

# LAWYERS COLLECTIVE SUBMISSIONS TO THE UN HIGH-LEVEL PANEL ON ACCESS TO MEDICINES

## I. INTERNATIONAL TRADE RULES IN THE CONTEXT OF THE HUMAN RIGHT TO HEALTH - CAN THEY BE RECONCILED?

### *Primacy of Human Rights in International law*

It is submitted that the High Level Panel on Access to Medicines (“the Panel”) must recognize the primacy of human rights and human rights obligations over intellectual property and related international trade obligations. The respect for and the realization of human rights lie at the heart of the United Nations and the modern international legal order.

The Charter of the United Nations, 1945 has been signed by nearly every nation-State in the world. It is considered by jurists to be the foundational international instrument, not just of the United Nations, but the modern international legal order.<sup>1</sup> Article 1 of the UN Charter recognizes its purpose to include the promotion and respect for human rights and fundamental freedoms in a non-discriminatory manner. Article 55 of the Charter declares that the UN shall promote solutions to international *health* problems and universal respect and observance for human rights, while Article 56 pledges that Members take joint and separate action in cooperation with the Organisation to achieve the purposes set out in Article 55. Articles 55 and 56, read together, can be construed as legal obligations upon States.<sup>2</sup> Further, Article 103 of the Charter contains a non-obstante clause, declaring that the obligations under the Charter shall prevail over any other international agreement in the event of a conflict.

The human rights to be observed and respected under the Charter necessarily include the right to health. The right to health has been specifically recognised in a number of international human rights instruments<sup>3</sup>, however the most important enumeration of the right to health is found in Article 12 the International Covenant on Economic, Social and Cultural Rights, 1966 (ICESCR), which forms a part of the International Bill of Human Rights.

### *Access to essential medicines is a non-derogable obligation upon States*

It is submitted that this Panel recognize that the right to access affordable essential medicines form an immediate and non-derogable obligation upon all States party to the

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<sup>1</sup> C. Tomuschat, “Introduction” in C. Tomuschat, ed., *THE UNITED NATIONS AT AGE FIFTY: A LEGAL PERSPECTIVE* (The Hague: Kluwer Law International, 1995); B. Simma, ed., *THE CHARTER OF THE UNITED NATIONS: A COMMENTARY*, 2<sup>nd</sup> ed., Vol. II (Oxford: Oxford University Press, 2002); I. Seiderman, *HIERARCHY IN INTERNATIONAL LAW: THE HUMAN RIGHTS DIMENSION* (Antwerp: Intersentia-Hart, 2001).

<sup>2</sup> Ian Brownlie, *PRINCIPLES OF PUBLIC INTERNATIONAL LAW*, 5<sup>th</sup> ed. (Oxford: Oxford University Press, 1998), at p. 574

<sup>3</sup> Universal Declaration of Human Rights (Art. 24); International Convention on the Elimination of All Forms of Racial Discrimination (Art. 5(e)(iv) 1965; International Covenant on Economic, Social, and Cultural Rights Art. 12, 1966; Convention on the Elimination of All Forms of Discrimination against Women (CEDAW). (Art. 11(1)(f), 12, 14(2)(b)) 1979; Convention on the Rights of the Child: Art (24) 1989; International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families: arts. (28, 43 (e), 45(c).) 1990; Convention on the Rights of Persons with Disabilities: art. 25 (2006); The Charter of Fundamental Rights of the European Union (2000); European Convention of the Protection of Human Rights and Fundamental Freedoms (1950)

ICESCR. The right to health, has been authoritatively interpreted by the Committee on Economic, Social and Cultural Rights (CESCR) in General Comment No.14 to the ICESCR.

That General Comment No.14 recognises that State parties have certain core obligations which ensure the minimum essential levels of the right to health.<sup>4</sup> The core obligations are non-derogable in nature, and a State party cannot in any circumstance justify its non-compliance with a core obligation.<sup>5</sup> The provision of essential medicines and the equitable distribution of health goods and services form core obligations upon State Parties.

*The human 'Right to Science' must be recognized and read along with the right to access essential medicines*

The human right to benefit from scientific progress, enunciated in Article 27 of the Universal Declaration of Human Rights and further in Article 15 of the ICESCR guarantees both the rights of everyone to share in the benefits of scientific progress and its applications. Special Rapporteurs on the right to food<sup>6</sup> and the right to health<sup>7</sup> have both held the right to science as being complementary to the aforesaid rights, particularly in the context of intellectual property rights limiting access to innovations such as seed technology and essential medicines.

*The human rights of inventors do not coincide with intellectual property laws and may not be used to undermine other rights in the Covenant, including the right to health.*

Article 27 of the UDHR and Article 15 of the ICESCR also guarantee authors and inventors the right to have their moral and material interests resulting from their production protected and promoted. It is pertinent to note here that the human rights of inventors are only applicable for natural persons, and no private or public entity can claim a "human right" to benefit from an invention.

The Committee on the Economic Social and Cultural Rights interpreted the normative content of this right in General Comment No.17. The Committee held that while Article 15.1 safeguards the personal link between inventors and their creations, and their basic material interests to enjoy an adequate standard of living, intellectual property rights were meant to protect corporate interests and investments. It further stated that "the scope of protection of the inventors' moral and material interests of the author provided for by Article 15.c, does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements."<sup>8</sup>

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<sup>4</sup> UN Committee on Economic, Social and Cultural Rights (CESCR), GENERAL COMMENT NO. 14: THE RIGHT TO THE HIGHEST ATTAINABLE STANDARD OF HEALTH (ART. 12 OF THE COVENANT), 11<sup>th</sup> August 2000, E/C.12/2000/4 at Para 43

<sup>5</sup> *Id.* at Para 47

<sup>6</sup> UN General Assembly, REPORT OF THE SPECIAL RAPPORTEUR ON THE RIGHT TO FOOD: "SEED POLICIES AND THE RIGHT TO FOOD: ENHANCING AGROBIODIVERSITY AND ENCOURAGING INNOVATION," UN Doc. A/64/170 (2009)

<sup>7</sup> Commission on Human Rights, REPORT OF THE SPECIAL RAPPORTEUR ON THE RIGHT OF EVERYONE TO THE HIGHEST ATTAINABLE STANDARD OF PHYSICAL AND MENTAL HEALTH, UN Doc. E/CN.4/2003/58 (2003)

<sup>8</sup> UN Committee on Economic, Social and Cultural Rights (CESCR), GENERAL COMMENT NO. 17: THE RIGHT OF EVERYONE TO BENEFIT FROM THE PROTECTION OF THE MORAL AND MATERIAL INTERESTS RESULTING FROM ANY SCIENTIFIC, LITERARY OR ARTISTIC PRODUCTION OF WHICH HE OR SHE IS THE AUTHOR (*Art. 15, Para. 1 (c) of the Covenant*), 12 January 2006, E/C.12/GC/17 at Para 2

The right is also intrinsically linked to the right to benefit from scientific progress in Article 15.1, being “mutually reinforcing and reciprocally limitative”.<sup>9</sup> The Committee holds States obligated to strike a balance between Article 15(1)(c) on one hand and the other rights under the Covenant, holding that there should be no impediment to the State’s duties to comply with Core obligations such as preventing unreasonably high costs for essential medicines.<sup>10</sup>

*International trade agreements must be interpreted in accordance with international human rights law*

It is submitted that this Panel recognize that legal obligations arising out of international trade agreements which result in unreasonably high prices for essential medicines are violative of the Charter of the UN and the ICESCR.

International trade instruments have to be interpreted in accordance with the State Parties’ obligations under international human rights instruments. That the WTO Appellate Body has recognized that trade law cannot be looked at in isolation from public international law.<sup>11</sup> It follows that international human rights law is therefore also required to be recognized and considered while deciding State obligations under the WTO Agreements.

*Enforcement of human rights instruments*

Unfortunately, State accountability towards protecting, respecting and fulfilling their human rights obligations is relatively weak compared to the enforcement of international trade laws. This has resulted in States choosing to ignore or limit their human rights obligations in favour of complying with their trade obligations; and thereby avoid trade sanctions and exorbitant compensations. Under the ICESCR, there is no requirement for States to incorporate the right to health in domestic legislation.

Currently, a relatively small number of States have signed and ratified the Optional Protocol to the International Covenant on Economic Social and Cultural Rights,<sup>12</sup> which recognizes the competence of the Human Rights Council to consider complaints from individuals or groups of violations of their Covenant rights. Even so, the Committee’s recommendations, which extend to recommendations for remedial action, are not binding upon States.

