Inequality & Health analysis of the US TPP Proposal for the IP chapter & pharmaceuticals[1]

June 11, 2014

Since negotiations for the Trans-Pacific Partnership (TPP) Agreement were launched in 2010, opposition to the United States (US) government position on intellectual property (IP) with regard to pharmaceuticals has grown among public health, development and consumer groups, as well as US negotiating partners. In response, the US Trade Representative (USTR) put forward a new proposal[2] for 'differential treatment' for certain provisions in the IP chapter affecting access to medicines during negotiations in Salt Lake City in November, 2013.

This USTR proposal remains unacceptable from a public health and development perspective for several reasons. It does not change the fundamental problem with the original USTR position, which limits generic competition and restricts the policy space available to governments to promote access to medicines for all.

Although the specific terms of the proposal are not public, several sources confirm that it would divide countries into two groups using the World Bank's income classification system. Countries below the 'high income' line would be exempted from implementing three specific TRIPS-plus provisions[3] for a certain period of time, but other TRIPS-plus provisions that are similarly harmful to public health would still be required. This limited exemption would remain in effect for a specific period of time, which would either be determined by when the country graduates to 'high-income' status according to the World Bank income classification system, or be arbitrarily set through an agreed TPP 'transition' period.

MSF, Oxfam and others have criticized[4] this proposal because it still contains unprecedented and excessive TRIPS-plus protections that would adversely affect millions of patients in need of affordable medicines around the world. It also draws an arbitrary and unfair line between countries that would be required to meet different standards of IP protection for an undetermined period of time. It also ignores the fact that the map of poverty is changing and the world is moving towards having rich countries with millions of poor people. Here we present additional evidence for why the US proposal is ill-designed and should be rejected by all TPP negotiating parties.

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[1] This memo is product of a joint research project by Oxfam America and the Access Campaign of Doctors Without Borders. Both organizations thank David Roodman for the research support provided.

[2] USTR Blog: "Stakeholder Input Sharpens, Focuses U.S. Work on Pharmaceutical Intellectual Property Rights in the Trans Pacific Partnership, November 2013. http://www.ustr.gov/about-us/press-office/blog/2013/November/stakeholder-input-sharpens-focuses-us-work-on-pharmaceutical-IP-in-TPP

[3] These provisions are: patent term extension, patent linkage and certain data exclusivity rules for small molecules.

[4] Civil Society Statement - USTR's proposal for the Intellectual Property Chapter of the Trans-Pacific Partnership (TPP) will endanger access to medicines for all (March 2013): http://www.msfaccess.org/content/ustr%E2%80%99s-proposal-intellectual-property-chapter-trans-pacific-partnership-tpp-will-endanger

I. Drawing a line to divide countries into 'high' and 'low' income is an unviable idea both conceptually and as a measure of capacity to afford medicines

Any line to separate countries between 'high' and 'low' income is somewhat arbitrary and inherently unfair at the point of division. Countries just above it will be hardly richer than those just below, yet would be subject to radically tougher IP protections that limit access to medicines under the USTR proposal. The notion of a clean split between rich and poor countries is becoming archaic as poverty is rooted in rich and poor countries alike. Similarly, there is no formula that can predict how many years it will take for a country to end, or at least significantly reduce, poverty.

The World Bank's system for classifying a country as 'high-income' dates back to the 1980s. Countries are sorted by 1987 Gross National Income (GNI) per capita, which is converted to dollars based on average exchange rates for 1985–87, with $6,000 judged to be a reasonable threshold for 'high-income'. That threshold has been regularly adjusted for average inflation in the US, Europe, and Japan, reaching $12,615 today with reference to 2012 GNI figures.

