MSF Revising TRIPS Ideas Contest Entry

Restoring Policy Space:

Excluding essential medicines from patentability in TRIPS

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Background: Prior to the 1994 TRIPS Agreement, many countries disallowed patents on medicines in their national laws, presumably because of the heavy social burdens such patents would impose.[a] Once TRIPS came into force, however, all WTO Members were bound to grant medicines on patents – in many countries, for the first time in their histories. By requiring the granting of monopolies on new medicines, TRIPS impedes the ability of States to meet their human rights obligations, particularly with regard to protecting the right to health and the right to life.

Access to medicines is a core component of realizing the human right to health. The right to health is recognized in numerous legal texts including the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights (ICESCR), the Constitution of the World Health Organization (WHO), and in many national constitutions (1), among others. In 2000, the UN Committee on Economic Social and Cultural Rights issued General Comment 14, which provides expert interpretation of right to health obligations in the ICESCR. The Comment specifies that "to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs" is a core obligation of States Parties (2). This Comment underscores the normative importance of the concept of essential medicines, which WHO has defined as "those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and *at a price the individual and the community can afford*." (emphasis added)

Proposal: TRIPS should be revised to be consistent with international human rights obligations. One relatively simple way to do so would be to allow WTO Members to exclude essential medicines from patentability, which could be achieved by amending Article 27(3)(a)[b] so that it reads:

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[a] Many countries also disallowed patents on food or agricultural technologies for similar reasons. At the time negotiations over the TRIPS Agreement began in 1986, 49 of the 98 members of the Paris Convention excluded pharmaceutical products from patent protection and 10 excluded pharmaceutical processes (13). I thank Ellen 't Hoen for having brought this point to my attention.

[b] Other ways to exclude essential medicines from patentability, de facto, would be 1) an interpretation of "exceptions to rights conferred" under Article 30; or 2) the granting of near-automatic compulsory licenses for all

> "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and medicines they designate as essential" (new language underlined).[c]

Such an amendment to Article 27 should go hand-in-hand with an amendment of Article 7 (on the treaty's Objectives) to insert human rights language, so that it reads:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to the fulfillment of human rights, and to a balance of rights and obligations. Members shall not implement the Agreement in a manner that weakens the promotion or protection of human rights."[d] (new language underlined)

Such amendments would be consistent with the Doha Declaration's recognition of "WTO Members' right to protect public health and, in particular, to promote access to medicines for all (3)." Such changes should not create new burdens for WTO Members, since all but one of 153 WTO Members (99%) is also a WHO Member State (and therefore have accepted the WHO

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patents covering essential medicines under Article 31. However, the Article 27 option above is preferred for the normative and political clarity it would provide.

[c] TRIPS Article 27 currently reads: Patentable Subject Matter 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. 3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

[d] TRIPS Article 7 currently reads: *Objectives.* The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. I thank Chan S. Park for the suggestion to incorporate human rights language into TRIPS.

Constitution) and 83% have ratified the ICESCR.[e] Rather, these amendments would help WTO Members to meet the human rights obligations they have already undertaken.

How should "essential" medicines be defined? The WHO Model List of Essential Medicines (EML) provides useful guidance for countries in determining national EMLs (4). However, as WHO advises, countries should adapt the model list to meet their own particular contexts and priorities. In addition, some have critiqued the WHO EML methodology for excluding therapeutically important drugs because they are not comparatively cost-effective, though the basis for making the 'cost' calculation is not clear. If 'cost' refers to the cost of production, then such comparative methodologies seem justified; however, if 'cost' is the market price under monopoly conditions (as under patents or other forms of exclusivity) then the 'cost' may be unnecessarily inflated, and thereby exclude important medicines unjustifiably.[f] Therefore, the Article 27 amendment proposed here should define "essential medicines" as those included in *national* EMLs. Many developing countries already have national EMLs, and many are now also moving to achieve universal health coverage. Excluding essential medicines from patentability can help such countries to achieve sustainable health systems and increase the depth and breadth of healthcare coverage for their populations.

However, an additional thorny problem must be addressed. It is precisely the most therapeutically important new medicines that should be candidates for national EMLs. By placing a new medicine on a national EML, a country is making a strong statement regarding that medicines' value. However, if a country does not grant patents as a means to contribute to the research and development (R&D) costs of the very drugs they find to be most valuable, what other avenues for contributions might there be?[g] In exchange for the above TRIPS amendments, a political bargain should be negotiated to establish norms on how individual states should contribute to R&D. The various proposals for an R&D treaty are an excellent place to start (5, 6), though detailed discussion of such treaties is beyond the scope of this essay. (Nevertheless, for the sake of illustration, Annex 1 contains a simplified possible approach to burden-sharing, in which countries collectively provide a lump-sum payment to reward the drug developer based on whether the drug is included on the country's national EML, and the country's share of the global or regional economy. The illustration is based on various proposals to grant prizes in lieu of market monopolies to reward innovation (7-12).)

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[e] The WHO has 194 Member states, the list of which is available at: http://www.who.int/countries/en/. ICESCR has a total of 160 States Parties, the list of which is available at: http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en. The list of WTO Members is available at: http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm

[f] I thank Jamie Love for bringing this point to my attention. See also: http://keionline.org/content/view/27/1

[g] Other countries that do contribute to R&D costs are likely to find this arrangement unfair and politically objectionable.

Adopting the above amendments to Articles 7 & 27 would help make TRIPS into a treaty that protects and promotes, rather than undermines, public health and human rights.