The Optional Protocol also provides for an “Inquiry procedure” and an “Inter-State complaints procedure”. The Inquiry procedure allows the Committee to conduct investigations if it receives reliable complaints of grave and systemic violations of the

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<sup>9</sup> *Id.* at Para 4

<sup>10</sup> *Id.* at Para 35

<sup>11</sup> In *US-Gasoline*, (Standards for Reformulated and Conventional Gasoline WT/DS2/AB/R, 17 (AB, WTO 1996), the WTO Appellate Body held that the judicial organs of the WTO should recognise that they should not interpret the WTO Agreements in clinical isolation from Public International Law.

<sup>12</sup> As of 27-02-2016, only 21 States have signed and ratified the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights.

[URL - [https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=IV-3-a&chapter=4&lang=en.](https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3-a&chapter=4&lang=en.)] (Last Accessed, 27<sup>th</sup> February, 2016, 17:28 IST)

Covenant rights.<sup>13</sup> Inquiry procedures are an optional mechanism which only operates if the State makes a declaration accepting the Committee's competence to make inquiries. The Inter-State complaints procedure permits a state to initiate a procedure against another state for breach of its obligations under the ICESCR.<sup>14</sup> Similar to the Inquiry mechanism, State signatories must explicitly declare the competence of the Committee to decide such complaints.

Human rights complaints may also be submitted to Special Rapporteurs appointed by the Commission on Human Rights, including the Special Rapporteur on the Right of everyone to the highest attainable standard of physical and mental health, who are empowered to inquire and report on individual complaints relating to the right to health and requesting information on steps taken by the State authorities to redress the violation. The public reports of the Special Rapporteur "name and shame" State authorities to take action. Ultimately however, they do not cast any legal obligations on States to enforce the ICESCR.

### RECOMMENDATIONS

The Panel is called upon to acknowledge and declare that international human rights treaties and principles take precedence over WTO Agreements in the international legal order. Further, the Panel is also called upon to promote the enforcement of violations of the right to access essential medicines through the mechanisms in place. The Panel must further encourage States to comply with their international obligations, and accede to the Optional Protocol to increase transparency and accountability for violations of the Covenant rights.

## II. THE PATENT SYSTEM HAS NOT CONTRIBUTED TO INCREASED INNOVATION

Pharmaceutical companies often justify the high price of drugs on the ground of high cost of research and development (*hereinafter*, R&D). In 2003, it was estimated that the R&D cost for a bringing a new drug to the market was USD 801 million.<sup>15</sup> This was further revised in 2013 by the Tufts Centre for Study of Drug Development (CSDD), an industry funded body, to be around USD 2.6 billion<sup>16</sup>. A 2011 study by Light and Warburton concurs that the actual costs for R&D for a new drug comes to around USD 75 million on an average.<sup>17</sup> MNCs argue that the patent system creates monopolies that allow inventors to recoup R&D costs incurred in developing new drugs and encourages further innovation. Available evidence on the pharmaceutical innovation, however, points to a completely contrary picture. According to a 2006 US Congressional Budget Office report, two thirds of R&D expenditure by companies is spent towards making minor improvements to existing products. Even though the total spending on health related research and

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<sup>13</sup> Article 11, OPTIONAL PROTOCOL TO THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 5<sup>th</sup> March 2009, A/RES/63/117

<sup>14</sup> Article 10, OPTIONAL PROTOCOL TO THE INTERNATIONAL COVENANT ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, 5<sup>th</sup> March 2009, A/RES/63/117

<sup>15</sup> DiMasi, Hansen *et al*, THE PRICE OF INNOVATION: NEW ESTIMATES OF DRUG DEVELOPMENT COSTS, J Health Econ (2003) 22[2]: 151-85

<sup>16</sup> Study reported at <http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html>

<sup>17</sup> Light and Warburton, DEMYTHOLOGIZING THE HIGH COSTS OF PHARMACEUTICAL RESEARCH, BioSocieties (2011) 6, 34

development by the US federal government and drug companies tripled between 1990 and 2005, this did not lead to an increase in the number of innovative new drugs approved by the FDA. It thus concluded that ‘the innovative performance of the drug industry appears to have declined.’<sup>18</sup> Boldrin and Levine have also supported this finding in their book where they clearly state that innovative output in the pharmaceutical industries in developed countries like Italy did not improve to any measurable extent after patents were adopted. On the other hand, to put claims of R & D expenditure in perspective, the top 30 representative pharma companies in the world spend twice as much on advertising and promotion than R & D. Even after fifty year of pharmaceutical patenting more than half of the top thirty selling medicines in the world have not originated from patents is another testament to their weak association with innovation.<sup>19</sup>

Claims of significant innovations are therefore highly misplaced. To encourage real innovation in pharmaceuticals through the patent system, countries must use the flexibility provided under the TRIPS Agreement to define their own patentability criteria as has been done under Section 3 (d) of the Patents Act, 1970 (India). Section 3 (d) discourages evergreening by only granting patents on real innovation and incentivizes R&D for new drugs.

### **III. UNHLP SHOULD RECOMMEND MAXIMIZING THE USE OF TRIPS FLEXIBILITIES AND RESIST THEIR DILUTION**

A fundamental way in which some developing countries have been able to address their public health needs in the prevailing multilateral system is by incorporating TRIPS flexibilities in their respective laws. For example, India recognized the need to avail the flexibilities under the TRIPS Agreement and incorporated provisions under its law which ensured sustained access to affordable treatment. India made use of the ten year transition period available for the developing and least developed. TRIPS left the policy space for countries to interpret patentability standards and India’s strict patent system rewards only genuine inventions. All developing and least developing countries should retain this policy space to facilitate its utilization to realize the public health objectives<sup>20</sup>.

It is imperative that developing countries should be encouraged and aided, through technical and other guidance, to maximize the use of all the available TRIPS flexibilities to take measures to address public health needs. Further TRIPS flexibilities should not be undermined or subject to underutilization through bilateral and regional free trade agreements negotiated by developed countries.

The UNHLP should urge developed countries to refrain from negotiating FTAs which dilute TRIPS flexibilities and developing countries should be encouraged to utilize TRIPS flexibilities to achieve the desired effect of technology transfer, innovation addressing the socio economic needs of these countries and prioritize the public health needs.

#### *Compulsory Licenses and the reasons for their poor use both domestically and internationally*

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<sup>18</sup> Congressional Budget Office, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY (October 2006) 35

<sup>19</sup> Boldrin and Levine, AGAINST INTELLECTUAL PROPERTY, Cambridge University Press, 2008, at p. 223, 226 and 230.

<sup>20</sup> Musungu and Oh, THE USE OF TRIPS FLEXIBILITIES IN TRIPS BY DEVELOPING COUNTRIES: CAN THEY PROMOTE ACCESS TO MEDICINES? , South Centre and WHO, (2006)

WTO defines Compulsory Licenses (*hereinafter*, CLs) as an instrument by which the Government allows someone else to produce a patented product or process without the consent of the patent owner.<sup>21</sup> Therefore, it compels an unwilling seller to produce at the behest of the state for a willing buyer. It is a TRIPS flexibility under Article 31 but one that has not been utilized fully. Using this flexibility is a vital part of increasing access to affordable medicines, by bypassing patent barriers placed by powerful pharmaceutical companies and forces them to pass on knowledge to generic companies that are able to produce and sell the same drugs at a much lower and therefore much more accessible price point.

CLs are subject to a few conditions that are outlined in TRIPS, the position on CLs and the method and practice of its use was further crystallized with the Doha Declaration in 2001.<sup>22</sup> TRIPS allow the use of compulsory licensing as part of its flexibilities particularly recognizing the economic and technological advantages that developed countries have over developing ones. The phrase “compulsory license” is not used but Article 31 of TRIPS talks of other use without authorization of the right holder, this article outlines cases where such a right to unauthorized use may be availed of and specifically mentions that the grant of such a right does not prevent the patent holder from continuing to produce (in this case) the drug himself. The grant of such a right is not without due consideration. A voluntary license must first be applied for and rejected and if compulsory license is granted then remuneration must still be paid to the patent holder, the exception to the requirement that a voluntary license must first be sought and then rejected is if there is a considerable public emergency that necessitates the issuing of a compulsory license.