Table 1: Projected GNI/capita, exchange rates, per U.S. proposal/World Bank "high-income" classification (2012 $)

Country	2012	2015	2020	2025	2030	2035
TPP Countries						
Australia	59,360	52,166	54,335	56,644	59,052	61,561
Brunei	44,331	39,890	39,142	39,010	38,877	38,745
Canada	50,970	47,927	49,112	49,522	49,936	50,353
Chile	14,310	14,079	17,555	21,979	27,516	34,449
Japan	47,880	38,999	42,473	46,470	50,843	55,627
Malaysia	9,820	11,231	14,422	18,358	23,368	29,745
Mexico	9,640	10,278	11,510	12,788	14,209	15,787
New Zealand	31,243	35,005	37,412	39,735	42,204	44,825
Peru	6,060	6,537	8,025	9,835	12,055	14,775
Singapore	47,210	48,474	52,179	56,314	60,777	65,594
United States	52,340	55,345	60,786	66,412	72,559	79,275
Vietnam	1,550	1,890	2,257	2,702	3,236	3,874
Non- TPP Countries						
Brazil	11,630	11,290	13,093	15,214	17,678	20,542
China	5,720	7,167	9,268	11,867	15,195	19,456
India	1,580	1,698	2,250	2,981	3,949	5,232
Indonesia	3,420	3,216	4,086	5,088	6,335	7,888
Philippines	2,500	3,003	4,338	6,247	8,998	12,960
South Korea	22,670	26,451	34,018	44,010	56,938	73,662
Thailand	5,210	5,274	6,201	7,252	8,482	9,919

Highlighted rows are above 1987 World Bank 'high-income' threshold of $6,000, as adjusted for general inflation to $12,615 in 2012.

Table 1 approximates when countries will cross the 'high-income' threshold under the World Bank classification system.[5] It lists more countries than those currently negotiating TPP for comparison purposes, given that the TPP is seen as a standard-setting agreement with a potentially much broader geographical scope of impact - through inclusion of other countries in TPP, or by setting the template for use in future trade negotiations. Only four of the 12 TPP countries are now under the threshold and would be eligible for 'differential treatment': Vietnam, Peru, Mexico and Malaysia. Yet, Malaysia will be classified as 'high-income' before 2020, Mexico before 2025, and Peru before 2035. If the 'differential treatment' were only granted for a fixed number of years instead of for the time it takes to reach the 'high-income' threshold, the situation would be even worse for these countries if the transition period expires before they reach the threshold.

Furthermore, the World Bank income classification system has several shortcomings. Because it relies on average income to designate whether countries are 'high' or 'low' income, it completely ignores how wealth is distributed within a country. Using averages means that the wealth of a minority of high income individuals skews the measure upward. Therefore, a country in which a large portion live at or below the poverty line can potentially be thrown into the 'high income' category if those at the top of the income distribution make further gains, even if everyone else remains the same.

For instance, if Bill Gates earned another billion dollars tomorrow, the average income of the United States would increase, despite no economic gains by anyone else in the country. Alas, a country where all families earn $50,000 per capita is not the same as another where half the people earn $10,000 and half earn $90,000 – in the latter, half the population may be unable to afford the medicines they need. Yet both countries have the same average income, so the World Bank metric treats them the same. Conversely, the median income – which represents the dividing line between the richest and poorest half of a population – offers a more realistic assessment of how income and wealth is distributed within a country. For example, average US income according to the 2004 US Census Bureau economic survey was $60,528 while the median income was $44,389 – a nearly 40 percent difference. Relying on the average overestimates the number of people within a population who can actually afford medicines by skewing in favor of those already well off by their country's standards.

Yet, median income alone is an inadequate indicator to reflect levels of inequality in a country, much less the impact of that inequality on access to affordable medicines for significant portions of the population. It would still be unable to account for dramatic differences in both morbidity and ability to access and afford health care within a country.

[5] The growth projections through 2019 come from the IMF's current-dollar GDP per capita projections in the April 2014 World Economic Outlook http://www.imf.org/external/pubs/ft/weo/2014/01/weodata/weoapr2014all.xls, adjusted for US inflation. Beyond 2019, growth is assumed to continue at the average projected rate of 2016–19.

Income inequality is a significant problem in many of the TPP countries, as indicated in Table 2.[6]

Table 2: Inequality indicators

Country name	Top 10% earn as much as bottom…
TPP Countries	
Australia	49%
Canada	48%
Chile	82%
Japan	35%
Malaysia	55%
Mexico	78%
Peru	74%
United States	59%
Vietnam	59%
Non-TPP Countries	
Brazil	85%
China	61%
India	52%
Indonesia	60%
Philippines	73%
South Korea	49%
Thailand	64%

NOTE: TPP countries Brunei, New Zealand and Singapore are excluded due to lack of comparable data.

