TRIPs & Access to Medicines

A choice between patents and patients!

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FAIR POLITICS
MAKE DEVELOPMENT WORK

Every year, 14 million people in developing countries unnecessarily die of poverty-related and infectious diseases, such as malaria, diarrhoea, tuberculosis and HIV/AIDS. The required medicines often exist, but the patients in developing countries simply cannot afford them, due to the patents on these medicines. There is little coherence in policies when the EUs development policy prioritises access to affordable medicines for developing countries, while at the same time, the EUs industrial and trade policy delays or complicates the access to developing countries markets of affordable medicines. Even the last Commission report on PCD ignores the risks in this field and the potentially damaging trade policies of the EU. Instead, it proposes to focus on synergies and claims that Intellectual Property Rights (IPRs) are a tool for development.

The fact that medicines are prohibitively expensive for many people in developing countries is partly due to patents on medicines. More than 96 percent of these patents are held by companies in Western countries. According to the pharmaceutical industry, patent protection is necessary to enable research into new drugs, that is costly and needs to be recouped. A patented drug cannot be manufactured by others than the patent holder without the latters explicit consent. Thus, in order to stimulate innovation, drug prices are substantially increased by an artificial monopoly of many years. Innovation - and in particular that needed to serve developing countries needs, such as in tropical diseases (for which there is no financial incentive to Western pharmaceutical industry that dominates the research agenda) has been lacking however.[1]

While patents on medicines bring little benefit to developing countries, they do keep existing medicines out of reach for the poor concludes the World Health Organization.[2]

Medicine spending in developing and transitional countries constitutes up to 60% of all spending on health, which is much more than in OECD countries. In addition, these OECD countries have not only more public provision of medicine, but also price regulation of pharmaceuticals in the private sector that developing countries do not have. Instead prices of medicine in the latter are often so high that a large part of the population lacks access to them. *There is a tension between the need to protect intellectual property rights and the need to ensure the availability and affordability of medicines*.[3]

And whereas there is not only large consensus that increasing IPR further does not benefit developing countries more and more alternatives to the traditional patents are being developed in the world, the EU and others still aim to increase patent protection

[1] 't Hoen, E. (2009) The Global Politics of Pharmaceutical Monopoly Power, Creative Commons.
[2] WHO, Commission on Intellectual Property Rights, Innovation and Public Health (December 2006).
[3] OECD, Policy Brief on 'Health: Improving Policy Coherence for Development', October 2009.

that already faces high standards with the ratification of the Trade Agreement on Trade Related Aspects of Intellectual Property (TRIPS) in 1995.[4]

International developments in Intellectual Property Regimes

Since January 2005, all WTO members (except the Least Developed Countries (LDCs), which are allowed to wait until 2016) are obliged to adapt their national patent legislation to the minimum standards of the TRIPS Agreement. These minimum standards result in a higher level of patent protection and at the same time significantly hamper the availability of cheap, generic medicines to the poorest, owing to the impediments to non-brand competition. The agreement was met with much protest from civil society and it is said that developing countries were disappointed in what they got in return for accepting this deal. TRIPS is often viewed as representing the interests of OECD countries (pharmaceutical) industry.[5]

In response to this, the Doha Declaration on TRIPS and Public Health of 2001 was to strengthen the importance of public health over IPR and specified flexibilities in order to achieve this. The compulsory license as a waiver to produce a generic (copy) version of a patent holding medicine, would now also allow developing countries without production capacity to import these in case of a national health emergency. Unfortunately not all countries have ratified this amendment however and in practice the waiver has turned out difficult if not impossible to use and only one developing country, Rwanda, has called upon it in a transaction with Canada.[6]

After TRIPS, first the US and later also the EU have pursued more stringent clauses on IPR in many bilateral (and bioregional) trade agreements, including with developing countries. Contested examples exist for South America, where the trade negotiations with the US in 2006 led to a split within the regional bloc and were strongly criticised by civil society from both sides , in particular for high demands in IPR. The EU, that was expected to be more social in its demands, actually went beyond both TRIPS and the US demands and was criticised for thus jeopardising access to health.