Para 6 of the Doha Declaration drew considerable interest due to its importance to Public Health. Para 6 specifically addresses the problems LDCs may face in fully utilizing CL provisions as they may not have adequate manufacturing capabilities. There was a long drawn out debate on this part of the declaration because of conflicting interests, the US and EU pushed for dilution of the provision as it meant giving more power to the growing generic manufacturing industry in countries like India and Brazil that would undercut the profits that companies in the US and EU stand to make. Para 6 also came under fire for being a lengthy and cumbersome provision in the Canadian Apotex case.<sup>23</sup> Pursuant to the Doha Declaration Para 6 requirement, Canada enacted Canada’s Access to Medicine Regime (CAMR) in order to ensure that generic medication reaches those who most need it. The drug Apotex used to treat HIV was sought to be shipped to Rwanda, the long drawn

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<sup>21</sup>The World Trade Organisation, TRIPS and PUBLIC Health : Frequently Asked Questions, [URL - [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)], (Last Accessed – 27<sup>th</sup> February, 2016, 17:32 IST) ; Maskus, ENSURING ACCESS TO ESSENTIAL MEDICINES: SOME ECONOMIC CONSIDERATIONS, 20 WIS. INT’L L.J. 563, 571 (2002).

<sup>22</sup>The Doha Declaration on the TRIPS Agreement and Public Health, 2001 (Adopted on November 14, 2001); Atteran, ASSESSING AND ANSWERING PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: THE CASE FOR GREATER FLEXIBILITY AND A NON-JUSTICIABILITY SOLUTION, Emory International Law Review, Vol. 17, pp. 743-780, 2003

<sup>23</sup> Cohen-Kohler, CANADA’S IMPLEMENTATION OF THE PARAGRAPH 6 DECISION: IS IT SUSTAINABLE PUBLIC POLICY? Globalization And Health 2007, Dec. 6, 2007, [URL - <http://www.globalizationandhealth.com/content/3/1/12>.], (Last Accessed – 27<sup>th</sup> February, 2016, 17:35 IST); Himmelfarb, THE LIMITATIONS OF CANADA’S ACCESS TO MEDICINES REGIME: LESSONS FROM APOTEX’S EXPORT OF ESSENTIAL MEDICINES TO RWANDA, Queen Mary Journal of IPR, [URL - <https://qmjip.wordpress.com/2015/03/22/the-limitations-of-canadas-access-to-medicines-regime-lessons-from-apotexs-export-of-essential-medicines-to-rwanda-2/>] (Last Accessed – 27<sup>th</sup> February, 2016, 17:40 IST)

out process by which the Doha declaration could be used to ship the consignments of Apotex was exhausting and by the accounts of several scholars and practitioners, unnecessary. It required Apotex to seek Compulsory Licenses from each patent holder before shipping the consignment and took nearly 4 year to complete all formalities. The procedure to seek the waiver in order to send generic cheaper medications have been criticized and never invoked since. This is a clear lacuna in the CL regime and needs to be urgently addressed to prevent a repeat of the same Apotex-Rwanda issue. The fact that it has never been invoked since is proof of the ineffectiveness of the provision.

The Indian Patent Act in section 83<sup>24</sup> spells out the general principles of the working of patented inventions, specifically that it is used to encourage innovation and inventiveness, facilitate the transfer of knowledge and not merely just to line the pockets of inventors. In sub sections, it specifically goes into the duty of the patentee to prioritise public health and requirement and ensure that patented inventions are available to the public at a reasonable price. The first and only CL granted in India was to the drug Nexavar manufactured by Bayer.<sup>25</sup> Bayer appealed against the CL grant at the Indian Patent Appellate Board which went on to reject the appeal on the grounds that access to medicine was a matter of dignity which would not be possible without the CL in place. Section 84 of the Indian Patent Act<sup>26</sup>, lays down the Indian position on CLs, it specifies that after a time period of 3 years from the date of grant of patent, a CL may be sought provided three conditions are met. That the reasonable requirements owed to the public by the patent haven't been met, that it has not been available at a reasonable price and it has not been worked in India.

CLs are still a nascent area of Indian Patent Law, there is not much clarity on how best to exploit them to add impetus to our growing generic industry and it is not fully understood by neither IP practitioners and Judges or generic manufacturers and patient groups. India and Brazil are viewed as offenders of the patent regime that is prized by the USA and the EU and have constantly been listed as prime IP violators under the USTR's Special 301 watch list due to the patent regime that focuses on innovation, balancing rights of consumers and not merely focused on enriching patent holders.<sup>27</sup> This position adopted by the country flies in the face of those nations who steer trade and investment treaties like the TRIPS, TPP and RCEPs as they are seen to dilute the effect of the patent by considering the use of compulsory licenses and increasing the standards for patentability and reducing patent terms. Very recently, in an effort to strengthen Indo-US ties, there have been verbal assurances on the part of Indian authorities to limit the number of CLs granted in order to not sour relations with the US - the originating company for most patented medication.<sup>28</sup> Further, there is a need for clarity on whether export is allowed under CL provisions to meet domestic regulatory requirements of exporting countries. Scholarship on this matter is continuing to evolve and this is an issue in *Natco v. Bayer*<sup>29</sup>, where it was argued that drugs can be exported for the purpose of carrying out trials in China as this is their domestic

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<sup>24</sup> §83, The Indian Patent Act, 1970

<sup>25</sup> Sood, NATCO PHARMA LTD. V. BAYER CORPORATION AND THE COMPULSORY LICENSING REGIME IN INDIA, NUJS L. Rev. Vol. 6, Issue No. 1, 2013

<sup>26</sup> §84, The Indian Patent Act, 1970

<sup>27</sup> Gupta, COMPULSORY LICENSING UNDER TRIPS: HOW FAR IT ADDRESSES PUBLIC HEALTH CONCERNS, JIPR, Vol. 15, September, 2010

<sup>28</sup> Basu, GENERIC DRUGS: 'INDIA MUST GIVE WRITTEN DECLARATION ON COMPULSORY LICENSING', THE HINDU BUSINESS LINE, 17<sup>TH</sup> FEB, 2016 [URL - <http://www.thehindubusinessline.com/economy/generic-drugs-india-must-give-written-declaration-on-compulsory-licensing/article8249342.ece>] (Last Accessed, 27<sup>th</sup> February, 2016, 18:09)

<sup>29</sup> Bayer Corporation v. Natco Pharma Ltd., Order No. 45/2013; *Id.* Sood [23]

regulatory requirement. Indian law (specifically section 107A),<sup>30</sup> which is modeled after the Canadian law allows for this as an exception and states that the act of importation is not an act of infringement. While the use of CLs is obviously hindered in countries with poor production capacity, this is not the case in India. Manufacturing facilities are widespread and there is no dearth of individuals with the skill to perform needed research and development on the basis of the licensed patents. However, this flexibility is very underused in India and other developing countries and as a result access to medicine continues to be out of reach.<sup>31</sup>

The blame for this may lay entirely on circuitous procedure that is often required in order to manufacture generics thus going against the touchstone of Doha 2001 and TRIPS itself by way of its flexibilities and proclamations in Article 27 and 30. What is required is therefore freedom from long drawn out procedures, which are unhelpful as can be clearly evidenced by the Apotex-Rwanda case.

It is most important to ensure that CLs work by easing its use by eliminating barriers caused due to procedure, unwillingness and lack of initiative on the part of LDCs and their Governments and by being proactive in creating a conducive and open environment where patent rights are sacrificed to satisfy a larger public health mandate.

#### **RECOMMENDATIONS**

The UNHLP should encourage countries to make full use of TRIPS flexibilities and especially ensure that there is a robust use of CLs. We recommend further research into why CLs are not used domestically and must strive to ensure that barriers to their use such as lack of awareness and a lack of production capabilities be tackled as efficiently and expeditiously as possible.

#### *Strong Push for incorporating Patent Oppositions into the law.*

Patent oppositions are a key mechanism which allows third parties to challenge the patent before or after the grant of a patent. By allowing third party observations against the grant of frivolous patents, the mechanism ensures stricter scrutiny of patent applications and grant of patents only to genuine inventions.

Many patent offices of developing countries also face the issue of limited access to key databases and lack of human resources, this in turn may not allow for strict scrutiny of patent applications. Third party representation through opposition will improve the efficiency of the examination process thereby ensuring only applications satisfying the patentability standards of the local law is granted patents and only deserving patents are allowed<sup>32</sup>.

