SUBMISSION OF CONTRIBUTIONS

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- **Section 1: ABSTRACT: Briefly describe your contribution**: (limit 300 words)

Countries have an obligation to take measures for the progressive realization and respect, protect and fulfil the right to health, including access to needed medicines. Evidence shows that the current IP system fails to provide the necessary health innovation for the largest part of global disease burden, discourages timely development of best possible treatments and orients R&D funding based on market and not on health needs. It also creates significant barriers to treatment access due to high prices substantially higher than generics and leads to extreme price variability among countries. Prices behave the same where there is a patent, patent application or where there is data exclusivity. Existing mechanisms that are supposed to be "access-maximizing", such as voluntary licenses negotiated by the Medicines Patent Pool, have been excluding millions of people, dividing territories, limiting API production/supply and undermining the use of TRIPS flexibilities by governments/civil society. In light of this evidence, the contribution presents proposals to remove barriers and promote access to medicines.
***Proposal 1: Systemic overhaul of R&D, production and access framework*:** A complete overhaul of national, regional and international frameworks is the only pathway to achieving Sustainable Development Goal 3 and fulfilment of the right to health; this would include:
1a. Alternative R&D systems and mechanisms.
1b. Abolition of IP protection in health technologies, products and processes in all countries from TRIPS, FTAs, BITs and national/regional legislation.
1c. Mandatory Local/Regional Public Production
1d. Transparency of Pricing, Procurement and Impact Assessment
Proposal 2: Transitional Measures while Proposal 1 is achieved
2a. Automatic compulsory licensing for patents and waivers of data exclusivity
2b. Mandatory use of public health safeguards
2c. Adding a fourth 90 (affordability) to UNAIDS 90-90-90 strategy

- **Section 2: YOUR CONTRIBUTION** (limit 3,000 words)

WHO estimates that deaths of 18 million people, 1/3rd of all deaths, are caused by treatable medical conditions.[1] About 100 million people globally are pushed below the poverty line due to healthcare expenditure.[2] In Latin America, 700,000 preventable deaths occur annually.[3] Countries have an obligation to take measures for the progressive realization and respect, protect and fulfil the right to health, including access to needed medicines. While several factors adversely impact availability, accessibility and affordability of medicines, the submission highlights the adverse impacts of **intellectual property (IP) protection** in Latin America. Through patents, pharmaceutical companies

charge high prices, compromising public budgets and access to medicines.[4] The ultimate cost of ensuring profit-maximizing sales to the top 5% of the population is that 95% are left to suffer without access to lifesaving or life-enhancing medicines.[5] This is a systematic gross-violation of human rights, deliberately set in place by pharmaceutical companies and States defending their financial interests and deeply rooted in the IP system.

A) Failure of the IP system: R&D on health

While promotion of R&D remains the primary justification for IP protection, **evidence shows that the system failed to provide the necessary health innovation for the largest part of global disease burden**[6] i.e. WHO classified type II&III diseases predominantly affecting the developing world that simply do not constitute a profitable market for transnational companies (TNCs). For type I diseases (and some type II), patented treatments consume a large proportion of national health budgets forcing governments into rationing treatment, jeopardising universal access programs and diverting resources that could be spent on R&D for other diseases. **The monopoly based-profit driven model of innovation also discourages the timely development of best possible treatments.** "Activists and the scientific community have known about the potential benefits of TAF, over those of TDF, for twelve years; it is disappointing that its clinical development was delayed until the twilight of TDF's patent protection."[7] Although TDF (tenofovir disoproxil fumarate) is the backbone of HIV treatment programmes, its liver and kidney toxicity concerns were insufficient to prompt Gilead towards the early development of TAF (tenofovir alafenamide), thus having deliberately endangered the lives and health of millions of PLHIV. For those co-infected with HepatitisC, Gilead's monopolistic moves have been even more costly as they are more likely to suffer renal failure with TDF-based regimens and would have better tolerated TAF-based regimens. Gilead's deadly game of monopoly for people living with Hepatitis C continues with its refusal to collaborate on a possible combination of sofosbuvir+daclatasvir in order to maintain the HCV market entirely for its own medicines.