In addition, the World Bank classification system converts GNI to dollars using exchange rates instead of purchasing power parities (PPPs), producing a less-accurate picture of absolute poverty levels and subjecting GNIs to currency swings that could cause a country to surge past the high-income threshold and then fall below it. And it is adjusted only for general inflation, thus failing to account for the potentially accelerated rise in medicine prices, as drug inflation rises faster than general economic inflation.

The USTR proposal for the TPP aims to reflect a US-style pharmaceutical regime, where strong IP protections and nearly non-existent government bargaining power have allowed drug prices to triple since 1987, while general prices have doubled.[7] To measure the ability to afford medicines under a US-style pharmaceutical market, the 'high-income' threshold should adjust for the higher drug price inflation that results. The US prescription drug price history is a good proxy for prices under a US-style IP system.[8]

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[6] The table draws data from Branko Milanovic, 'All the Ginis Dataset' (World Bank) last updated in June 2013, which uses 2005 figures. See http://go.worldbank.org/9VCQW66LA0 . Brunei, New Zealand, and Singapore are excluded due to lack of comparable data.

[7] Drug price data from http://download.bls.gov/pub/time.series/cu/cu.data.15.USMedical, series code CUSR0000SEMF01. General price data from http://www.bls.gov/cpi/cpid1403.pdf, Table 24.

[8] US drug price inflation averaged about 4.7 percent/year over the period 1987-2012, while general inflation averaged about 2.9 percent/year. Thus, prescription drug prices rose an average of 1.78 percent/year above general inflation.

Table 3 modifies the World Bank income classification system using the median instead of average per-capita GNI, converting to dollars using PPPs instead of exchange rates, and adjusting for US-style drug price inflation rather than simply general inflation.[9] The difference is notable. Chile joins the four countries that started below the World Bank classification threshold, and none of the five cross the threshold before 2035.

Table 3: Projected GNI/capita, adjusted for median income, PPP and drug price inflation

Country	2012	2015	2020	2025	2030	2035
TPP Countries						
Australia	37,238	38,899	42,433	46,251	50,413	54,949
Canada	36,533	37,897	40,269	42,674	45,224	47,925
Chile	12,509	13,741	16,470	19,781	23,756	28,531
Japan	31,908	33,496	35,850	38,514	41,375	44,450
Malaysia	11,161	12,401	14,568	17,100	20,073	23,563
Mexico	10,964	11,484	13,155	15,059	17,237	19,731
New Zealand	24,117	25,681	28,016	30,519	33,245	36,215
Peru	6,876	7,725	9,498	11,669	14,336	17,613
Singapore	43,730	47,094	53,864	61,597	70,440	80,553
South Korea	27,796	30,458	35,930	42,355	49,929	58,857
United States	41,194	43,558	47,841	52,269	57,107	62,393
Vietnam	2,862	3,275	4,153	5,270	6,689	8,489
Non-TPP Countries						
Brazil	7,154	7,479	8,474	9,631	10,946	12,440
China	6,920	8,498	11,483	15,456	20,804	28,003
India	3,067	3,462	4,485	5,819	7,549	9,793
Indonesia	3,512	3,982	4,971	6,202	7,737	9,652
Philippines	3,038	3,498	4,257	5,168	6,274	7,616
Thailand	6,784	7,342	9,028	11,073	13,581	16,657

Highlighted rows are above 1987 threshold of $7,000, as adjusted for US drug price inflation to $22,010 in 2012, and 1.78%/year real growth beyond. Brunei is excluded due to lack of comparable data.

[9] Median income is estimated as $GNI/capita \times \frac{\text{income share of middle quintile}}{20\%}$, using income distribution data for the most recent year from the World Bank Poverty and Inequality Database http://databank.worldbank.org/data/views/variableselection/selectvariables.aspx?source=poverty-and-inequality-database Inequality is assumed to be static. As in the World Bank's classification system, a rounded threshold is chosen for 1987 and then adjusted forward for inflation. The threshold for median income and PPP is obtained by regressing those variables on GNI/capita and exchange rates. This was done for those countries for 1986, 1987, or 1988 for all variables in the data set; projecting the World Bank's $6,000 threshold for GNI/capita (Atlas method) onto the other variables via these best-fit lines; then rounding. The resulting threshold is $7,000.