It is emphasized that by including opposition mechanism in domestic patent laws and by insisting on greater use of this mechanism in the process of patent protection the balance

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<sup>30</sup> §107A, The Indian Patent Act, 1970

<sup>31</sup> Sykes, TRIPS, PHARMACEUTICALS, DEVELOPING COUNTRIES AND THE DOHA SOLUTION, U. Chicago, Law and Economics, Working Paper No. 140; Hilty, Liu, COMPULSORY LICENSING : PRACTICAL EXPERIENCES AND WAYS FORWARD, Springer (2015)

<sup>32</sup>Puasiri, IMPROVING PATENT QUALITY THROUGH PRE-GRANT OPPOSITION IN THAILAND, Journal of International Commercial Law and Technology (JICLT), Vol.8, No. 4 (2013)

of rights of inventor's, innovation and access to affordable medicines can be achieved to an extent.

Patent oppositions have enabled availability of affordable lifesaving medicines to millions of needy patients not just in India but also to other developing countries through export of generic medicines. India is one of the key countries wherein utilization of the opposition mechanism by third parties both patient groups and domestic generic industries has resulted in rejection of patents on applications failing to comply with the patentability standards of Indian law and revocation of unworthy patents<sup>33</sup>. One empirical study of pre-grant opposition decisions between 2007-2014, it was found that pre-grant oppositions had a very high rate of success, resulting in either rejection, withdrawal and abandonment in 101 out of 155 cases.<sup>34</sup>

Due to patent oppositions filed against key lifesaving medicines in developing countries such as India, Brazil, and Thailand the grant of patent for unworthy applications were thwarted and resulted in availability of generic equivalents of these medicines.

Even in developed countries such as United States where there is the option of post-grant review for interested parties, it has been noted that in many cases the patents gets invalidated thereby allowing early entry of generic equivalents to the market and expanding its access to many patients.<sup>35</sup>

Though there is no restriction under TRIPS agreement on inclusion of provisions related to opposition proceedings not all developing countries have been successful in incorporating a robust mechanism of third party examination and intervention in the patent grant procedure in their domestic law. To a large extent many countries do not include a system of monitoring patent applications, substantive examination process and intervention by third parties before the grant of a patent<sup>36</sup>. For example China being a major Active Pharmaceutical Ingredient (API) producer and exporter base does not have a pre-grant opposition mechanism.

Evidence from developing countries informs the remarkable achievements made in making available affordable lifesaving medicines by utilization of the patent opposition mechanism. It is important to encourage developing countries especially with a fledging and thriving pharmaceutical industry to include a liberal and robust examination process before the grant of patent.

## RECOMMENDATIONS

We urge the panel to endorse the Indian example where both pre and post grant opposition mechanisms have yielded in social benefits in terms of access to affordable medicines. We

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<sup>33</sup> Civil Society Resistance, INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO ARV MEDICINES, ABIA and Ford Foundation (2009)

<sup>34</sup> Feroze Ali Khader. Findings presented at Lawyers Collective's Workshop on Patent Oppositions and Access to Affordable Medicines, 27-28 February 2016 at the India Habitat Centre, New Delhi.

<sup>35</sup> Amin, Rajkumar *et al*, EXPERT REVIEW OF DRUG PATENT APPLICATIONS: IMPROVING HEALTH IN THE DEVELOPING WORLD, Vol. 28, no. 5, w948-w956

<sup>36</sup> Park, INTELLECTUAL PROPERTY RIGHTS AND ACCESS TO MEDICINES: PAPERS AND PERSPECTIVES, Paper 9: Challenging Pharmaceutical Patents: The Case Of India WHO (2010)

would also like the panel to give pertinence to the fact that such mechanisms ensure that only high quality patent applications are granted patent rights.

The Panel should urge countries to implement this mechanism within the law and the panel should strongly recommend that developing and under-developed countries with existing opposition mechanisms shouldn't do away with the mechanisms due to pressures from developed countries to undermine the use of oppositions.

Since information dissemination on patents and life-saving medicines are limited, we recommend that the panel should make a pool of lawyers and civil society organizations who work on this issue and push for capacity building to effectively file and fight patent oppositions in both developing and under-developed countries.

In addition to the above, the panel should recommend to governments with thriving domestic pharmaceutical industry and governments aiming at developing local and robust pharmaceutical industry to incorporate promote and utilize this flexibility effectively. This would ensure all the key actors will get an opportunity to engage and participate in the process of grant of patent and there is adequate scrutiny when it involves a question of life-saving medicines. This could be one of the steps to address the policy incoherence present while balancing the rights of innovators *vis-a-vis* patient's right to access affordable medicines.

*Higher patentability standards to deny protection to incremental innovation and promote higher innovativeness of medicines sought to be patented*

The object of patent system is to reward inventions and allow innovators to recoup investment and encourage them to engage in further research to innovate for betterment and benefit of human kind. The pharmaceutical industry is supposed to work on this very premise to develop and innovate medicines for diseases plaguing the man kind, however the problem is, by seeking patent protection for new forms and new uses of known medicines as new invention - termed "evergreening" they extend the monopoly and limit the accessibility of these medicine to few<sup>37</sup>. US Congressional Budget Study (October 2006) titled, 'Research and Development in the Pharmaceutical Industry found that 76% of the new drugs approved related to new forms of known substances.<sup>38</sup> Truly innovative medicines in the US, EU and other developed countries have substantially diminished over a period of time.

Novartis AG by applying for a patent on beta crystalline form of imatinib mesylate (Gleevec - an anti-cancer drug) in India tried to seek patent protection for the new form of an already known drug, it intended to seek patent protection on a secondary application. However due to presence of a key public health safe guard Section 3(d) in the Indian Patent Law, Gleevec was denied a patent for failing to fulfill the requirements under Section 3(d) and for lack of inventive step<sup>39</sup>.

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<sup>37</sup> Park *et al*, POLYMORPHS AND PRODRUGS AND SALTS (OH MY!): EMPIRICAL ANALYSIS OF SECONDARY PHARMACEUTICAL PATENTS, PLoS ONE 7(12): e49470; 1371/journal.pone.0049470 (2012)

<sup>38</sup> "CHANGING PATTERNS OF PHARMACEUTICAL INNOVATION", A research report by the National Institute for Health Care Management Research and Educational Foundation, May 2002. Management Research and Educational Foundation, May 2002]

<sup>39</sup>Chaudhuri, LARGER IMPLICATIONS OF THE NOVARTIS-GLEEVEC JUDGMENT, Economic and Political Weekly Vol XLVIII, no.17, (2013)

Novartis challenged application of Section 3(d) for denying a patent for its drug by litigating in patent appellate board, High Court and in the Supreme Court. After a protracted legal battle the highest court of the land settled the ambiguities present in Section 3(d) and provided strict, clear interpretation and application of Section 3(d) for pharmaceutical patents.

The interpretation of Section 3(d) as held by the Supreme Court of India will ensure only genuine inventions i.e New Chemical or Molecular Entities (NCMEs) will be granted patent protection, disallow extension of patent on spurious grounds and incremental inventions in pharmaceutical sectors claiming pharmacokinetic advantages will not be accorded patent protection.

Section 3(d) has also been one of the key grounds for rejection of patents on many important lifesaving antiviral medicines in India. This includes tenofovir disoproxil fumarate, nevirapine, valganciclovir, pegasys. It is further hoped by adopting strict interpretation of Section 3(d) patent office will deny patents on Hepatitis C medicines such as sofosbuvir, sofosbuvir+ledipasvir combinations etc. which would substantially reduce the cost of medicines making it available and accessible to everyone.

Taking lead from India countries such as Argentina, Philippines and Zanzibar have incorporated provision similar to section 3(d) in their domestic law to adopt and increase the standard of patentability and negate the effect of granting patents on incremental innovations<sup>4041</sup>.

Developing countries can salvage the situation of high cost of medicines due to patent monopoly by adopting strict patentability standards and limit the scope of patentability while granting patent protection. They should adopt strategies that would allow patent protection for genuine, breakthrough innovations, have examination guidelines to distinguish between ‘discoveries’ and ‘innovations’ to determine the patentability of a claimed invention<sup>42</sup> and effectively implement these standards while examining applications for patent and while reviewing validity of the granted patents<sup>43</sup>.

However challenges continue to persist for developing countries with regard to incorporation and implementation of strict patentability standards in the domestic patent law. Many patent applications though fail to satisfy the requirements under Section 3(d)

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<sup>40</sup> Said and Kapczynski, ACCESS TO MEDICINES: THE ROLE OF INTELLECTUAL PROPERTY LAW AND POLICY. Working Paper prepared for Global Commission on HIV and Law (2011)

<sup>41</sup> Grover, GLEEVEC RULING PUTTING PATIENTS BEFORE PROFITS, Live Mint, 2<sup>nd</sup> April 2013, [URL - <http://www.livemint.com/Companies/HycCXfMie1ELvbkYPSBUpN/Glivec-ruling-Putting-patients-before-profits.html>] (Last Accessed, 27<sup>th</sup> February, 2016, 18:19 IST)

<sup>42</sup>Correa, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE, ICTSD-UNCTAD (2007)

<sup>43</sup> *Id.* Said and Kapczynski at n[36]

are granted patent in India due to multiple factors<sup>4445</sup> and bilateral trade agreements imposed by developed countries attempts to dilute these provisions<sup>46</sup>.