Pharmaceutical TNCs claim that high prices are necessary to recover innovation costs. Even though that statement has been challenged (regarding actual costs[8] and role of public funding as 70% of medicines with therapeutic gain were produced with public resources[9]), this claim begs the question: is a system dependant on setting prices that are unaffordable for most of the world's population really effective? For medical products, is that system even legal under human rights obligations? Is it ethical? We believe it is not. The logic of recovering R&D costs with remuneration obtained by commercialization of products with exclusive rights is the very basis of the IP system; therefore it is not possible to think of solutions within the system to solve the problem of access inherent in the system. Therefore, **it is necessary to shift the paradigm of the current IP system and adopt new mechanisms that separate the cost of innovation from the final price of the products.** The claim also highlights not only an inefficient system with a poor track record of genuine innovation but also one that is extremely expensive. Light and Lexchin note, "available data indicate that the vaunted "innovation crisis" in pharmaceuticals is a myth. The real crisis of innovation is a result of the current system of incentives for innovation, which rewards companies to develop a large number of new drugs with few clinical advantages over those already available. "[10] Recent experience shows **collaborative models delivering R&D based on open innovation mechanisms can lead to reduced costs in drug development and facilitate the development of products that meet health needs** [see 8]**.**

B) Failure of the IP system: Access to medicines

REDLAM Study Findings: To assess the impact of IP monopolies on prices in Latin America, RedLAM conducted a comparative analysis of ARV prices in Argentina, Colombia, Brazil, Mexico and Peru, with an international generic reference price.[11] Each Study country, in keeping with the right to health, has committed to providing universal HIV treatment; Table 1 demonstrates ART coverage:

Countries	People on ART	People in need of ART	ART coverage (%) (adults and children)	ART Coverage range (%) (adults and children)	Children on ART	ART coverage chidren (%)	ART coverage adults (%)
Colombia	39.397	71.000	55	(44-71)	6.249	(62-95)	51 (41-65)
Peru	22.157	37.000	59	(38-95)	596	(21-83)	60 (39-95)
Brazil	297.138	---	---	[82-93]	6.150	[92->95]	(81-93)
Argentina	50.725	62.000	81	[72-90]	3.000	[90-94]	81 (71-90)
México	84.058	103.000	82	[74-91]	1.744	[83->96]	82 (74-91)

Table 1: Source: Tratamiento Antirretroviral Bajo la Lupa - un análisis de salud pública en Latinoamérica y el Caribe 2013. Numbers on December 2012.

The 7 ARVs studied are relevant to the treatment programmes of each country and have patent applications/granted or data exclusivity as seen in Table 2:

ARV	Countries with patents	WO patent number	Countries with data exclusivity	Under monopoly
Abacavir 300 mg	Argentina, Peru	WO9939691	None	No (Perú)
	Argentina, Brazil	WO9852949		Yes (Brazil)
	Argentina	WO9919327 (A1)		
Atazanavir 300 mg	Argentina	US6294540 (B1)		
	Argentina, Peru	WO9740029	Colombia	Yes
	Argentina, Brasil, México	WO9936404		Yes
Etravirina 100 mg	Argentina	WO2005108349		
	Argentina, Peru, Brasil	WO0027825	Colombia	Yes
	Argentina, México	WO1999050250		Yes
	Argentina	WO0027828 (A2)		
Lopinavir – Ritonavir 200 mg - 50 mg	Argentina, Colombia, Perú, Brasil, México	WO9822106	None	Yes No (Perú)
Raltegravir 400 mg	Colombia, México, Brazil (pending)	WO2006060730; US2006122205	Colombia	Yes
Emtricitabina – Tenofovir 200 mg - 300 mg	México, Argentina (pending), Brazil (pending)	WO2004064845	None	Yes
Emtricitabina - Tenofovir – Efavirenz 600/300/200mg	México, Argentina (pending)	WO2006135933	None	Yes

Table 2

Table 3 shows the unit prices (in US$) of the 7 ARVs in each country and the generic reference price (data from 2013).