II. Any line intended to divide countries between 'high' and 'low' income fails to take into account patients left behind who cannot afford medicines

Even when countries are considered 'high-income' according to the World Bank, many people live in poverty and cannot afford high drug prices. Table 4 estimates how many people will be poor when their country is classified as 'high income'.

It is difficult to choose an appropriate globally applicable poverty line. Nevertheless, we chose to look at poverty using a line that can take into account ability to afford medicines and to avoid falling into a poverty trap due to a serious medical problem. In the US, the typical income cap for Medicaid, a US government program that provides free health care for the poor, could be a useful benchmark – calculated in many US states as 133 percent of the federal poverty line or $21.50/person per day. Table 4 below uses this poverty line, converted to other currencies using PPPs. The table excludes India, Indonesia, Thailand, and Vietnam because it is projected they will still not be 'high-income' in 2035, and Brunei, New Zealand and Singapore because there is no comparable inequality data.

Table 4: Poverty in 'high income' countries: year when 'high income' status is estimated to be reached, and population that will fall below a Medicaid-defined poverty line ($21.50/day PPP)

Country	Estimated year becomes 'high income'	Predicted % of population below Medicaid poverty line	Millions below Medicaid poverty line
TPP Countries			
Australia	2012	18%	4
Canada	2012	11%	4
Chile	2012	69%	12
Japan	2012	1%	1
Malaysia	2018	82%	26
Mexico	2025	81%	112
Peru	2032	62%	23
United States	2012	14%	45
Non-TPP Countries			
Brazil	2019	79%	165
China	2027	47%	679
Philippines	2035	77%	105
South Korea	2012	14%	7

In Malaysia, the high percentage of people below this poverty line is particularly notable given that the country did not register such high levels of inequality as did Chile, Mexico and Peru.

If a TPP agreement were to exempt all TPP countries not currently classified as high-income (Malaysia, Mexico, Peru and Vietnam) from having to adopt certain IP provisions only for a fixed transition period, the number of people below the Medicaid poverty line would be substantially larger. Table 5 below indicates how many

people will remain under the Medicaid poverty line if the transition period were set to end in 2020, 2025, 2030 or 2035.

Table 5: Population that will fall below a Medicaid-defined poverty line ($21.50/day PPP)

	2012		2020		2025		2030		2035	
TPP Countries										
	Millions	%	Millions	%	Millions	%	Millions	%	Millions	%
Australia	4	18%	3	14%	3	11%	3	9%	2	7%
Canada	4	11%	3	9%	3	8%	3	7%	2	6%
Chile	12	69%	11	57%	10	49%	8	42%	7	34%
Japan	1	1%	0	0%	0	0%	0	0%	0	0%
Malaysia	26	88%	26	79%	25	72%	23	64%	21	54%
Mexico	108	89%	112	85%	112	81%	110	76%	105	71%
Peru	27	89%	27	81%	26	74%	24	65%	21	56%
United States	45	14%	38	11%	34	10%	30	8%	27	7%
Vietnam	89	98%	93	95%	92	92%	89	87%	83	80%
Non-TPP countries										
Brazil	164	83%	165	78%	161	74%	155	70%	148	65%
China	1,191	86%	971	68%	767	53%	547	38%	349	24%
India	1,234	100%	1,346	99%	1,405	99%	1,451	98%	1,477	97%
Indonesia	245	99%	265	98%	274	97%	280	95%	280	92%
Philippines	92	95%	100	91%	104	87%	106	83%	105	77%
South Korea	7	14%	5	9%	3	7%	3	5%	2	4%
Thailand	62	92%	59	87%	55	80%	49	72%	42	62%

This table excludes Brunei, New Zealand, and Singapore because of non-comparable inequality data.

Medicines at any price are not affordable to those below the aforementioned poverty line. Governments must pay for these medicines and offer them free of charge. And while many of these governments are financing free public health care, including medicines, those investments are often offsetting a parallel reduction in donor assistance for expanding access to treatment, as middle income countries are rapidly 'graduating' from donor development assistance. Furthermore, even as countries invest more funds towards health care and medicines, governments need to be able to purchase low-cost generic medicines in order to expand access to health care rather than merely maintaining the status quo.

