licences. The Ecuadorian National Assembly Committee's Resolution on Compulsory Licensing of Coronavirus Patents provides for the provision of free or cheap access to COVID-19-related preventive, diagnostic, and treatment technologies through the use of compulsory licensing.
- 280 Wong, supra note 276.
- 281 Frank Tietze et al., Crisis-Critical Intellectual Property: Findings From the COVID-19 Pandemic, IEEE Trans. Eng. Manag. 1–18 (2020); See generally World Trade Organisation; World Intellectual Property Organisation and World Health Organisation, Promoting Access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade (2nd ed. 2020), www.wto.org/Publications (last visited May 1, 2022).
- 282 Francis Gurry, Intellectual property, innovation, access and COVID-19, WIPO Mag. (2020), available at: https://www.wipo.int/wipo\_magazine/en/2020/02/article\_0002.html (last visited May 14, 2022).
- 283 WTO, Waiver from Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19: Communication from India and South Africa [IP/C/W/669] (2020), available at: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True (last visited June 10, 2022).

<sup>275</sup> Patentscope Covid-19 Index, available at: https://patentscope.wipo.int/search/en/covid19.jsf (last visited May 1, 2022).

information and industrial designs related to inhibition, control, or treatment of COVID-19 till extensive vaccination is globally made available.<sup>284</sup> However a consensus could not be reached and the decision of WTO is deferred, as at that time there was opposition for request of the waiver from the United States, European Union, United Kingdom, and other developed nations. An IP waiver, it is argued, would undermine the incentives necessary to stimulate new medical innovations. <sup>285</sup>However, later on May 5 2021 the United Sates declared its support for the proposal to temporarily waive IPRs relating COVID-19 vaccines<sup>286</sup> and the TRIPS Council has agreed to continue the discussions on IP response to COVID 19<sup>287</sup>. Also, the response to Covid pandemic would be a main subject of deliberation at WTO's 12th Ministerial Conference (MC12) ought to be held at Geneva from 30 November to 3 December, 2021. <sup>288</sup>

The investment of public monies involved in development of vaccines, even more emphasize the issue of equitable access to vaccine. The pharma companies are profiting from the public-funded research, and there is strong critique of them profiteering in the middles of Covid pandemic.<sup>289</sup> The Amnesty International in its report of September, 2021 on Pharma companies and COVID-19 vaccines, focused on six foremost companies developing the vaccine *i.e.*, Johnson and Johnson, Novavax, AstraZeneca, Pfizer, BioNTech and Moderna, by assessing the policy on human rights,

<sup>284</sup> James Bacchus, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines" | Cato Institute, Free Trade Bulletin No.78, 2020, available at: https://www.cato.org/publications/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid (last visited May 20, 2022).

<sup>285</sup> Priti Krishtel and Rohit Malpani, "Suspend intellectual property rights for covid-19 vaccines", 373 The BMJ (2021), https://www.bmj.com/content/373/bmj.n1344 (last visited May 20, 2022).

<sup>286</sup> WTO | 2021 News items - TRIPS Council agrees to continue discussions on IP response to COVID-19, (2021), available at: https://www.wto.org/english/news\_e/news21\_e/trip\_20jul21\_e.htm (last visited May 20, 2022).

<sup>287</sup> WTO | Ministerial conferences - Twelfth WTO Ministerial Conference - Geneva Switzerland, avialable at: https://www.wto.org/english/thewto\_e/minist\_e/mc12\_e/mc12\_e.htm (last visited Oct 1, 2021).

<sup>288</sup> Moderna has obtained almost \$1 billion in tax-funded funding from BARDA (Biomedical Advanced Research and Development Authority, a division of the US Department of Health and Human Services) for the development of 'mRNA vaccine.' Additionally, the firm struck an agreement with the federal government for more than \$1.5 billion for an initial 100 million doses of the vaccine. Moderna executives also benefitted from stock sales in conjunction with results releases, with the top three earning about \$100 million, and the firm is expected to add up to \$30 billion to its revenues; Judy Stone, *The People's Vaccine — Moderna's Coronavirus Vaccine Was Largely Funded By Taxpayer Dollars* 2020–2022 (2021), available at: https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/?sh=370e491a6303 (last visited May 20, 2022).

<sup>289</sup> Amnesty International, A Double Dose of Inequality: Pharma Companies and the Covid-19 Vaccines Crisis (2021), available at: https://www.amnesty.nl/content/uploads/2021/09/Double-Dose-of-inequality-FINAL-.pdf?x88229 (last visited May 20, 2022).