Table 1. Country group and per capita contributions to R&D reward for Hypothetical Drug X with Worldwide therapeutic value* (e.g. pandemic flu drug)

Country group	GNI, Atlas method (current US$)	Proportion of global economy**	Population, total	Per capita GNI (Atlas method)	Contribution to a $1 billion R&D reward	Contribution per capita
High income	$ 42,262,882,623,625	71.5%	1,120,454,525	$ 37,719.41	$ 714,799,323	$ 0.64
Upper middle income	$ 12,787,424,552,294	21.6%	2,435,250,359	$ 5,250.97	$ 216,275,887	$ 0.09
Lower middle income	$ 3,694,886,867,447	6.2%	2,428,089,996	$ 1,521.73	$ 62,492,250	$ 0.03
Low income	$ 380,327,317,743	0.6%	779,877,025	$ 487.68	$ 6,432,541	$ 0.01
Total global GNI 2009	**$ 59,125,521,361,109**					

*Assumes every country includes Drug X in its national essential medicines list.

**Proportions could be adjusted to make the contribution rates more progressive, rather than directly proportional to share of the global economy

Table 2. Country and per capita contributions to R&D reward for Hypothetical Drug X with regional therapeutic value* (e.g. Chagas disease drug in Latin America)

Country Name**	GNI, Atlas method (current US$)	Proportion of regional economy***	Population, total	GNI per capita, Atlas method (current US$)	Country contribution to a $500 million R&D reward	Contribution per capita
Antigua and Barbuda	$ 1,030,316,831	0.03%	87,802	$ 11,730.00	$ 129,072	$ 1.47
Argentina	$ 303,864,006,634	7.61%	40,062,470	$ 7,580.00	$ 38,066,227	$ 0.95
Bahamas, The	$ 6,972,807,953	0.17%	338,358	$ 20,610.00	$ 873,511	$ 2.58
Barbados	$ 3,453,684,349	0.09%	272,750	$ 12,660.00	$ 432,656	$ 1.59
Belize	$ 1,265,036,146	0.03%	333,200	$ 3,800.00	$ 158,476	$ 0.48
Bolivia	$ 16,050,794,127	0.40%	9,773,441	$ 1,640.00	$ 2,010,745	$ 0.21
Brazil	$ 1,563,126,193,614	39.16%	193,246,610	$ 8,090.00	$ 195,818,904	$ 1.01
Chile	$ 157,789,312,302	3.95%	16,955,737	$ 9,310.00	$ 19,766,881	$ 1.17
Colombia	$ 230,528,648,059	5.78%	45,654,044	$ 5,050.00	$ 28,879,221	$ 0.63
Costa Rica	$ 28,644,892,687	0.72%	4,590,790	$ 6,240.00	$ 3,588,457	$ 0.78

Dominica	$ 361,049,283	0.01%	67,922	$ 5,320.00	$ 45,230	$ 0.67
Dominican Republic	$ 45,734,370,975	1.15%	9,796,852	$ 4,670.00	$ 5,729,323	$ 0.58
Ecuador	$ 57,382,449,178	1.44%	14,261,566	$ 4,020.00	$ 7,188,523	$ 0.50
El Salvador	$ 20,771,333,188	0.52%	6,160,423	$ 3,370.00	$ 2,602,106	$ 0.42
Grenada	$ 580,085,446	0.01%	104,097	$ 5,570.00	$ 72,670	$ 0.70
Guatemala	$ 37,375,156,227	0.94%	14,033,623	$ 2,660.00	$ 4,682,131	$ 0.33
Guyana	$ 2,298,788,592	0.06%	753,013	$ 3,050.00	$ 287,978	$ 0.38
Haiti	$ 6,617,341,951	0.17%	9,864,241	$ 670.00	$ 828,980	$ 0.08
Honduras	$ 13,443,220,461	0.34%	7,449,923	$ 1,800.00	$ 1,684,085	$ 0.23
Jamaica	$ 12,749,793,744	0.32%	2,695,600	$ 4,730.00	$ 1,597,216	$ 0.59
Mexico	$ 972,405,437,495	24.36%	112,033,369	$ 8,680.00	$ 121,817,015	$ 1.09
Nicaragua	$ 5,988,385,587	0.15%	5,710,230	$ 1,050.00	$ 750,188	$ 0.13
Panama	$ 22,641,214,499	0.57%	3,461,901	$ 6,540.00	$ 2,836,353	$ 0.82
Paraguay	$ 14,270,425,840	0.36%	6,341,892	$ 2,250.00	$ 1,787,712	$ 0.28
Peru	$ 123,646,733,912	3.10%	28,765,162	$ 4,300.00	$ 15,489,708	$ 0.54
St. Kitts and Nevis	$ 484,742,951	0.01%	51,752	$ 9,370.00	$ 60,726	$ 1.17
St. Lucia	$ 883,075,729	0.02%	172,092	$ 5,130.00	$ 110,626	$ 0.64
St. Vincent and the Grenadines	$ 559,202,718	0.01%	109,269	$ 5,120.00	$ 70,054	$ 0.64
Suriname	$ 3,076,374,034	0.08%	519,861	$ 5,920.00	$ 385,389	$ 0.74
Trinidad and Tobago	$ 21,316,081,537	0.53%	1,336,349	$ 15,950.00	$ 2,670,349	$ 2.00
Uruguay	$ 30,015,232,940	0.75%	3,344,938	$ 8,970.00	$ 3,760,125	$ 1.12
Venezuela, RB	$ 285,928,385,350	7.16%	28,384,000	$ 10,070.00	$ 35,819,362	$ 1.26
Total Regional GNI	**$ 3,991,254,574,342**					

*Assumes every country in the region includes Drug X in its national essential medicines list.

**All Latin American countries (as classified by the World Bank) included, except those without GNI data.

***Proportions could be adjusted to make the contribution rates more progressive, rather than directly proportional to share of the regional economy

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