Country	Abacavir	Atazanavir	Etravirine	Lopinavir/ Ritonavir	Raltegravir	Emtricitabine / tenofovir	Emtricitabine/ tenofovir/ Efavirenz
Argentina	2.27	8.91	13.75	2.80	18.40	17.71	12.93
Brazil	0.32	2.90	3.98	0.49	7.25	-	-
Colombia	1.14	9.54	4.46	0.75	14.63	0.29	-
Mexico	0.99	10.55	5.08	0.60	18.19	8.08	9.41
Peru	0.11	18.60	8.98	0.60	10.77	-	-
Generic Reference Price	0.23	0.63	0.32	0.25	2.40	0.27	0.5

Table 3

Detailed examples of two ARVs are below to demonstrate the impact of patents and data exclusivity and the impact that just filing patent applications can have on prices.

The example of atazanavir

Table 4 shows price comparisons of atazanavir 300 mg. Atazanavir is patented in all the study countries except Colombia; however, as Colombia granted data exclusivity (DE) to atazanavir it does not have access to generics. Peru pays 28 times the generic price at one end and Brazil pays 4 times the generic price at the other.

Country	Unit price (US$)	Number of times more expensive than generic	Patent Granted	Data Exclusivity	Monopoly Situation	Brand Name
Argentina	8.91	13	Yes	No	Yes	Reyataz
Brazil	2.90	4	Yes	No	Yes	Reyataz
Colombia	9.54	14	No	Yes	Yes	Reyataz
Mexico	10.55	16	Yes	No	Yes	Reyataz
Peru	18.60	28	Yes	No	Yes	Reyataz
Generic Reference price (Mylan Laboratories)	0.63					

Table 4

The example of etravirine

For Etravirine 100 mg., we observe pricing behavior similar to atazanavir 300 mg even though there is no patent in force in two of the Study countries (Table5). With a patent application alone, single source supply in these countries has been assured.

Country	Unit price (US$)	Number of times more expensive than generic	Patent Granted	Data Exclusivity	Monopoly Situation	Brand Name
Argentina	13.75	42	Yes	No	Yes	Intellence
Brazil	3.98	11	No (patent application pending)	No	Yes	Intellence
Colombia	4.46	13	No (patent application pending)	No	Yes	Intellence
Mexico	5.08	15	Yes	No	Yes	Intellence
Peru	8.98	27	Yes	No	Yes	Intellence
Generic Reference price (Aspen Laboratories, South Africa)	0.32					

Table 5

Conclusions: The Study shows extreme price variability for the same medicine across countries; mostly these are substantially higher than the generic reference price. Prices behave the same where there is a patent, a patent application or where there is DE even in the absence of a patent. Although Brazil, Peru and Mexico are countries with centralized procurement of medicines and should be able to better negotiate prices, another recent study of ARVs in Brazil shows that for medicines are under monopolies, the power of the government to negotiate price is limited, despite high purchase volumes and centralized purchase mechanisms[12].

Other disease areas

Patents are increasingly a barrier for access to treatments for cancer, hepatitis C[14] and other diseases. For HCV treatments, **we see a combination of high prices** (Table 6) **and lack of registration as barriers to access**. For sofosbuvir, patent applications have been filed in Argentina, Brazil, Chile, Costa Rica, Colombia, Mexico, Peru and Uruguay; but even without patents granted, prices are unaffordable. Patents or just patent applications also allow TNCs to determine when a country gets access and to what version of the drug. Gilead has dragged its feet on the registration of sofosbuvir+ledipasvir.[15] For sofosbuvir, Gilead filed for registration in Peru only in November 2015, a full 16 months after the first developing country approval in Egypt.[16]

Medicine	Unit price (US$) Brazil*	Unit price (US$) Argentina*	Unit price (US$) Peru*	Unit Price (US$) Colombia*	Unit Price (US$) Indian generic**	Lowest potential price***
Sofosbuvir	82.14	73.30	N/A	N/A	1.28	0.80 - 1.619
Daclatasvir	30.07	43.57	N/A	N/A	0.72	0.119 - 0.357

Table 6 * Prices gathered by Redlam; ** Prices from: Generic daclatasvir (60 mg) availability and India market pricing as of 30 January 2016 (https://testandtreathepatitisc.files.wordpress.com/2014/11/indian-generic-dac-summary.pdf); *** Prices from: Hill A et al, Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale Treatment Access Programs in Developing Countries, *Clin Infect Dis.* 2014; 58: 928–936

In Table 7 we see annual prices for 3 cancer drugs in Brazil as compared to Indian generic and potentially even lower prices.[17]

Name of drug	Price in Brazil	Indian Generic Price	Lowest potential price (target price)
Erlotinib 150 mg	US$ 17,637	US$ 1,932	US$ 240
Sorefanib 400 mg twice a day	US$ 27,170	US$ 1332	US$ 1450
Lapatanib 1500 mg	US$ 25,508	N/A	US$ 4020

Table 7

In Table 8 we see prices per unit for 3 other cancer medicines in Argentina, Peru and Colombia as compared with Indian generic prices.