IP records, pricing structure, sharing of technology and knowledge, distribution of vaccine doses and transparency of the companies. In the study, it is found that "vaccine developers have monopolized intellectual property and blocked technology transfers. Some companies have charged high prices for their vaccines, sold predominantly to rich countries, and stand to make enormous profits - despite receiving billions in public funding. While the vaccine developers claim to respect human rights, all of them - to differing degrees - have failed to meet their responsibilities."<sup>290</sup>

Despite the fact that 6.39 billion doses of COVID-19 vaccine are administered worldwide, only 2.3% of individuals in low-income countries have gotten at least one dose of immunisation as of October 5, 2021 which demonstrates the grave inequality in the global distribution of the vaccine.<sup>291</sup> However, to boost vaccine manufacturing and ensure that it is available to everybody, just using an IP waiver will not be sufficient.<sup>292</sup> Institutional capacity would have to be built in numerous nations, systemic bottlenecks would have to be overcome, and administrative and legislative changes would have to be implemented, but a TRIPS waiver may be a significant step in increasing vaccine manufacturing.<sup>293</sup> The WHO also has supported the proposal to ease WTO rules,<sup>294</sup> and NGOs pressured wealthy countries to temporarily relax regulations as was done in the wake of the AIDS pandemic. The WTO Deputy Director-General Xiangchen Zhang has also opined that, "To achieve meaningful results that will make a difference in responding to this and any future pandemics, we are focusing on three key areas: One, free up vaccine supply chains by lowering export restrictions and facilitating trade; Two, work with manufacturers to identify supply chain bottlenecks and increase production in developing countries; And three, find pragmatic solutions to technology transfer, knowhow, and intellectual property questions." 295

The race to develop a COVID-19 vaccine must prioritise the prevention of further deaths and the protection of all people, regardless of race, ethnicity, or country

<sup>290</sup> The data is as on 28-09-2021. See Coronavirus (COVID-19) Vaccinations - Statistics and Research - Our World in Data, (2021), avaialable at: https://ourworldindata.org/covid-vaccinations (last visited May 10, 2022).

<sup>291</sup> Thambisetty, supra note 271.

<sup>292</sup> Prabhash Ranjan, The Case for Waiving Intellectual Property Protection for Covid-19 Vaccines, ORF Issue Brief No.456 (2021).

<sup>293</sup> Tedros Adhanom Ghebreyesus, @DrTedros | Twitter (2020), avaialable at: https://twitter.com/DrTedros/status/1317449471727407104 (last visited May 20, 2022).

<sup>294</sup> Speaking at the LLDC ministerial meeting held virtually on the margins of the UN General Assembly on 23 September, 2021; WTO | 2021 News items - Access to COVID-19 vaccine, ministerial outcomes key to driving development in LLDCs, (2021), available at: https://www.wto.org/english/news\_e/news21\_e/ddgxz\_23sep21\_e.htm (last visited May 20, 2022).

<sup>295</sup> OHCHR, OHCHR | Statement by UN Human Rights Experts Universal access to vaccines is essential for prevention and containment of COVID-19 around the world\*, OHCHR (2020), available at: https://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=26484&LangID=E (last visited June 10, 2022).

origin.<sup>296</sup>A global system based on genuine global solidarity must be used to produce, finance, allocate, distribute, and deploy the COVID-19 vaccine.<sup>297</sup> High-income nations should provide access to vaccines for low-to-middle-income countries, with a focus on vaccines having the best data on effectiveness for everyone, as was the case with the smallpox vaccination campaign, which might serve as a model for COVID-19 vaccines, by seeing it as global public goods<sup>298</sup>. The UNHRC in its report also pointed out that the COVID-19 pandemic has shown that failure to integrate human rights-based approaches into health emergency preparedness, response and recovery efforts has serious consequences for human rights and development, and it has made recommendations for building back better by ensuring that human rights principles inform implementation of Sustainable Development Goals (SDGs) set for 2030.<sup>299</sup>

Now is the time to realize that IPRs are not only restrictions on HRs, rather they are the means through which HRs could be protected. This shift in perception is necessary in view of the significance of non-trade aspects of IPRs which got ignored after the TRIPS agreement. It is hoped that the nations at large more particularly the developed ones would start looking and acting beyond the TRIPS, and might facilitate serving larger human interest throughout the globe. The much-desired balance between public interest and protected rights can be secured only when the IPR and HRs are accepted as complementary to each other by all the stakeholders.

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<sup>296</sup> Olivier J. Wouters et al., Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment, 397 The Lancet 1023–1034 (2021), avaialable at: https://pubmed.ncbi.nlm.nih.gov/33587887/ (last visited June 10, 2022).

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