Besides the WTO and bilateral negotiations on IPR protection, there is an increased focus of developed countries, such as the EU, on enforcement of IPR. Whereas nothing is wrong with protecting your citizens from truly counterfeit (deliberately mislabeled) medicine, the framework currently being developed could lead to extraterritorial

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[4] TRIPS agreement http://www.wto.org/english/tratop_e/TRIPS_e/t_agm0_e.htm

[5] Sell, S.K. (2006) Big business, the WTO and Development. In: Stubbs, R. & Underhill, G.R.D. "Political Economy and the Changing Global Order". Oxford University Press.

[6] Because of its complexity and lack of clarity – e.g. a country is required to have attempted to strike a deal with a patent-holder for 'a reasonable period' at 'a reasonable commercial' price, neither of which is specified. The case of Rwanda was said to show the power of the brand pharmaceutical to set the conditions as well. http://ictsd.org/i/news/bridgesweekly/6556/ September 2007

enforcement of IPR (that are territorial by origin). Running the risk of increasing space for seizures of legitimate generic medicine in transit and hampering trade in general (including between developing countries). One way in which it does this, is by empowering customs officials, this led to the seizures of generic medicine in 2008 and 2009,[7] which of course negatively affect access to medicine in developing countries. Within this broader framework, the Anti-Counterfeiting Trade Agreement (ACTA) is an initiative of developed countries to set the guidelines for an international regulatory framework for enforcement. Unfortunately the process of ACTA, has until just recently taken place in full secrecy, excluding both relevant Commission departments, such as DG Development, and the European Parliament as well as civil society from any information.[8]

EU Trade & IPR Policy

The European Union was one of the architects of the TRIPS Agreement. By favouring the highest international intellectual-property standards in its trade policy it seeks to protect domestic industry at the expense of people in poor countries. Until 2006 it did not actively or aggressively seek to strengthen international intellectual-property standards outside of WTO negotiations.

In the last few years however the EU has been pursuing TRIPS plus commitments of third countries, including developing countries. Among its trade goals the European Commission now explicitly states that *the EU should seek to strengthen IPR provisions in future bilateral agreements*.[9] This is demonstrated in the demands made in the Andean negotiations discussed below as well as the agreement with CARIFORUM, in which IPR provisions are said that they *can in no way be considered as aimed at sustainable development for ACP countries. Rather, they almost exclusively reflect the EUs mercantile interests, as expressed in its Global Europe Strategy*.[10] Others speak of a *substantial burden* for developing countries with adverse consequences for public health.[11] In its bilateral negotiations the EU is even said to put pressure to prevent developing countries to use compulsory licensing, such as with Thailand.[12]

The EU is particularly interested in increased enforcement of IPR and pushes for criminal punishment and border measures in case of alleged infringing of IPR in multilateral,

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[7] HAI Europe & Oxfam International, Trading Away Access to Medicines: How the European Commission's trade agenda has taken a wrong turn, October 2009.
[8] Ibid.
[9] European Commission, Global Europe: competing in the world. EC Policy Review (4 October 2006). http://ec.europa.eu/trade/issues/sectoral/competitiveness/global_europe_en.htm
[10] Centre for International Environmental Law Intellectual Property in European Union Economic Partnership Agreements with the African, Caribbean and Pacific Countries: What way Forward after the Cariforum EPA and the interim EPAs? April 2008.
[11] according to law professor Frederic Abbott in the article of June 6, 2007 on EU Urged To Back Poor Countries' Use Of TRIPS Flexibilities on intellectual property watch http://www.ip-watch.org/weblog/2007/06/06/eu-urged-to-back-poor-countries-use-of-TRIPS-flexibilities/
[12] HAI Europe & Oxfam International, Trading Away Access to Medicines: How the European Commission's trade agenda has taken a wrong turn, October 2009.

bilateral and the ACTA agreement. In the meanwhile EC customs regulation (1383/2003) has resulted in extraterritorial enforcement of IPR and led to seizures of legal generic medicines in transit and is considered *trade restrictive and easily abused*.[13] By trying to export this regulation through FTAs, the EU is paving the way for seizures also in developing countries and impeding generics trade in general.

Bilateral and Bioregional Negotiations: the Andean Example[14]

Since September 2007, CAN (the Andean Community of Nations) and the EC have been negotiating an association agreement (AA) based on three pillars: cooperation, political dialogue and trade. Partly due to disagreement on IPR however, this bloc fell apart and the EU decided to continue with the more willing Peru and Colombia on the basis of only a free trade agreement (excluding the other pillars).[15]

IPR was an important factor in this split, as the countries involved, and developing countries in general, often have very different approaches and capacity in this field. Considering the EUs commitment to regional integration, this push for including sensitive issues such as IPR despite these consequences is highly incoherent in itself.

