Arguments*:* Access to Healthcare and IPRs — The Normative Issues

(long version)

This file contains full length arguments pertaining to normative issues that raised with respect to the legitimacy and justification of IPR regimes (especially patents) and the TRIPS Agreement. The leading question is whether existing IPR regimes (and TRIPS) must be revised or supplemented in order to provide respect for human rights, moral values and norms of justice and fairness. We survey the arguments of the participants and the documents consulted under three more specific questions:

1. Do patents on essential medicines violate the human right of access to healthcare?
2. Do companies have moral obligations to contribute to the solution of the health crisis in developing countries?
3. Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

The reasons for distinguishing these questions are further explained in the *Introduction* of the *condensed version* file.

The documents consulted by the WZB team are listed in the *appendix* at the end of this file.

Must Existing IPR Regimes (and TRIPS) be modified/rejected for Normative Reasons?

1. Do patents on essential medicines violate the human right of access to healthcare?

Issues	*Pro*	*Contra*
Strict (enforceable) vs. conditional human rights	**1.** Access to healthcare (including medicines) is a basic human right that "should have higher status than international trade agreements" [which require IPR protection]. (M 13/14-1a 4)	**2.** The addressee of the human right of access to healthcare are States (governments), not private companies (M 13/14-1a 4; M15/276, 1400). And the obligations of States are conditional on "resource constraints applying within the country". (M 13/14-1a 7, 11, 15, 156)
		2a. There is no "right of access to health care" but a "right to a standard of living adequate…" (Art 25.1 Univ. Declaration of Human Rights) (R8:2)
	4. The right of access to healthcare implies a duty of States to create "conditions which would assure to all medical service and medical attention in the event of sickness" (M 13/14-1a 4). This duty is strict with respect to a "minimum core obligation". (M 13/14-1a 7)	**3.** Access to medicines is an "aspirational right, not a fundamental right" (M 13/14-1b). One must distinguish human rights which can be enforced vis-à-vis governments from other human rights (social rights), which are (less binding) policy goals. "All over the world … governments have not … treated the rights to food and health as true [strict] human rights. Overstressing [social rights] claims runs the risk of strangling the systems". (M15/236)
Obligations under TRIPS and human rights	**5.** "There is a pressing constitutional obligation on the State to take all measures at its disposal to reduce the price of [essential] drugs" - "even if this means breaking the TRIPS Agreement" (M 13/14-1a 6/7).	
	6. The legitimacy of IPRs is questionable also because the most important measures States may possibly take to reduce drug prices, namely compulsory licensing (CL) and parallel imports (PI), are being denied and undermined by many forms of pressure and TRIPS-*Plus* legislation (M 13/14-1a 9, 10; cf. also 5th Circular).	**7.** CL and PI, properly applied, are legitimate options under TRIPS and are beginning to be fully accepted. (see below no. 45). Little TRIPS-*Plus* legislation is being advocated and TRIPS-*Minus* is designed to foster industrial development, not access to healthcare (R8:5)

Issues	*Pro*	*Contra*
Medicines as private goods		**8.** If companies have obligations it is „not because there are rights to medicines and not because medicines are a public good“ (M15/354). “Goods and services which may be used to produce a public good are thereby not themselves public goods. … The suppliers [of medicines] … to a health program are providing private goods to a purchaser who may then supply a public good …” (M 13/14-1b). Hence, if the private goods (medicines) are to become part of a public good like equal access to essential medicines the respective policy objective has to be defined and health promotion programs have to be set up (M 13/14-1b).
IPRs and the public interest *affordable medicines*	**9.** The patent system has to further the public interest while at the same time “fairly rewarding innovators”. “The public interest is served by ensuring access to essential drugs for all, not just for the wealthy or those with drug insurance. If people do not have access to life-saving drugs it does not make sense to provide incentives for their innovation” (M 13/14-1a 10). In this respect one may plausibly “question the economic, social and political foundations of the TRIPS Agreement“, i.e. its legitimacy. (M 13/14-1a 9)	**10.** A drug or any other health intervention cannot be “affordable to everyone as long as incomes are unequally distributed” (Bale 12). Governments can not always deliver. Special measures/programs are needed to provide access to medicines for the poorest populations (cf. below nos. 23,26, R8:4, R8:5)
	9a. IPRs are a question of a delicate balance between public and private interests that must be adapted to each country. The current system seems to favour too much private interests (R8:4).	**11.** The public goods provided through the patent system are information and research and development (derived from M 13/14-1b), not private, physical goods (R8:5).
	12. “Nobody will discuss [deny] that medicines as such, the physical product, are a private good. The problem is that the information that allows you to produce these medicines is a public good”. (M15/368, 374)	**13.** “We all know that intellectual property is a restriction on the public good quality” [of information] (M15/447)
		13a. Public sector research rarely results in a medicine (R8:5)