It is therefore recommended that the UNHLP should encourage developing countries to adopt higher patentability standards to promote innovation in its true sense and disallow grant of patent on minor modifications. We also urge the UNHLP to call up on developed countries to not include provisions in bilateral trade agreements aimed at diluting provisions on higher patentability standards such as section 3(d) and allow developing countries to incorporate and utilize this key flexibility.

#### *Promote the use of Drug Price Control mechanisms*

Drug Price Control has been approached as a possible method to increase access by ensuring that prices are maintained at an accessible price point, the WHO, economists and various civil society groups have discussed this method. Price control is an important tool considering the effect pharmaceutical market monopolies have on the price of drugs. There are various pricing control mechanisms that are followed, the most common of which are cost-plus, reference and profit pricing. However, there is no perfect system in place to determine price. Therefore, purely on the basis of costs, keeping the price down through drug control mechanisms has the definite effect of ensuring and widening access. The link between access and drug price control is therefore undeniable.

However, this method is not without criticism. Drug Price Control mechanisms have been viewed by some as arbitrary and self-serving as it could well enable Governments that are hand in glove with manufacturers to set a price point that is out of reach to many. Another aspect of Drug Price Control that is attacked is how it is, in some cases, dependent on categorization of drugs for it to effectively work. With pharmaceutical companies exiting certain categories in order to escape having to sell for lower prices, the entire point of the mechanism comes into question and becomes an exercise in futility. This was especially true with India's experience with a Drug Price Control in 2013, the sales of HIV drugs fell by almost 45% due to continuing high prices and the mechanism only seemed to affect drugs that continued to cater to a luxury category which would enjoy a certain quantum of sales regardless the price. With almost 80% of drugs that high prices hindered access to out of any category, the policy was regarded a failure. Even in other jurisdictions, drug price control mechanisms have been criticized. In the United States, it has come under fire for creating a waste of resources and hurting production. Moreover, proponents of the Free Market System view price control as harmful in the sense that it completely disregards the process by which market prices are set and how it motivates producers to strive to put out the best product possible in the cost set by market forces.

Therefore, there are still several kinks that need to be straightened out in order to ensure the success of Drug Price Control, they are a certainly important aspect of TRIPS flexibilities and can be used to ensure access to not just developing countries but also in wealthy nations where access is not always possible due to financial constraints. More than price control, what is most necessary is price regulation. In developed countries if there is

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<sup>44</sup>Sampat et al, CHALLENGES TO INDIA'S PHARMACEUTICAL PATENT LAWS, Science AAAS; 10.1126/science.1224892 (2012)

<sup>45</sup>Sampat and Shalden, TRIPS IMPLEMENTATION AND SECONDARY PHARMACEUTICAL PATENTING IN BRAZIL AND INDIA (2014)

<sup>46</sup>Correa, IMPLICATIONS OF BILATERAL TRADE AGREEMENTS ON ACCESS TO MEDICINES, Public Health Reviews – WHO 84:399-044 (2006)

no price control there is every danger of pharmaceuticals that have large market shares exerting an unfair monopoly over the market and having the freedom to set unfair prices. The most strongly established method by which pricing control strategies stand to work is by ensuring that the Government is proactive and impartial and makes sure pharmaceutical companies tow the line, by not disregarding the importance of allowing competition to function and by having a clear and transparent system of categorization that doesn't allow for loopholes. There is a danger of adopting unscrupulous methods to prevent price transparency and the only way to combat all of these concerns is to adopt benchmark prices with countries that most closely resemble the economic and developmental progress of the home country.

The success of such ventures are theoretically and practically sound and the case for inclusion into domestic laws depends on the identification of areas where such inclusion makes sense and whether the success of such mechanisms is well documented across a period of time. The Drug Price Policy of India, 2013 was a step in the right direction but recommendations to ensure transparency must be implemented seriously if it is to have any positive impact.

#### **RECOMMENDATIONS**

We urge the panel to seriously consider Drug Price Control mechanisms as a viable alternative and to encourage research into the best methods that may be followed to ensure that this is considered a good option to compulsory and voluntary licensing. Care must be taken to ensure that there is a balance between accessible and affordable pricing and ensuring that competition is maintained and respected in the market.

#### **IV. IMPACT OF FREE TRADE AGREEMENTS AND BILATERAL INVESTMENT AGREEMENTS**

Countries enter into trade and investment agreements (TIAs) with the objective of reducing barriers to trade and commerce. This has the dual purpose of attracting investment as well as opening up the international market for their own domestic producers. In the recent past, however, there has been an increased emphasis on the reduction of non-tariff barriers through these TIAs. One of these 'barriers' is measures related to intellectual property rights in trade<sup>47</sup>.

At the same time, WTO member states have also signed on to the TRIPS agreement, which sets down minimum standards for many forms of intellectual property regulation. It also provides for several flexibilities to allow member states to act in the interest of public health. These include the freedom to determine the method of implementation of the agreement, patentability criteria, set down an international exhaustion principle for parallel imports, determine grounds for compulsory licenses as well as opposition and revocation procedures for patents.

Under the guise of harmonization of international standards, however, there has been an attempt by several countries in the global North to bilaterally or plurilaterally negotiate intellectual property related requirements with their trading partners much beyond those required under TRIPS. These requirements, popularly known as 'TRIPS+' standards, pose a grave threat to public health and access to medicines in these countries.

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<sup>47</sup> UNCTAD, INTERNATIONAL CLASSIFICATION OF NON-TARIFF MEASURES, 43 (2012).

Several scholars have pointed out the potential and documented impact of TRIPS+ provisions (such as patentability standards<sup>48</sup>, data exclusivity<sup>49</sup>, patent linkages<sup>50</sup>, patent term extensions) on access to medicines. For the sake of brevity, we are not discussing them in detail in our submissions. However, these requirements are still being introduced in several trade agreements currently being negotiated.

Further, considerable international pressure is exerted through mechanisms such as the Special 301 procedure to pressurize countries to adopt TRIPS+ provisions in their domestic legislation. Pharma industry lobbies exert a disproportionate influence on the treaty negotiation process itself which is a matter of concern. While countries like India have so far resisted these pressures, several developing and least developed countries have integrated them in their domestic legal systems and we are seeing a negative impact in access to medicines in these countries.<sup>51</sup>

### RECOMMENDATIONS

The UNHLP should condemn the pressure tactics employed by countries in the global north to force developing countries to adopt TRIPS+ measures in their domestic legislation

- (i) List and call out the countries that regularly introduce TRIPS+ measures in their trade negotiations
- (ii) acknowledge the adverse impact of TRIPS+ provisions on access to medicines and the need for developing countries to resist the introduction of these provisions in their domestic legislation.
- (iii) Re-inforce through its work the right of countries to employ TRIPS flexibilities to ensure access to essential medicines for their citizens. In fact, the use of these flexibilities must be encouraged and the threat of trade sanctions for countries employing TRIPS flexibilities must be condemned.

#### *FTAs/BITs lack of transparency and legitimacy*

In the recent past, countries have negotiated or are in the process of negotiating mega-regional trade pacts such as the Trans-Pacific Partnership (TPP), Transatlantic Trade and Investment Partnership (TTIP) and the Regional Comprehensive Economic Partnership (RCEP). These agreements will directly affect a large proportion of the global population, with implications for free speech, privacy and public health.