Name of drug	Unit price (US$) Argentina*	Unit price (US$) Peru*	Unit Price (US$) Colombia*	Unit Price - (US$) Indian generic*
Imatinib 400 mg	71.00	74.32	34.61	5.67**
Trastuzumab (Herceptin) 4400 mg	2,996.74	1,509.88	1,190.00	933**
Rituximab 100 mg	1,112.41	897.96	-	76.31***
Rituximab 500 mg	3,131.63	-	910.00	351.02***

Table 8 * Prices gathered by Redlam; ** Prices from: Ellen T' Hoen, Access to Cancer Treatment: A Study of Medicine Pricing Issues with Recommendations for Improving Access to Cancer Medication, 2015, http://apps.who.int/medicinedocs/documents/s21758en/s21758en.pdf; *** Prices from: Revised List Of Lifesaving Drugs Of Central Government Health Scheme MSD Delhi (http://cghs.nic.in/REVISED%20LIST%20OF%20LIFESAVING%20DRUGS%20OF%20CGHS%20MSD%20DELHI.pdf)

C) Failure of the IP system: Blocking access to generic medicines

"We do not do business to save lives but to make money. Saving lives is not our business" - Roche, Korea. What is business for TNC pharma is ensuring profits by a variety of strategies at the expense of people's lives. One strategy is the segmentation of people by national GDP through voluntary licenses (VLs) that limit territories in which medicines can be sold, place limitations on API production/ supply and undermine the use of TRIPS flexibilities by governments and civil society. Touted as "access-maximising" mechanisms, these VLs are in fact **profit maximising tools** and are systematically excluding people in MICs and HICs from the affordable, generic access; including those negotiated through the Medicines Patent Pool (MPP) - Table 9.

MPP Licenses	Argentina	Brazil	Peru	Colombia	Mexico
Lopinavir/ritonavir (Dec 2015)	Excluded	Excluded	Excluded	Excluded	Excluded
Raltegravir pediatric (Feb 2015)	Excluded	Excluded	Excluded	Excluded	Excluded
Tenofovir - TAF	Excluded	Excluded	Excluded	Excluded	Excluded
Cobicistat	Excluded	Excluded	Excluded	Excluded	Excluded
Elvitegravir - QUAD	Excluded	Excluded	Excluded	Excluded	Excluded
Dolutegravir pediatric (Apr 2014)	Excluded	Excluded	*Included*	*Included*	Excluded
Dolutegravir adult (Apr 2014)	Excluded	Excluded	Excluded	Excluded	Excluded
Abacavir adult (Apr 2014)	Excluded	Excluded	Excluded	Excluded	Excluded
Atazanavir (Dec 2013)	Excluded	Excluded	Excluded	Excluded	Excluded
Valganciclovir pricing agreement (Aug 2013)	*Included*	Excluded	*Included*	Excluded	Excluded
Abacavir pediatric	*Included*	Excluded	*Included*	*Included*	Excluded
Daclatasvir (Nov 2015)	Excluded	Excluded	Excluded	Excluded	Excluded

Table 9

In HCV, this exclusion is worse as the epidemic is highly concentrated in these countries. Although this was brought to the attention of UNITAID[19], the MPP was given the go-ahead to negotiate. Astonishingly in 2 weeks, the MPP announced a license for daclatasvir with BMS with a coverage of 112 countries that account for only **65.4%** of those in need of treatment; this sort of coverage would never be accepted in the HIV field where the MPP touts coverage in excess of 90%. The MPP license stands the concept of VLs on its head as the license for 112 countries is based on 2 granted patents in South Africa and 4 patent applications in India and **none** in the other 110 countries. Countries that **do** have patent applications and granted patents and therefore it would be argued could actually benefit from a license are Argentina, Brazil, Colombia, Mexico and Peru, among many others. Unfortunately as a result of this

highly limited license, the MPP has indirectly put a stamp of approval on the Gilead license on sofosbuvir that similarly covers only 101 countries.