Issues	*Pro*	*Contra*
Human rights and property rights	**15.** "[Human] rights suggests generally some kind of higher standard. … [To put them on the same level as property rights] is a wrong conception. … These [latter] rights are really [a] social creation". (M2A/342)	**14.** The protection of property, including intellectual property, is a human right, too (Art. 17.2 and 27.2 of the Univ. Declaration of Human Rights, R8:2), and "property rights are an enormously important element of the rule of law". (M2A/251)
	15a. Citizens of developed countries would not allow governments to respect patent rights if that meant death of 10 to 25 percent of the population (R8:3)	**14a.** Respecting and enforcing human rights cannot be done by undermining other similarly basic human rights (R8:2).
	16. "Property rights and human rights are two totally different systems that should not be subsumed under one umbrella…Belonging to the human kind you have some inalienable rights. That…is not addressed by the TRIPS regime. This is [only] a regime of exclusivity". (M2A/342, 356)	**17.**"Let us not argue over the fact that societies have evolved mechanisms of exclusion from privately produced knowledge…even from public domain knowledge…[Also in the case when] you want benefits to be given to communities and individuals who have produced traditional knowledge then you must accept that there must be [exclusion] certain rights.…Rights can only exist by exclusion". (M2B/150, 176)
	18. "What property is being created by somebody advancing knowledge, for instance in drug manufacturing? There is no property being created, so there are no property rights". (M2A/342)	
The analogy of the International Undertaking	**19.** The International Undertaking for genetic resources demonstrates that public benefits result from having less IP protection, namely: "free access to new varieties as a benefit for the whole society". (M 2B/186)	**19a.** This is a static argument around currently existing technology (R8:5). State-run approaches to innovation do nor work (R8:5)
The scope of a human right to essential medicines ***The need to sustain the funding of R&D of new medicines***		**20.** "If we agree that there is the basic human right of access to essential medicines…where do we draw the line? Would you also argue that there is a basic human right to have access to the latest technology on cancer drugs …? So the question is where to draw the line and how can we find the proper tools … [such] that there is research and development done on these drugs" (M15/574).

Issues	*Pro*	*Contra*
		21. "You can't address the [relation of] human rights standards and commercial law properly without looking into the funding structures" [for R&D that provides new medicines]. (M 13(14)/609)
Indirect contributions of the private sector to social human rights: The crucial role of governmental action		**22.** "If we design [access to medicines] as a human rights issue and actually engage the private sector, we have to redo the whole debate.…To what extent are companies actually bound by the human rights standards other than through their own governments? … It's a question of how do we fund the whole thing.… You can actually justify human rights obligations with governments' funding efforts and the rights then being realized by private actions as well". (M 15/504)

2. Do companies have moral obligations to contribute to the solution of the health crisis in developing countries?

Issues	*Pro*	*Contra*
The case for a direct contribution of the private sector to social human rights: ***The moral duty to help***	**23.** Even if one agrees that it is governments who are responsible for realizing human rights, one may raise the question, "whether the companies should … contribute to health needs which would under any definition of human rights be the minimum standard". (M15/518).	
*Obligations to****"care"***	**24.** Companies see themselves as part of social and economic solutions; they are being observed by a public with moral convictions and run by employees who "are actual humans who do care. [Such persons go] into the pharmaceuticals industry because they are motivated by high ideals". (M13/1245; M 13/14-1b)	

Issues	*Pro*	*Contra*
*Commitment to **Social Responsibility***	**25.** There are obligations of "corporate social responsibility" (Oxfam 7); these imply "a moral duty for companies to provide medicines… in the least developed countries at cost prices". (M 13/831) That is why companies are prepared to back a global system of differential pricing. (see 5th Circular)	**26**. [There cannot be a duty to provide essential medicines at cost prices] for the developing countries, because the latter can be expected to contribute to R & D "according to ability to pay". (M13/1090).
		26a. The ideal scheme is hard to implement (R8:5)
	27. There will be no solution for the health crisis in the South without additional public money. But this is "not to remove every responsibility from the industries.…Industry has a responsibility in the game, but others [do] too". (M15/1380)	