Despite their potential impact, the negotiations of several of these trade agreements are shrouded in complete secrecy. For example, the recently concluded TPP agreement was negotiated for almost 5 years but the public did not have access to an official version of the negotiating text till the last stage of finalisation. This, despite the fact that the TPP was being touted as a 'model FTA' for other trade agreements being negotiated by its parties. Similarly, the negotiating parties of the RCEP, which account for almost 50 per cent of the global

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<sup>48</sup>Correa, IMPLICATIONS OF BILATERAL FREE TRADE AGREEMENTS ON ACCESS TO MEDICINES, Bulletin of the World Health Organization, 84(5), 399-404. (2006)

<sup>49</sup>El-Said and El-Said, TRIPS-PLUS IMPLICATIONS FOR ACCESS TO MEDICINES IN DEVELOPING COUNTRIES: LESSONS FROM JORDAN–UNITED STATES FREE TRADE AGREEMENT, WILEY, (2007)

<sup>50</sup>Tsui M, ACCESS TO MEDICINE AND THE DANGERS OF PATENT LINKAGE: LESSONS FROM BAYER CORP v. UNION OF INDIA, J Law Med. 2011 Mar;18(3):577-88

<sup>51</sup> Infojustice.org, THE EFFECT OF TRIPS PLUS IP PROVISIONS ON ACCESS TO AFFORDABLE MEDICINES, June 2015 [URL - <http://infojustice.org/wp-content/uploads/2015/06/Effects-of-TRIPS-Plus-IP-Provisions-on-Access-to-Affordable-Medicines.pdf>] (Last accessed on February 27<sup>th</sup> 2016, 18:38 IST)

population, are set to conclude negotiations on the agreement in 2016. However, the negotiating text has not been officially released so far.

This lack of transparency is undemocratic and has serious implications for the legitimacy of these agreements. The Anti-Counterfeiting Trade Agreement (ACTA) for example, was rejected by the European Commission largely due to concerns with respect to legitimacy.<sup>52</sup> Further, trade and industrial lobbies are commonly known to have privileged access to these trade negotiations and influence the content of these agreements. In their report, 'Trade Invaders: How Big Business is Driving the India-EU FTA', the public interest group Corporate Europe documents the disproportionate influence exercised by pharmaceutical industry lobbies in the India-EU FTA and the potential impact on access to medicines.<sup>53</sup> They are in a position to introduce provisions that maximize their profits at the expense of accessible and affordable medicines. This also necessitates transparency in the negotiation of these FTAs and BITs to ensure the interests of patients are taken into account in the final text.

There have been some attempts to force transparency into the treaty negotiation process through the legal system- but these have been unsuccessful. The Court of Justice of the European Union, in a dispute brought by the group Corporate Europe Observatory, ruled that the European Commission could keep documents related to negotiations in the India-EU FTA hidden from the public, even if big corporate lobby groups had access to them.<sup>54</sup> In the United States, the Media Freedom and Information Access Clinic at Yale Law School had filed a lawsuit on behalf of IP-Watch to disclose information about the draft texts of the TPP, the US negotiating positions and the advice negotiators are receiving from industry trade advisors. In October 2015, the federal district court (in Manhattan) held that the United States Trade Representative (USTR) had failed to justify its withholding of communications with industry representatives and lobbyists.<sup>55</sup> In India as well, a petition has been filed before the Supreme Court in *D.G. Shah v. Union of India* asking for the negotiating texts of the India-EU FTA to be made public.

As compared to the United States of America (USA) and India, the European Union has incorporated some transparency measures in its treaty and trade agreement process.<sup>56</sup> The dates, locations and topics of discussion of all bilateral meetings, along with the name of the organizations or self-employed individuals are published on the website within 2 weeks of being held. A mandatory register has also been created for lobbyists. On January 7, 2015, the EU released the negotiating texts for the TTIP that were shared with US negotiators as well as positions papers on areas for which a negotiating text had not yet been prepared. It has also proposed providing access to the TTIP text to more Members of the European Parliament through the institution of 'reading rooms' so that more MEPs can access texts and documents

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<sup>52</sup> The Telegraph, EUROPEAN PARLIAMENT REJECTS ACTA PIRACY TREATY, 16<sup>th</sup> February 2016, [ URL - <http://www.telegraph.co.uk/technology/news/9375822/European-Parliament-rejects-ACTA-piracy-treaty.html>] (Last Accessed, 27<sup>th</sup> February, 2016, 18:24)

<sup>53</sup> Corporate Europe, Trade Invaders: How Big Business is Driving the India-EU FTA

<sup>54</sup> *Stichting Corporate Europe Observatory v. European Commission*, C-399/13 P, Court of Justice of the European Union, Judgment of the Court (Tenth Chamber) of 4 June 2015.

<sup>55</sup> *Intellectual Property Watch v. United States Trade Representative* 13 Civ. 8955 (ER), United States District Court, Southern District of New York dated September 25, 2015. SEE ALSO, IP-Watch, COURT ORDERS USTR TO JUSTIFY INDUSTRY ADVISOR CONFIDENTIALITY IN TPP, October 29<sup>th</sup> 2015, [URL-<http://www.ip-watch.org/2015/10/29/ustr-called-on-to-justify-industry-advisor-confidentiality-in-tpp/>] (Last accessed on February 27<sup>th</sup>, 2016, 18:40 IST)

<sup>56</sup> Press Release by the European Commission, OPENING THE WINDOWS: COMMISSION COMMITS TO ENHANCED TRANSPARENCY, November 25<sup>th</sup>, 2014.

that were restricted in the past. Finally, a public list of TTIP documents shared with the European Council and Commission will be published and updated on a regular basis.

The EU has also introduced a novel process of undertaking a Trade Sustainability and Impact Assessment in its negotiations for the Japan-EU Free Trade Agreement. For this purpose, it has engaged the London School of Economics Enterprises, which will undertake an independent economic, social and human rights, environment and sectoral analysis, give policy recommendations and manage ongoing stakeholder consultations.

Several other treaties that have been concluded show that transparency can be increased and is necessary to ensure a fair and legitimate outcome. The WIPO treaty to Facilitate Access to Published Works by Visually Impaired Persons and Persons with Print Disabilities was concluded “under conditions of unprecedented... transparency and public participation”<sup>57</sup>. Some of the elements of transparency were: ongoing releases of the draft negotiating documents from the very beginning, negotiations were webcasted, listening rooms were set up where stakeholders could listen in on negotiators discussing certain issues. Further, the negotiations provided for structured and transparent stakeholder input, with reports and summaries of stakeholder working groups (representing both commercial and non-commercial interests) being published.

### RECOMMENDATIONS

We urge the UNHLP to –

- (i) Condemn the pervasive and harmful influence of big industry lobbies in the process of negotiating FTAs and BITs.
- (ii) Recognise the need to involve diverse stakeholders in an open, transparent and fair manner that gives representation to all concerned stakeholders.
- (iii) Suggest a concrete list of measures that can be incorporated by countries to increase the transparency and legitimacy of these agreements.

#### *Issues with Bilateral Investment Treaties*

The current system of international investment arbitration has features that impact its legitimacy. Adjudicators at ISDS Courts are composed of mostly European and American commercial lawyers. They are experts in arbitration and commercial laws and are not equipped to address or take into account the public health or environmental impact of their decisions.

Further, there is a lack of transparency in these proceedings and the final outcome. Hearings and proceedings are completely confidential. Texts of the decisions are not made available in the public domain. This is made worse by the fact that courts are not bound by precedent and apply vague legal principles. In the recent Chevron case, for example, Chevron challenged a decision of the Ecuadorian Supreme Court asking it to pay damages to the tune of \$ 9.5 Billion for environmental damage caused in the Amazon. An arbitration tribunal, convened under the US- Ecuador BIT, ruled in favour of Chevron, effectively overturning the decision of the Supreme Court. In doing so, it applied the 1995 BIT retrospectively, for environmental damage that had been done by Chevron prior to 1992.

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<sup>57</sup>Flynn, WIPO TREATY FOR THE BLIND SHOWS THAT TRANSPARENCY CAN WORK (AND IS NECESSARY), June 26<sup>th</sup> 2013, [URL - <http://infojustice.org/archives/300271>] (Last accessed on February 22<sup>nd</sup>, 2016, 18:42 IST)

There are also several instances of conflicts of interest in the constitution of these arbitration tribunals. Lawyers take turns representing the complainant organizations and acting as arbitrators on these secretive courts.

### *Impact on sovereignty and policy space of states*

Measures taken in the interest of environment, public health, access to basic amenities like food and water and minimum wages have been challenged in ISDS courts. This has a chilling effect on states' ability to take such measures.

### *Disproportionate impact on developing and least developed countries*

While data showing an almost equal number of cases being brought to arbitration by developing and least developed countries is presented to show an equal playing field, the statistics on cases won by either paints a different picture. The US, for example, has never lost an ISDS case.