These VLs undermine the hard work of CS in challenging blocking patent applications. They also undermine the use of parallel imports, a critical TRIPS flexibility, and in the case of Gilead's VL, patient privacy.[20] They prevent the supply of API, maximizing market control and limiting local production options. Brazil has now negotiated a price of US$6,900 for 12-weeks treatment of sofosbuvir while generic prices range from $969-$324[21] and could fall to as low as $102.[22] This represents an additional cost of at least US$9 billion to treat all people living with hepatitisC in Brazil. The high prices have led to severe rationing of HCV treatment in Brazil, in violation of the universal right to health guaranteed by the country's constitution[23].

PROPOSALS TO REMOVE BARRIERS AND PROMOTE ACCESS TO MEDICINES

Proposal 1: Systemic overhaul of R&D, production and access framework

The current systems for innovation and access are failing millions of people. The use of TRIPS flexibilities, the promise of the Doha Declaration has been broken through trade pressure like the US Special 301,[24] excessive litigation by TNCs and FTAs. In Latin America, only Brazil and Ecuador have used compulsory licenses; Argentina's strict patentability guidelines and Brazil's ANVISA pharmaceutical patent examination are under massive litigation by TNCs. Temporary, restricted voluntary mechanisms including VLs, tiered pricing and donations are part of the problem, not the solution. A complete overhaul of national, regional and international frameworks is the only pathway to achieving Goal 3 of the SDGs and fulfilment of the right to health. Critical to such an overhaul are the following four measures that we call on the UN HLP to recommend:

1a. Alternative R&D systems and mechanisms: "We do not develop drugs for the Indians. We do it for Western patients who can afford them" - Bayer. It is increasingly apparent that the majority of "Western" population are also unable to afford these drugs. It is necessary to shift the paradigm and adopt new mechanisms that separate the cost of innovation from the final price of the products, and make existing knowledge available for expanded production of health technologies. We support proposals for the legal recognition of knowledge as a public good and of the CEWG established by resolution WHA63.28 for a global binding instrument to promote a R&D system in which the outcomes are public goods, freely available for further research and production.

1b. Abolition of IP protection in health technologies, products and processes in all countries from TRIPS, FTAs and national/regional legislation.

20 years of TRIPS has resulted in placing pharmaceutical innovation at the mercy of the drug "business." It is time to abolish this system with regard to pharmaceuticals. This proposal is neither extreme nor impractical. That this recommendation also forms part of the proposals arising out of the report of the Global Commission on HIV which comprised eminent personalities including lawyers and judges is an indication not only of its urgency but its practicality. The Doha Declaration (2001), the rejection of ACTA, the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008) and the burial of the FTAA were considered at some point in history to be impractical.

The UN should encourage countries to amend TRIPS and FTAs to exclude all IP protection (including copyright, trademarks,[26] data exclusivity) for the pharmaceutical sector. The Eli Lily v. Canada case[27] demonstrates the need for amending Bilateral Investment Treaties (BITs) to exclude

investment protection provisions related to health. This is not to say that countries return to the pre-TRIPS era where several countries applied IP systems inherited from their colonial masters or by pressure of other countries. With the removal of international obligations to impose IP on medicines, countries must accordingly amend national laws and engage in public, consultative and evidence-based discussions to determine national legislative frameworks governing innovation and access.

The first step for the amendment of TRIPS to return national sovereignty on IP to countries lies in Article X of the Marrakesh Agreement, where **any WTO member** may table an amendment to TRIPS, amendments require 2/3rd majority (except for Article 4). Article 71.1, TRIPS also requires a review of the Agreement.[28] Precedents exist as with the drafting of Article 31bis. Even without that amendment coming into effect, a waiver is in effect from the General Council.[29] FTAs and BITs similarly have provisions for their amendment and even termination.