After this split the EU revealed its demands in IPR, these appeared to be very high and contentious, especially considering the large poor populations that these countries inhabit, while failing to make any commitments to technology transfer. Below an overview of the EU demands in this specific example of the EU- CAN agreement.

General Approach/Provisions

The objectives of the general provisions on IP almost exclusively adopt the position of IP holders. This severely limits any interpretation of the treaty that allows for the protection of public health. Furthermore, the ECs proposal limits the ability of the CAN countries to use certain TRIPS flexibilities. For example, the European proposal avoids the TRIPS reference to the freedom to establish "*the appropriate method of implementing the provisions of this Agreement within their own legal system and practice*."

A reference is made to the Doha declaration, but at the same time such strong potential legal barriers to this (as outlined below) are proposed that this looses its strength and credibility. Instead specific exceptions (such as for compulsory licensing) need to be

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[13] Seuba, X. Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights, ICTSD 2009.
[14]]Largely based on: Seuba, Xavier, Health Protection in the new Association Agreement between the Andean Community and the European Community in light of its provisions concerning Intellectual Property and Recent Experiences, Executive summary, p.V.
[15] Such a split also occurred – and was strongly criticised - in the agreements between the EC and ACP countries. As Peru and Colombia were expected to accept the European proposals without raising significant objections in problematic areas such as intellectual property in exchange for a more open European market, whereas Ecuador and mainly Bolivia were very critical in this field and wanted to exclude the whole issue.

explicitly mentioned within those provisions in order to ensure commitment to Doha, as well as allow for export of these to developing countries that do not qualify as LDCs.

Patents

The article on patents (article 9) extends obligations to comply with international treaties that were not foreseen in the TRIPS Agreement. It was also demanded that patent monopolies would be extended with supplementary protection certificates (SPC).

Data protection

In practice, data protection is an additional monopoly of the product owner. Whereas TRIPS does not provide for this, the EU has proposed to introduce up to 11 years of data exclusivity, which is more than the 5 years the US demanded and was criticised for.

Enforcement

Provisions on enforcement are the main focus of the chapter on intellectual property,[16] reflecting the main priority of the EC. Not only does the EC go beyond TRIPS, relinquishing the flexibility on enforcement,[17] but even beyond current Community law (EU Plus). The EC proposed to extend criminal sanctions to all IP infringements, something that the European Parliament refused in the well-known IPRED2. Border measures, that we have seen can hamper trade in generic medicine, were also an important part of the demands on enforcement.

Impact studies

Estimated impacts of fulfilling these demands in patent and data protection in the case of Peru (defined using WHO guidelines) showed strong price rises and increase in pharmaceutical expenditure that is estimated at 459 million USD in 2025, particularly hindering access to new pharmaceutical products (a consumption decrease of 11%).[18] The EUs own trade sustainability impact study only came out in July 2009 and has received little attention since.

Fortunately, due to strong public pressure in Peru and Colombia, most of these demands were not accepted. The EU demands are very relevant though as they are indicative of the offensive interests of the EU (and its pharmaceutical companies) and are expected to arise in following negotiations as well. Also European Voice (3/12/2009) in the fact sheet

[16] In this regard, the EC exports the contents of the European Directive 2004/48/EC and the European Regulation 1383/2003.

[17] The TRIPS Agreement, in article 41.5, states that it "does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general."

[18] IFARMA "Impact of the EU-Andean Trade Agreement on Access to Medicines in Peru", 2009.

trade gone wrong considers Peru as a legendary *warning what developing countries should look out for when they discuss trade in medicines*.

Unfair Politics on Multiple Fronts

In the Lisbon Treaty (art 208), the EU has committed itself to Policy Coherence for Development, which means that other fields of policy making should be in line with commitments made in development. We will see however that the policies outlined above for trade and IPR do not match well with the Health and Development commitments explained below.