The ability to manufacture and/or purchase low-cost generic medicines requires maintaining balance in a country's patent system between monopoly protection and public health. Yet the TPP will reduce or eliminate that balance and the legal flexibilities needed to ensure affordable medicines and curtail government discretion to set medicine prices. This will not only prevent governments from negotiating affordable prices for medicines due to restrictions on their pharmaceutical reimbursement policies as well as barriers to using compulsory licensing due to data exclusivity rules and investor-state dispute settlement clauses. It will also expand monopoly protection by facilitating patent 'evergreening' and lengthy terms of regulatory data exclusivity.

For example, generic competition could play an important role to effectively scale up the urgently needed treatment of Hepatitis C – which affects over 180 million people worldwide. New anti-viral medicines to treat

Hepatitis C are under patent protection around the world. One new drug, sofosbuvir (marketed by Gilead Sciences as Solvadi), costs $1,000 per pill – or $84,000 in total - for a full treatment course in the United States. While prices are lower for patented versions of the medicine in some developing countries, the price for most middle income countries, including those in the TPP, could potentially be anywhere from $1,000 to $15,000 (or beyond for countries such as China and Ukraine – which are expected to pay prices similar to those charged in the US and European Union) for a full treatment course – which is far too expensive for those countries and patients to afford. On the other hand, generic competition, facilitated through the use of TRIPS flexibilities or other measures, would reduce the price of the medicine substantially. A study released last year by the University of Liverpool indicates that the cost of sofosbuvir for 12 weeks is no more than $150 and is simple to manufacture (therefore potentially requiring no technology transfer).

Pharmaceutical companies have claimed that segmenting markets can ensure affordable prices for medicines. Yet the strategy of segmenting markets has been more effective as a tool to expand the industry's own markets. For example, the practice of setting different prices in different markets for the same product, known as 'tiered pricing' (sometimes also called 'differential pricing'), has long been used as a strategy by pharmaceutical companies to maximise revenue from both developing and developed economies. There are a multitude of problems with such strategies to segment markets – and particularly with respect to affordability of medicines for the large numbers of people living in poverty in middle-income countries. There are four key problems.

1. *Tiered pricing is less effective than generic competition at lowering drug prices:* A review of 7,000 developing country antiretroviral (ARV) purchases from 2002-2007 found that tiered prices were between 23 and 498 percent higher than generic prices.[10] Another analysis found that, comparing tiered prices with generic prices, 90 percent of products reviewed were more affordable as generic versions.[11] This holds for both low and middle income countries.

2. *People living in middle-income countries are often excluded:* Even if multinational companies would reduce medicine prices in developing countries to match price reductions achieved through generic competition, middle-income countries are habitually excluded from the most significant price reductions and thus still pay considerably higher prices. Although such countries are home to the majority of the world's poor, they are increasingly the target of multinational pharmaceutical company ambitions to tap into their sizeable emerging and rapidly growing 'middle class'. In reality, this 'middle class' spans a broad range, including some who may be able to pay high prices and those just above the 'low-income' threshold who can fall into poverty due to high medicine prices. The WHO estimates that 100 million people fall into poverty every year due to the cost of health care, of which medicine is a big part. Emerging markets accounted for less than 10 percent of global pharmaceutical spending in 2013, a figure expected to reach 30 percent by 2016.[12]

3. *Within countries, medicines are rationed to the rich:* Because tiered pricing allows companies to price a product on the basis of what a segment of a population is willing to pay, in countries with considerable inequality, prices are habitually set according to the means of the richest segments of society. Although it may seem logical for a country to pay higher prices as metrics on the national economy improve, tiered

[10] Moon S, Jambert E, Childs M, Schoen-Angerer T. "A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries." *Globalization and Health* 2011, **7**:39. http://www.globalizationandhealth.com/content/7/1/39

[11] Ibid.