1c: Mandatory Local/Regional Public Production: Against the current failing system, some countries (Brazil, Argentina, Cuba) have implemented an alternative for several decades: local production. In Brazil, 20 public laboratories produce 80% of drugs distributed free of charge by the Brazilian Unified Health System. In Argentina, 58% of the domestic market is supplied by national laboratories. In Cuba, an estimated 1,150 biologic drugs, 30 OTC drugs and 132 generic products are manufactured by public local production; it may be noted that this is the only country in the world that has developed and produced an effective vaccine against meningitis B.[30] A policy of local, public drug production, based on the strengthening of the capacity installed and skilled labor manufacturing as well as institutions to ensure their sustainability, is critical to ensure supply of essential drugs at reasonable prices to fulfil the right to health.

1d. ***Transparency of Regional Pricing, Procurement and Impact Assessment:*** The results of the Redlam study have been eye-opening. Based on our findings, we recommend that the UN establishes an online public portal that provides regularly updated (1) evaluations of the economic and health impact of the prices paid by the countries compared to the lowest available price; and (2) comparative price studies to act as references for different governments at the time of designing public health policies including, but not limited to, those related to HIV, HCV and cancer treatment.

Proposal 2: Transitional Measures while Proposal 1 is achieved

2.a: Automatic Licensing for patents and waivers of data exclusivity: For patents and data exclusivity on pharmaceuticals in force, a system of automatic licensing where patent holders will be entitled only to royalty or compensation on their patents should be introduced.[32] Similarly waivers of data exclusivity should be introduced.

2.b Mandatory use of public health safeguards; exclusion of TRIPS-plus measures and annulment of VLs between manufacturers undermining TRIPS flexibilities: The right to health obliges governments to use TRIPS flexibilities to mitigate the harmful effects of IP on pharmaceuticals[31]. For patents applications that are still pending, countries should assure expedite mechanisms of analyses of patent application for health-related technologies (in order to avoid 'de facto' monopoly due to 'expectation of right') and adopt strict patentability criteria. Argentina's new pharmaceutical examination guidelines of 2012 and Brazil's ANVISA examination process have has led to the rejection of many unmerited patent applications and stricter scope of protection in granted patents. Country practices should also ensure that the mere filing of a patent application does not lead to monopolies, adopting measures necessary to

produce or import generic versions when there is no patent in force. Countries should also exclude any TRIPS-plus measures adopted in their national law that doesn't depend on proposal 1b. VLs that restrict the production/supply of API or finished product to a limited number of countries or undermine TRIPS flexibilities should be annulled.

2c. Adding a fourth* "sustainability 90" *to UNAIDS 90-90-90 strategy: UNAIDS must amend its 90-90-90 strategy to add a fourth "sustainability 90" i.e. 90% of HIV treatment to be affordable in all countries to guarantee availability and access to HIV medicines, diagnosis and prevention for all, to promote the adoption, use and defense of TRIPS health safeguards, leverage public production of medicines and promote other measures to ensure affordability of HIV commodities.[33]

IMPACT AND IMPLEMENTATION

The proposal is a comprehensive and undoubtedly ambitious one seeking to address the failure of the current system. Coupled with a new R&D framework, we believe the removal of mandatory IP requirements in TRIPS, FTAs and BITs for pharmaceuticals, followed by reforms of national laws, would simultaneously address issues related to policy coherence, public health and human rights. For patients, the immediate impact of access to affordable generic medicines will serve both public health and human rights obligations. The overhaul would provide the opportunity for governments to adopt appropriate legislative frameworks that balance human rights obligations relating to inventors rights and the right to health. As to implementation, it is evident that different parts of the proposal require different actions from various stakeholders; primarily governments. For amendments to TRIPS, FTAs and BITs, we note above the steps towards initiating the process of amendments and precedents in this regard. The proposal cites both existing evidence in the references and bibliography section as well as new evidence based on pricing studies undertaken by REDLAM recently. The ambition of the proposal will doubtless be met with intense opposition from pharmaceutical TNCs and developed countries. However, this should be separated from actual negative impacts of this proposal. We believe that given that the cost of developing a new molecule is far lower than the amount projected by TNCs, that R&D costs are largely borne by the public (and appropriated by the private through IP) and only 14-16% of new drugs are genuine inventions in any case, a re-working of the IP system will not have the end-of-the-world scenario that TNCs will likely paint for this proposal.