Poor countries can't afford being sued: Uruguay is financially backed by Bloomberg Philanthropies and the Gates Foundation in the Phillip Morris arbitration. Ecuador has been asked to pay an amount equivalent to 3% of its annual national budget in a recent ISDS case.<sup>58</sup> A recent paper also showed that ISDS mostly benefits large corporations with an annual turnover of more than \$ 1 billion and does not benefit smaller traders.<sup>59</sup>

### *Defining IP as investment*

The aspect of these BITs that most threaten access to medicines arises from the fact that intellectual property is usually included within the definition of 'investment'. Since intellectual property disputes are already in the domain of the WTO dispute settlement mechanism, there is no justification to turn these into private claims through investment arbitrations. While several BITs do carve out an exception for measures that are 'TRIPS compliant', it is not clear how this determination is to be made and whether the arbitration courts themselves decide whether a measure is in fact TRIPS compliant.<sup>60</sup>

### *Eli Lilly v. Canada and the threat to access to medicines*

Canada recently became the first country to be sued for an intellectual property related violation under NAFTA by pharmaceutical giant Eli Lilly seeking greater monopoly patent protections. After a patent on one of its drugs (Strattera) was invalidated by the Canadian Supreme Court, Eli Lilly has now claimed \$ 100 million as damages and has also challenged the legal doctrine under which the patent was invalidated. Though the outcome of this case is still awaited, it illustrates the harm that these BITs can cause and the need to guard against them.

## **RECOMMENDATIONS**

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<sup>58</sup> Herrera, OXY V. ECUADOR: CHRONICLE OF A DEATH FORETOLD, December 4<sup>th</sup> 2015, [URL-<http://kluwerarbitrationblog.com/2015/12/04/oxy-vs-ecuador-chronicle-of-a-death-foretold/>] (Last accessed on February 27<sup>th</sup> 2016, 18:38 IST).

<sup>59</sup> Harten and Malysheuski, WHO HAS BENEFITED FINANCIALLY FROM INVESTMENT TREATY ARBITRATION? AN EVALUATION OF THE SIZE AND WEALTH OF CLAIMANTS, Osgoode Legal Studies Research Paper No. 14/2016

<sup>60</sup> Flynn, TTIP STAKEHOLDER STATEMENT: PROTECT IP FROM ISDS, April 23<sup>rd</sup>, 2015 [URL - <http://infojustice.org/archives/34319>] (Last accessed February 27<sup>th</sup>, 2016, 18:32 IST).

The UNHLP must –

- (i) Recognise and further assess the potential impact of BITs on access to medicines.
- (ii) Suggest the removal of ‘intellectual property’ from the scope of investment under these investment agreements.
- (iii) Recognise the sovereign powers of states to legislate in the interest of public health, including the employment of TRIPS flexibilities without the threat of being sued in an investment court.

## **V. BUSINESS MODEL OF VOLUNTARY LICENSES – PROCESSES AND PRACTICES OF MNCs INDICATE VLS BEING USED TO THWART MARKET COMPETITION AND UNDERMINE USE OF TRIPS FLEXIBILITIES**

Though in recent years some scholars and activists have advocated voluntary license as the best mechanism to tackle the issue of accessibility to and affordability of medicines, there are credible concerns that this business model by innovator companies have undermined the use of TRIPS flexibilities and stifled healthy competition in the market by restricting number of generic competitors in the market. It must be noted that for pharmaceutical companies, particularly MNCs, the main goal is to maximize profits and capture a larger share of the market. The voluntary license model indicates that access to affordable medicines is secondary to business interests<sup>61</sup>.

### *Provisions in Voluntary License Agreements that hinder access*

Many voluntary licenses signed individually between innovator companies and generic companies and also those signed with the Medicines patent pool include provisions that could affect access to medicines. The key concerns are:

- i. *Restricting sourcing of API*: These licenses allow innovator companies to dictate terms on generic companies for sourcing of APIs only from innovator suppliers for production of formulations. Since the generic companies are compelled to buy APIs only from the innovator suppliers or licensed suppliers under the clause, scope to buy low priced APIs. Since the main cost incurred in pharmaceutical formulation preparation is for APIs the final formulations will be priced accordingly. This cost, has a direct impact on access to medicines<sup>62</sup>.
- ii. *Restricting number of countries under the license*: Many of these licenses have deliberately excluded countries with high burden of disease out of the license. For Example – for Sovaldi Gilead has signed Voluntary Licenses with several generic companies in India. Indian made generic versions of sofosbuvir could not be exported to 50 middle-income, high burden countries, or any high income nations including much of Western Europe, and the U.S<sup>63</sup>. This voluntary license excludes almost 49 million Hepatitis-C patients from ambit of getting treatment.

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<sup>61</sup> Amin, VOLUNTARY LICENSING PRACTICES IN THE PHARMACEUTICAL SECTOR: AN ACCEPTABLE SOLUTION TO IMPROVING ACCESS TO AFFORDABLE MEDICINES, Oxfam GB (2007)

<sup>62</sup> ANALYSIS OF KEY CLAUSES FROM GILEAD SCIENCES INC.'S EXAMPLE LICENSE AGREEMENT, I-MAK, (2006)

<sup>63</sup> ACCESS TO SOFOSBUVIR, LEDIPASVIR AND VELPATASVIR: ANALYSIS OF KEY RECOMMENDATIONS ON GILEAD'S VOLUNTARY LICENSE – MSF Access Campaign Publication (2015)

- iii. *Restriction on Unbundling of licenses:* These licenses do not allow generic companies to terminate or unbundle from the license even if patents are not in force. For example Gilead's voluntary license on sofosbuvir with generic companies are bound for five years, therefore even in absence of patent generic companies continue to pay royalties to Gilead.
- iv. *Undermines the use of TRIPS flexibilities:* Further by tying up the generic companies in these licenses Gilead has effectively undermine the use of TRIPS flexibility of opposition to their patents as well compulsory licenses negating the possibility of making available generic medicines at much reduced price.
- v. *Absence of complete technology transfer:* By entering into voluntary license for new products many generic companies would seek to get complete technology to manufacture the product. However in case of voluntary license on TDF signed by Gilead it was noted the licensees were only provided the technology which was mentioned in the patent specification and the technology transfer through the VL was of no use. Some of the licensees had to invest time and resources to develop a better process to manufacture the product. By reducing the scope of technology transfer through these license Gilead was able to delay the entry of the generics to the market<sup>64</sup>.
- vi. *Segmentation of Markets:* Most of these licenses segment the markets by allowing licensees to sell only to the public sector. This could be a disincentive to the generics whose market has been restricted and further would position the generic companies to demand a price they deem fit for the product from the public sector<sup>65</sup>.

#### *Restrictive Clauses limiting competition – impact on prices*

- i. *Limiting Number of Players in the Market:* Though it is known competition leads to reduction in price of medicines, these voluntary licenses allow innovator companies to restrict number of players in the market and limit competition. Further the licenses are made available only to Indian generic manufacturers and does not include generic companies from other developing countries such as Brazil, Thailand etc. This in turn has a direct effect on pricing of medicine and access to patients.
- ii. *Paying Royalty in absence of patents:* Innovator companies usually file multiple patent applications on a single drug and, more recently, generic companies sign voluntary licenses even before a patent is granted. Since these licenses also cover pending patent applications, innovator companies file multiple secondary and divisional patent applications to continue to enjoy market monopoly and earn royalty. In practice generic companies end up paying royalty to Innovator Company even in absence of patent protection and this royalty payment in absence of patent protection is included in the pricing of the drugs. The opportunity of fair competition is taken away and thus results in higher prices. For example Tenofovir disoproxil fumarate (TDF) voluntary licensing agreements were signed by generic companies with Gilead.
  - Cipla did not sign the VL agreement because of the restrictive provisions under the license which prohibited the sale of TDF in China and Brazil.

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<sup>64</sup> THE BROADER IMPLICATIONS OF MPP AND GILEAD LICENSES ON ACCESS TO TREATMENT – Briefing Paper by ITPC and I-MAK (2011)

<sup>65</sup> *Id.* Amin at n [58]

- Cipla chose to fight the frivolous patent application filed in the patent office.
  - Cipla won the patent battle and could export TDF and was free to export the medicine at 700 USD per patient per year. (This price was amongst the lowest in the world.)
- iii. *Restrictive clauses in licenses:* The voluntary licenses filed by Gilead for TDF included clauses which also dictate terms on licensees to assist Gilead in getting the patents issued thereby restricting the companies to not challenge the grant of patent. Further if the licensee chose to engage in opposition then Gilead would terminate the license with the company<sup>66</sup>.
  - iv. *Anti-diversion programme:* The recently concluded license on sofosbuvir by Gilead include anti-diversion clause which puts onerous demand on the licensees, treatment providers and patients while distributing sofosbuvir. They undermine the rights of patients, interfere with the fiduciary relationship between doctor and patient and also undermine the use of parallel importation flexibility<sup>67</sup>.
  - v. *Restrictions on countries to export - reduced export volumes for generic companies:* By choosing only generic companies from India, restricting the number of countries to which generic companies can export these medicines under the voluntary license innovator companies are able to micro manage production and supply chain. It is done to an extent of deciding the source of APIs, volume of the medicines produced and countries eligible to receive these medicines.