3. Is the IPR system (TRIPS) flawed because injustice and unfairness are built into it?

a. Pressure and Lack of Participation

Issues	*Pro*	*Contra*
Flaws in the TRIPS negotiations? *Because of pressure from developed countries*	**28.** The negotiation process has been unduly influenced by "quite powerful industries in the United States and other developed countries". (M1/348)	**28a.** Doha showed that developing countries do have a say (R8:5)

Issues	*Pro*	*Contra*
Because of lack of equal participation	**29.** The system has to be reformed fundamentally—"fundamental in the sense that to have a global treaty that does not represent three-quarters of the world in the decision making is patently unjust" (M3A/300). "The negotiation was then … very non-transparent …" between developed and developing countries; "the rest of the countries in fact almost never participated at all"—in particular, "there was no African input at all in this negotiation". (M3A/188, 235, 262).	**30.** "Decision making in the WTO is generally made by consensus. … If somebody were to disagree, there is no way that that decision would go through.…The fact that developing countries were not widely represented…is because of the way it is done" [i.e., small groups drafting texts for larger groups]. "The fact that some countries don't have enough expertise to get represented in these drafting groups etc. is another problem, but it's not as if the rules of the WTO are somehow loaded against the countries" (M3A/71). [cont'd]
		[32. cont'd] Proof is *inter alia* "the flexibility in the TRIPS agreement" which "didn't come about by sheer accident", but by a "tough battle". The same holds for the "ambiguities in the agreement" which leave room for interpretations in accordance with countries' needs and interests. "And, therefore, it isn't exactly as one-sided as people think it is". (M3A/84)
	31. "It's not due to incompetence. … As a matter of fact,…the CBD was headed by an African, and they did not allow us to participate.…Imagine a small country like Burkina Faso opposing the United States openly: … Burkina Faso's loan [would] not be negotiated…Burkina Faso [would] be sanctioned…made a pariah State" (M3A/291). "There was a lot of coercion also during the negotiation [of TRIPS]" (M1B/358).	**32**. African delegations "never developed an interest in this question. … But with respect to Latin American and Asian countries, … there has been a very long process in the beginning", characterized by "ideological debates" and "blockages". And, in the end, "a lot of Western concepts were extended without having time to adjust them to a global situation" (M, 3A, 235 ff.)
Because of uneven distribution of expertise	**33**. The "issue [of IPRs] was very new for developing countries…There were no resources for a country like ours—and perhaps the same applies to African countries and many Asian countries—to have expertise really, to have a real expert to discuss all these very difficult problems at that time" (M3A/195)	

Issues	*Pro*	*Contra*
Because cultural differences have been disregarded	**34**. "If the process is flawed, the product cannot be any better" (M3A/264). "The process is flawed in the sense that the whole cultural dimension has not been inputted. … As far back as 1992, … we did mention that there is a very strong problem between WTO, GATT, the CBD and our way of life. … People then assumed that we [were] not right. … Silence to us … means you don't agree, and this was the kind of position we took" (M3A/264)	
Because the interests of the West predominate	**35.** "The patent system is just one idea that came essentially from the West. … Now that it is in the interest of the West, patents have been encouraged. Very soon they will realize that it is no longer in their interest … and [they] will appropriate the value from other parts of the world: …The rest of the world considers this whole apparatus as one simple system of neo-colonialism". (M3A/322)	**35a.** It is no coincidence, that the highest level of innovation is in countries that reward creativity (R8:5)

b. Inequalities and Development

Issues	*Pro*	*Contra*
Violation of the right to development? *Uniform IPRs foreclose the standard route of copying advanced technology*	**36.** TRIPS implies "the imposition of standards prevailing in developed countries on developing countries" (M1B/346), despite the fact that, in the area of science and technology, we probably face the most dramatic asymmetry in the North-South relationship (M1B/368). "Unlike other agreements within the WTO, the TRIPS Agreement does not contain any special or differential treatment for developing countries except the transitional periods which for developing countries have already expired and are still valid only for the least developed countries" (M1B/361). But this "one-size-fits-all approach" (Oxfam) denies the "right to development" (M1B/391): "Industrialization usually relies on reproducing the technologies of the more advanced economies. … By depriving developing countries of a policy instrument	**36a.** The argument is false in general thrust, a.o. because the development of an indigenous pharmaceutical industry will be the wrong way for industrialization in many cases (overcapacity competitive advantages of few countries, high-tech-low-employment as characteristic of pharmaceutical industry) (R8:5).