- **Section 3: Reference and bibliography**

REFERENCES

[1] World Health Organization, The World Health Report 2004
[2] WHO. Health and Human Rights. Fact sheet N°323. December 2015. Available at: http://www.who.int/mediacentre/factsheets/fs323/en/.
[3] PAHO – Pan America Health Organization, 2012.
[4] Several studies show that there is a drastic reduction in the price of drugs once patents expire, due to competition from generic products that become available in the market (see, among others, "Integrating Intellectual Property Rights and Developing policy", Report of the Commission on Intellectual Property Rights, London, 2002, especially pages 29-56). In addition, a comprehensive study by the U.S. government found that on average the price of generic drugs is 43% of the branded medicine price practiced during the term of the patent (Generic drug industry dynamics. U.S. Federal Trade

Commission Working Paper 248, 2002. Available at: <www.ftc.gov/be/workpapers/industrydynamicsreiffenwp.pdf>.
[5] Sean Flynn, Aidan Hollis & Mike Palmedo, An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries, 37 J.L. MED. & ETHICS 184 (2009); Eina V. Wong, Inequality and Pharmaceutical Drug Pricing: An Empirical Exercise (Ctr. for Econ. Analysis, Econ. Department, University of Colo. at Boulder, Working Paper No. 02-19, 2002).
[6] WHO - World Health Organization. Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). Geneva, 2012. Available at: http://www.who.int/phi/news/cewg_2011/en/
PEDRIQUE, B. et al. The drug and vaccine landscape for neglected diseases (2000–11): a systematic assessment. Lancet Global Health, 2013. doi:10.1016/S2214-109X(13)70078-0. Available at: http://www.thelancet.com/journals/langlo/article/PIIS2214-109X(13)70078-0/fulltext
[7] Tenefovir Alafenamide Fumarate (TAF) Sign-On Letter to Gilead**,** T**reatment** Action Group, HIV i-Base, and Project Inform, 13 June 13, 2013, http://www.treatmentactiongroup.org/hiv/taf-letter
[8] ST-ONGE, J.-CLAUDE. L'envers de la pilule: les dessous de l'industrie pharmaceutique. Ecosociété, 2004; WHO. Final Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). Geneva: WHO, 2006; DNDi Model Report. 'An Innovative Approach to R&D for Neglected Patients: Ten Years of Experience and Lessons Learned by DNDi, 2013. Available at: http://www.dndi.org/images/stories/pdf_aboutDNDi/DNDiModel/DNDi_Modelpaper_2013.pdf.
[9] CORREA, C. Public Health and Intellectual Property Rights. Global Public Policy 2, no. 3, 2002.
ANGELL, M. The Truth About the Drug Companies. Random House Trade, 2005.
[10] Light and Lexchin: http://poseidon01.ssrn.com/delivery.php?ID=428101121103106019081071082077089111015069058086095042085120116113111081124093122108004117037031126012054126126121120121066069102029022089006123114101088119092122039037048097087100111021007104083077010107121121112109121087080086072082095069119116094&EXT=pdf
[11] MSF Access Campaign, Untangling the web of Antiretroviral price reductions, July 2012
[12] CHAVES, GC. et al. Strategies for price reduction of HIV medicines under a monopoly situation in Brazil, Rev Saúde Pública 2015;49:86. Available at: http://www.scielo.br/pdf/rsp/v49/0034-8910-rsp-S0034-89102015049005459.pdf.
[13] MdM - MEDECINS DU MONDE. New Treatments for Hepatitis C Virus: Strategies for Achieving Universal Access. Report by Pauline Londeix. Paris, 2014. Available at: http://hepcoalition.org/IMG/pdf/web_daas_strategies_for_achieving_universal_access_en.pdf
[15] Gilead, Harvoni Registration in the Developing World, December 2015. http://www.gilead.com/~/media/files/pdfs/other/harvoniregistrationdocument121815.pdf
[16] Gilead, Sovaldi Registration in the Developing World, December 2015, http://www.gilead.com/~/media/files/pdfs/other/sovaldiregistration121815.pdf
[17]
[19] Hepcoalition. Civil Society Groups Tell UNITAID: Support access mechanisms led by civil society, not the pharmaceutical industry. Available at: http://www.hepcoalition.org/news/article/civil-society-groups-tell-unitaid