*The role of VLS in undermining the use of TRIPS flexibilities – dilution of patentability standards, patent oppositions and weakening the potential of compulsory license*

- i. *Overriding patentability standards:* The broad definition on patents in these licenses includes new use, methods, type of treatment etc thereby legitimizing the practice of evergreening in the pharmaceutical field. The license includes secondary patent applications which would not otherwise qualify for patent protection in countries with higher patentability standard clauses, thus undermining the use of this key TRIPS flexibility.
- ii. *Limiting the use Patent Oppositions Mechanism:* As many generic companies do not want to engage in lengthy and expensive litigation with innovator drug companies by filing patent oppositions, they enter into voluntary licenses with restrictive terms. VLS are the new business strategies which are being used by the innovator companies to keep generics from fighting the patent applications. For example in the TDF license between Gilead and Indian Generics (2006) the license included clause that licensee where not supposed to file oppositions. With such provisions in place, it would be a contractual violation to be a party to the voluntary license and also challenge the patent/patent application. Since the balance is skewed in the favour of originator drug companies, generics either choose not to oppose the grant of patent or are forced to withdraw their patent oppositions against the originator companies. Recent examples include sofosbuvir patent applications – against which many generics once they filed license with Gilead withdrew their oppositions.

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<sup>66</sup> *Id.* I-MAK at n [59]

<sup>67</sup> BARRIERS TO ACCESS AND SCALE UP OF HEPATITIS - C TREATMENT: GILEAD'S ANTI-DIVERSION PROGRAM – MSF Access Campaign, Briefing Document 2015.

- iii. *Negating the use of Compulsory license and government use provisions:* One of the other major impact of these license is its impact on use of compulsory license and government use provisions. CL safeguard will not be operational where a patent has not been issued in either or both the countries (i.e. India and / or the excluded territory). It is also noted that innovator companies are citing these licenses as an answer to address the issue of access to medicines and are discouraging governments to use Compulsory License and government use mechanisms even on public interest grounds. Further by opting for voluntary license innovator companies are binding major generic companies capable of applying and full filing the eligibility criteria under CL. These measures are severely undermining the use of TRIPS flexibilities<sup>68</sup>.

For example in the voluntary license filed between Gilead and MPPF even in the absence of a patent in both India and the excluded territory, the sub-licensees are bound by the MPPF-Gilead license not to supply to the excluded territories. It is only when a patent is granted, either in India or the excluded territory, that a CL can be issued. The MPPF-Gilead license does not clarify if the sub-licensee can apply for a CL or it can take advantage of a CL issued to another company. It is likely that the action of the sub-licensee of applying for a CL could be construed as constituting material breach of the agreement (MPPF-Gilead license) that would allow Gilead to terminate the agreement. This uncertainty could prevent the sub-licensee for applying for a CL in the first place and even if there were no breach it would still not apply for a CL. It should also be noted that the CL safeguard allows the generic sub-licensee to provide the medicine under a CL only to the excluded country that issues a CL. It is not available to the other excluded countries, until they too issue CLs. It is also not available for CLs issued by the included countries. For instance, the CL safeguard is not available were South Africa to issue a CL because South Africa is an included country.

## **VI. Domestic enforcement of IP – balancing public interest with rights of inventors.**

Courts must refrain from granting Ex-parte injunctions for pharmaceuticals where public interest is involved.

Since the introduction of patent protection in India, the pharmaceutical sector has witness a spile in the number of infringement suits filed to specifically deter competition from Indian generic companies. In most of these cases the Courts routinely grant injunctions in favour of the patent holder without hearing the Defendant party (the alleged infringer). Thereafter the patentee sits on the injunction for years together given the delays in the legal system. It is important to underscore in many infringement suits the validity of the patent would be challenged and at times the patent in question should not have been granted in the first instance. The implication of such ex-parte injunction is it adversely affects public health, the patients in need of affordable medicines are denied its availability due to the decision of the Court.

The UN HLP must highlight the importance of balancing and even according primacy to human rights, which are often codified in law and constitutional guarantees in several

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<sup>68</sup> Lawyers Collective, PATENT POOL: LEGITIMIZING BIG PHARMA'S PRACTICES, Newsletter, (2012)

jurisdictions, over private property rights while seeking to enforce the latter against the former. A strong recommendation should be made to governments in this respect.

### **RECOMMENDATIONS**

We urge the UNHLP to reassess and examine whether voluntary licenses is a cost effective mechanism which is holistically addressing the issue of access to affordable medicines. We need to explore whether we are paying too high a prize by allowing and adopting this model thereby legitimizing innovator companies' practices and undermining the role and utilization of TRIPS flexibility. For example under the voluntary license though LDCs have time to adopt TRIPS regime and introduce patent protection, generic companies supplying medicines to LDCs under the license are still made to pay royalty to innovator companies when there is no scope for patent protection. If access to affordable medicines and expanding the treatment base is the object of these licenses then royalty should be waived off for all the medicines supplied to LDCs under this license.

### **VII. LDCs WAIVER FROM TRIPS COMPLIANCE**

Least Developed Countries (LDCs) represent the poorest sections of the world's economy. As per UNCTAD, there are forty eight LDCs. Most of them lack the technical know-how as well as infrastructural capability to produce their own medicines. Other constraints faced by LDCs and developing countries in the manufacture of drugs include; scarcity of technical human resource and limited access to international markets. Further, the "high cost" of essential medicines have not made it easier for LDCs to provide adequate health care to their population in need of treatment.

Additionally, LDCs are under pressure, particularly from the developed country lobbies, to comply with obligations under TRIPS Agreement despite recognised flexibilities accorded to them acknowledging their developmental status. Article 66.1 provides LDCs with a transition period of ten years to fully meet with TRIPS standards i.e. till the 1st of January 2016. On the 20th of February 2015 LDC members made a request to the TRIPS Council to waive off obligations under Articles 70.8 and 70.9 of TRIPS for LDCs as the WTO Member remains a LDC. Several patient groups, international health groups, activists and advocates as also the UN agencies such as the UNDP and UNAIDS endorsed this proposal. The TRIPS Council /extended the transition period further till the 1st of July 2021 for LDCs. The UNHLP must unequivocally recommend that it is imperative that LDCs be given an indefinite waiver to comply with TRIPS standards until they are able to sustain their economy.

### **RECOMMENDATIONS**

We urge the UNHLP to understand the strain that TRIPS compliance places on nations regardless of their state of development, in such a scenario it is wholly unfair to force nations who cannot reasonably comply with the indicated norms to do so in a short time period. While the UNHLP must continue to initiate countries into adopting flexibilities, there is also an urgent need to waive certain compliances for least developed countries so that they may build up necessary production capabilities to fully utilize the alleged benefits of TRIPS.

## **VIII. LOCAL PRODUCTION**

In the early 1930's US and Germany were leaders in the chemical industry, their pharmaceutical production capacity were highly advanced. On the other hand at this particular time; Japan, Switzerland and Italy tried to catch up by not extending patents to products. It was only in 1978 that Italy and Switzerland introduced product patent. Spain, Portugal and Norway joined as late as 1992. Their progress in the pharmaceutical industry is correlated with an initially less strict patent legal system.

Currently, manufacturing capacities in developing countries are limited to a few countries such as China, India, Brazil, South Africa and Egypt. Even in the developed world, large innovator multinational companies are concentrated in a small number of countries such as Switzerland, the United Kingdom, the United States, Germany, France and Japan. According to the surveys undertaken at different times from 2007 to 2014 in low-income and lower-middle-income countries indicate that, on average, generic medicines were available in 58 per cent of public health facilities compared to an average of 67 per cent of private sector facilities that had such medicines available.

## **RECOMMENDATIONS**

While WHO and other UN agencies have stressed upon the need for local production of medicines is essential to meet with local needs in case of a localized threat to public health and also because market-based producers do not adequately address local needs , it is important to note that not all countries have the structural capacity to produce medicines locally and attempts to do so have not always been successful. Uganda was been able to supply ten percent of its local medicinal need, ninety percent of which are imports from Asian countries. Despite its significant progress there are still many challenges that need to be addressed including lack of technology base and expertise.