The Millennium Development Goals

Health is one of the priority areas of the Millennium Development Goals (MDGs) adopted by the United Nations in 2000. The EU is committed to reduce by two thirds the mortality rate among children under five (MDG4) and halt the spread of HIV/AIDS, malaria and other major diseases (MDG 6) before 2015. Access to essential medicines is crucial to attaining these goals. In both its health and development policies, the European Union stresses the importance of improved healthcare for economic growth and development. The European Commission recognizes that *the price of essential medicines is one of the major obstacles to improved health and access to healthcare for the poorest people in developing countries*.[19]

Global Strategy & Plan of Action on Public Health, Innovation and Intellectual Property (GSPA)

In May 2009, the EC committed itself to the GSPA, adopted by the World Health Assembly. Government delegations recognised that market-driven research and development (R&D) must be supplemented with additional incentives for needs-driven research and development, and that those initiatives need to ensure that these advances are affordable and accessible to developing countries. The GSPA, devotes considerable attention to IPRs and their impact on public health, pointing out the worrying practice of over-reaching IPR protection clauses negotiated in bilateral FTAs. In adopting the GSPA, the EC abided to the protection of public health over commercial interests. In its Action Plan to combat HIV/AIDS, malaria and tuberculosis,[20] the EU also explicitly prioritizes access to essential medicines.

The Doha Declaration

The Doha Declaration signed by WTO Members in 2001 reaffirmed the importance of upholding TRIPS flexibilities to protect public health;

We agree that the TRIPS Agreement does not and should not prevent Members from

[19] Communication from the Commission of 20 September 2000 to the Council and the European Parliament on accelerated action targeted at major communicable diseases within the context of poverty reduction.
[20] Communication from the Commission to the Council and the European Parliament dated 21 February 2001.

taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

The EC has also committed itself to the Doha Declaration of 2001. While quoting the Doha Declaration, we have seen the EC bilateral proposals such as with the Andean countries could establish legal barriers, failing to meet the spirit of the text.

Recommendations of the Parliament in its 2006 and 2007 Resolution

The following recommendations feature in resolutions given to the EC by the European Parliament:[21] i) Using negotiating guidelines on development cooperation designed to achieve MDGS, including the protection of public health, ii) ensuring coherence of development policies in line with the principle enshrined in Article 178 of the EC Treaty (now 208 Lisbon), iii) granting high priority for greater access to education and health, iv) fostering regional integration by negotiating bloc by bloc.

Clearly, these recommendations are in conflict with the ECs stand on limiting TRIPS flexibilities and the one-sided perspective of IPR holders. The European Parliament pointed out the importance of fostering regional integration in the CAN through the AA. Clearly the opposite happened and bilateral negotiations grant the EC greater bargaining power and are likely to result in the adoption of more stringent IP provisions.[22]

On July 12th, 2007, the European Parliament resolution on the TRIPS Agreement and access to medicines (P6_TA(2007)0353), was adopted, urging the EC not to demand for TRIPS plus provisions in bilateral agreements. The EP should be aware of how these negotiations are being conducted and, in particular, the process through which IP rights are being upheld, which conflicts with the recommendations given by the EP to the Commission.

DG competition report[23] & internal health policy

Following an inquiry on conditions in the pharmaceutical sector and ways to improve access to safe, innovative and affordable medicines within the EU, a strong DG competition Communication came out in 2008. The report showed the anti-competitive

[21] P6_TA(2007)0080, http:*www.europarl.europa.eu/sides/getDoc.do?pubRef=-EPTEXT+TA+P6-TA-2007-0080+0+DOC+XML+V0*EN&language=EN
[22] Xavier Seuba, idem.
[23] DG Competition, Executive Summary of the Parmaceutical Sector Inquiry Report, 2008. Also: press article 'Antitrust: shortcomings in pharmaceutical sector require further action' see http://europa.eu/rapid/pressReleasesAction.do?reference=IP/09/1098

conditions present in this sector and the variety of ways in which drug companies delay the introduction of generic versions of their commercial medicines. This leads to higher prices and less patients being helped, while at the same time innovation is limited. High scrutiny of the sector will follow to protect EU citizens. If this is important internally, shouldnt these same practices be prevented outside the EU, and in particularly in developing countries, as well? Instead power and manoeuvring space of these pharmaceutical companies is increased with the trade and IPR policies described above.