[20] Gilead Sciences gathering details of buyers of hepatitis-C drug to prevent its diversion, DIVYA RAJAGOPAL, Economic Times. Mar 19, 2015, http://articles.economictimes.indiatimes.com/2015-03-19/news/60286568_1_gilead-sciences-sofosbuvir-hepatitis-c-drug
[21] Generic sofosbuvir availability and India market pricing as of 30 January 2016 https://testandtreathepatitisc.files.wordpress.com/2014/11/31-jan-2016-indian-generic-sofosbuvir.pdf
[22] WHO, September 2015. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV
http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/
[23] GTPI. Preço de tratamento mantém a cura da hepatite C fora do alcance dos pacientes, 2015. Available at: http://deolhonaspatentes.org.br/blog/blog/preco_de_tratamento_mantem_a_cura_da_hepatite_c_fora_do_alcance_dos_pacientes.html
[24] GHJP - GLOBAL HEALTH JUSTICE PARTNERSHIP. A Human Rights Approach to Intellectual Property and Access to Medicines. Yale Law School and Yale School of Public Health. 2013. Available at: http://media.wix.com/ugd/148599_c76ed6f7341fa426bc22f5ccf543ea04.pdf
[26] The Trans-Pacific Partnership Agreement: Implications For Access To Medicines And Public Health, Unitaid, 2014, Http://Www.Unitaid.Eu/Images/Marketdynamics/Publications/Tppa-Report_Final.Pdf; See Also Biocon, Mylan Challenge Ban On Using Roche Data, Economic Times, Feb 17, 2014, Http://Articles.Economictimes.Indiatimes.Com/2014-02-17/News/47412108_1_Biocon-And-Mylan-Trastuzumab-Herclon; See also The Twist In The Trastuzumab Tale, Pt Jyothi Datta, The Hindu, Http://Www.Thehindubusinessline.Com/Companies/The-Twist-In-The-Trastuzumab-Tale/Article5670571.Ece
[27] Eli Lilly files $500M NAFTA suit against Canada over drug patents, CBCNews, September 2013, http://www.cbc.ca/news/business/eli-lilly-files-500m-nafta-suit-against-canada-over-drug-patents-1.1829854
[28] "*The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.*".
[29] General Council Decision of 6 December 2005 (WT/L/641)
[30] Kaplan et al, 2005
[31] Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/HRC/11/12
[32] Ruben Abete, Automatic License System For Pharmaceutical Patents In Developing And Least-Developed Countries, 2010, http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Contest_AutomaticLicenseSystem_Abete_Eng_2011.pdf; see also Karin Timmermans, Monopolizing Clinical Trial Data: Implications and Trends, 2007, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1796904/
[33] UNAIDS has seen Argentina´s proposal to add a 4th "90" to its 909090 strategy as a model to be implemented worldwide, Buenos Aires, September 2015, http://www.redlam.org/the-4th-90-affordability-of-medicines-unaids-90-90-90-strategy/

BIBLIOGRAPHY

1. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/HRC/11/12
2. Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, A/63/263

3. Human Rights and Intellectual Property, Committee on Economic, Social and Cultural Rights [CESCR], E/C.12/2001/15
4. Report of the High Commissioner, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, E/CN.4/Sub.2/2001/13
5. CHAVES, Gabriela Costa; VIEIRA, Marcela Fogaça; REIS, Renata. Access to medicines and intellectual property in Brazil: reflections and strategies of civil society. Sur, Rev. int. direitos human., São Paulo, 2008. Available at http://www.scielo.br/scielo.php?pid=S1806-64452008000100009&script=sci_arttext&tlng=en
6. SELL, Susan. TRIPS: fifteen years later. Prepared for the American Political Science Association annual convention. September 1-5, 2011, Seattle, Washington. 2011. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1900102
7. REIS, R. (org.) Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South. Rio de Janeiro, ABIA, 2009. Available at http://deolhonaspatentes.org.br/media/file/Publica%C3%A7%C3%B5es/Intelectual%20Property.pdf
8. VELÁSQUEZ, G.; SEUBA, X. Rethinking Global health: A Binding Convention for R&D for Pharmaceutical Products. Research Papers 42. Geneva, South Centre, 2011. Available at: http://www.southcentre.int/wp-content/uploads/2013/04/RP42_Rethinking-global-health_EN.pdf.

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