Issues	*Pro*	*Contra*
	for promoting national development that they themselves used, the rich countries are effectively 'pulling up the ladder'" (Oxfam 6, M2A/138)	
	36b. In industrial countries the introduction of patents was always fostered by clear gains to the domestic economy while in developing countries this policy was forced for the benefit of international companies. "And in advanced countries public health goals were never under threat" (by patents) This is different for developing countries today (R5:8).	
Options for differential treatment of developing countries	**37**. "There is a need for looking at contingent conditions under which different kinds of IP systems would be appropriate" (M2B/125). "We have areas such as trade secrets and many cases under copyright in which the right is a right to a remuneration and not a right to exclusion". (M3A/134, M2A/230)	**38.** There are a number of provisions (safeguards) in the TRIPS Agreement that provide flexibility for developing countries (e.g. delays until 2016, compulsory licenes). (M1B/401, *see 5th Circular*)
	39. Recourse to the flexibilities offered by the IP system is often blocked through pressure from industrialized countries and bilateralism. (M2A/3, 384, *see 5th Circular*)	**40.** The WTO assembly at Doha reaffirmed the "right of WTO members to use to the full the provisions in the TRIPS Agreement". (WTO 2001)
Special aspects of gene patents: *Blocking competition with generics*	**41.** Problems are aggravated because "the information which is protected is unique. … There is no possibility at all to invent around, and to find something which is similar. So the ethical and economic and social consequences of patenting genes are serious (M2A/25). Among other things, patents can be abused "to block genuine competition" (generic products)—"evergreening" on the basis of "very poor contributions to the state of the art". (M2A/58, M2B/6)	**42.** *See 9th Circular on Gene Patenting* **43.** Patents by definition exclude competition through copies of protected inventions. Compulsory licensing, while possible in principle, can as well be abused. To that extent competition through generics constitutes unfair competition. *(See 5th Circular)*

c. Other normative Infringements

Issues	*Pro*	*Contra*
Unfair benefits through patenting? *Discoveries*	**44.** "One element of unfairness relates to the appropriation of nature" in the form of protecting mere "discoveries which should belong to humanity as a whole". (M2A/15)	**45.** "There are no uniform standards" for inventiveness; "the line [distinguishing discovery and invention] can be drawn by the courts, and every country can draw its own lines". (M2A/265, Correa 2000, 19) (*see 9th Circular Gen Patenting*)
		45a. Gene discoveries are not medicine innovations (R8:5)
Lack of inventive steps	**46.** In addition, there is the appropriation of knowledge that should remain in the public domain because of too little inventiveness (M, 2A, 58 ff.)	**47.** How can TRIPS allow public domain "knowledge to be privatized? … Once it is demonstrated that public domain knowledge existed, … one can certainly revoke the patent". (M3A/326)
	48. To revoke a patent is extremely costly and time consuming. (M4/11)	
Unequal acknowledgement of inventions? *Seed companies vs. farmers* *"Biopiracy"*	**49.** It's also unfair that "the seed companies can get benefits through the intellectual property system, [but that] this does not apply to the farmers [who,] in the first place, conserved, improved, and provided germ plasm [to the gene banks]" (M2A/47). To this come cases of biopiracy where "traditional and indigenous knowledge" is being appropriated. (M2A/47)	
Unkept promises? *Technology transfer*	**50.** There are unkept promises: Instead of investments and technology transfers, "the introduction of patents has led, in many countries, to de-investment", and TRIPS will not in any way increase the flow of technology transfer as such. (M2B/27)	**51. "**Many of the provisions [of TRIPS] are not even in force, … so it's probably too early to make [a negative] assessment". (M2A/261)
	50a. There are unkept promises with respect to textiles and agricultural products, too, - with the effect of lacking reciprocity of benefits and uncompensated transfers of rent to the North (R8:5)	

Issues	*Pro*	*Contra*
Unequal access to the IPR system	**52.** "The current system is not accessible for many poor people" because "the transaction costs" (filing, disputing, enforcing) are too high (M3A/313, R8:6). There is "a huge administrative and financial burden of instituting complex IP systems" (Oxfam 2000, 6)	**52a.** Most patents are not taken by "poor people" but by companies (R8:5)

Appendix: Additional documents consulted for the survey of arguments in the 8th Circular

Correa, Carlos (2000): Integrating Public Health Concerns into Patent Legislation in Developing Countries

Oxfam (ed.) (2000): Fatal Side Effects. Medicine Patents under the Microscope