The 2nd biannual report on PCD in comparison to the 1st

The European Commission as becomes apparent in the 2009 biannual PCD report, refuses to admit that they are being incoherent with development by demanding stronger commitments to IPR in negotiations with developing countries. Instead, they consider this approach coherent with development as they view IPR as a tool for development as it would enhance innovation and technology transfer. This has not only often been proved wrong by several studies[24] but also shows from the historical development of the EU itself, without any IPR protection in place. In addition, strengthening and enforcement of IPR are very costly to developing countries that also end up net payers of royalties on IPR almost fully owned by developed countries. Risks, that were acknowledged in the PCD report of 2007[25] seem now largely ignored or denied.

Conclusion

Rigid IP regulations and enforcement restrict and delay generic competition, thereby increasing the price of medicines or keeping the prices high, negatively affecting access to medicine, especially in countries with large poor populations. In theory, commitment to Policy Coherence for Development (PCD) should compel the European Commission to recognise developing countries and public health interests also in its trade and IPR policies. Yet, the pursuit of high IP standards, including patent extensions and data protection, and strong enforcement measures through different channels remains a consistent part of EC trade policy.

The TRIPS-plus and extra standards secure and extend monopolies for brand name pharmaceuticals, allowing companies to charge monopoly prices and reap huge revenues. These commercial benefits are gained at the expense of the well-being of populations in developing countries with poor resources. Generics play a vital role in lowering medicine prices and raising public health standards and should therefore be promoted.

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[24] Stiglitz, J.E. (2006) Making Globalization Work. Norton, New York; Katz, J. (2001) Structural reforms and technological behaviour: The sources and nature of technological change in Latin America in the 1990s , Research Policy 30(1), pp 1-19; Chang, H.J. (2001) Intellectual Property Rights and Economic Development: historical emerging issues, Journal of Human Development, 2(2), pp 287-309.

[25] European Commission report on PCD, November 2007.

Fair Politics believes strengthening of IPR in developing countries should not be a goal in itself as the rationale behind this and promoted by the EC - is highly doubtful, whilst large risks are present. The EU should not demand any TRIPS plus commitments or introduce stringent border rules, especially where public health can be negatively affected. Instead, developing countries should be supported in their use of TRIPS flexibilities and other, more effective, ways to stimulate innovation and promote transfer of technology should be explored and promoted.

Next to the general policy recommendations given in the blue box, the following policy recommendations are more specified on bilateral agreements and negotiations;

• The negotiated text on IP should be coherent with, and refer to the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.
• The EC should not demand TRIPS plus provisions, especially where likely to affect public health such as patent extensions, data protection and enforcement rules.
• There should be reference made to the Doha Declaration relating to all IP provisions in the text, truly ensuring policy space for using compulsory licensing.
• The proposed text of the agreement should emphasise that IP enforcement measures should not divert resources away from other priority areas, such as health protection.
• Not to push for such sensitive issues that are likely to cause regional disintegration as apposed to the integration the EU has committed itself to.

Policy recommendations

- In its trade and industrial policies, the EU should take account of its development and public health commitments. Possible impact on developing countries of actions in the trade and industry domains should be assessed thoroughly and impact studies of civil society should be taken into account in a serious manner. The current belief in IPR as a 'tool for development' and the policy coherence in this field' should be reassessed objectively and discussed with civil society in a transparent manner.
- The European Union should refrain from pursuing the inclusion of TRIPS+, WTO+ and even EU+ provisions designed to protect intellectual property rights in any bilateral or multilateral trade agreements with developing countries (including those not defined as LDCs).
- The EU should not limit, and instead encourage, the efforts of developing countries to use (TRIPS) flexibilities as a public health strategy. In addition it should lobby for the compulsory licence for developing countries without production facilities to

be made valid for all similar countries at once (including non-LDC developing countries) and (considering the limits) for other initiatives to be developed, such as patent pools. The EU should actively stand up to European pharmaceutical companies that try to limit the use of compulsory licensing in developing countries.

- The EU should ensure its interests in enforcement and developments in ACTA will not hamper trade in generic medicine or lead to any more seizures of these. In particular it should not demand adoption of current EU or EU+ enforcement rules, such as border measures, to be introduced in developing countries.
- The European Parliament should adopt a Resolution on these recommendations with a view to affirming the EC's commitments to Health and Development, as well as demand its right of access to all negotiation documents (such as ACTA) and the use of co-decision power to prevent the EU from pursuing agreements that can damage public health.

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