[12] Mooraj H. "How Big Pharma Can Win In Emerging Markets." *Industry Week*, June 19 2013, http://www.industryweek.com/emerging-markets/how-big-pharma-can-win-emerging-markets

pricing assumes that all people in the country have increased means at their disposal, which is far from reality. Tiered pricing directly excludes all those who are unable to keep up with the country's rising income. A 2010 study on tiered pricing found that offering a single and relatively high price to a middle-income country is estimated to result in less than 30 percent of its population accessing the drug.[13]

4. *Even where medicine prices are reduced significantly in developing countries, restrictive terms exclude many from accessing the price reductions advertised by companies*. For example, sofosbuvir, the Hepatitis C medicine mentioned above, is said to be priced at approximately 1000 USD in Egypt – a 99 percent discount on the price offered in the United States (though still significantly more expensive than the cost of production). However, the medicine is only available at this price to a limited number of patients who qualify for treatment in the public sector, in a country where approximately 25 percent of the population, or 20 million people, have Hepatitis C.

Finally, to fully understand the situation of access to medicines in a particular country would require having several metrics, including: the capacity of the government and patients to cover the costs of medicines in the country, and what portion of health-care costs are for medicines; the extent of coverage of public and private insurance among the population, and to what extent medicines are covered; and the portion of medicine costs that are paid by patients out of pocket. Governments in particular have to deal with competing priorities between new and potentially costly medicines for a variety of diseases covered by the public health system. But such data for each country is difficult to generate.

Instead, as an indicator for a government's ability to pay for medicines for the poor, we looked at what it would take for a government to fill the poverty gap – bringing everyone up to a poverty line above which it is assumed that a person can afford to buy needed medicines.

As proxy indicators, we look first at government revenue per capita on a PPP basis.[14] We then calculate the cost to bring everyone in a country up to the Medicaid poverty line, as a share of government revenue. This approach factors in both the extent of need—the depth of poverty—and the capacity to redress it from government coffers.[15] Table 6 shows the results.

[13] Yadav P. "Differential Pricing for Pharmaceuticals: Review of current knowledge, new findings and ideas for action," Study conducted for the UK Department for International Development, August 2010.

[14] Based on World Bank Revenue, excluding grants (% of GDP) http://data.worldbank.org/indicator/GC.REV.XGRT.GD.ZS and GDP/capita, PPP, series from IMF, as computed earlier.

[15] The distributions are projected forward from 2005 to 2012 using IMF PPP GDP/capita growth figures and the assumption of distributional constancy.

Table 6: Revenue/capita and share of revenue needed to lift all to Medicaid poverty line

Country name	Revenue/capita, PPP $	Gap fill/revenue
TPP countries		
Australia	9,598	0.1%
Canada	7,118	0.0%
Chile	4,121	3.2%
Japan	4,057	0.0%
Malaysia	3,725	6.3%
Mexico	1,900	16.9%
Peru	2,067	11.6%
United States	8,462	0.1%
Non-TPP countries		
Brazil	2,965	8.2%
China	1,043	14.5%
India	459	85.5%
Indonesia	800	50.7%
Philippines	633	56.8%
South Korea	7,434	0.1%
Thailand	2,022	15.0%

Brunei, New Zealand, Singapore, and Vietnam are excluded due to lack of comparable data.

Yet even with such significant financial investments to bring the entire population up to and over the poverty line, many people just above (and even comfortably above) the poverty line will encounter serious financial difficulties to pay for medicines, especially new medicines under patent protection. Even one expensive course of treatment – whether for cancer, hepatitis C or diabetes – can mean that those patients no longer classified as poor could quickly become bankrupted or have to forego treatment due to unaffordable prices. This is certainly an every-day occurrence in the United States, which has already introduced a range of TRIPS-plus rules and restrictions on the ability of public sector purchasers to negotiate drug prices, often leaving households that can ill afford to pay high prices with significant debt. The cost of medicines was the number one cause of bankruptcy in the United States.[16] Even as the other TPP countries reach and move beyond a minimum level of shared wealth and government capacity to pay for medicines, adopting rules demanded by the US under the TPP will still leave large segments of the population unable to pay for life-saving treatment.

[16] Dan Mangan, "Medical Bills Are the Biggest Cause of US Bankruptcies: Study", CNBC, 25 June 2013 http://www.cnbc.com/id/100840148