

# Notes on ACTA and Public Health

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This document is an adapted version of the [FFII analysis on ACTA](#), based on the December 2010 text, the “Final ACTA text following legal verification”. ([pdf version](#))

## Introduction

The European Parliament Committee on International Trade (INTA) commissioned [a study on ACTA](#) (Anti-Counterfeiting Trade Agreement). The INTA study highlights problematic aspects of ACTA and makes recommendations. According to the study, “unconditional consent would be an inappropriate response”, and “There does not therefore appear to be any immediate benefit from ACTA for EU citizens”. The study confirms ACTA goes beyond current EU legislation.

With regards to access to medicines, the INTA study concludes that adding some annotations will solve the problems. There is a huge gap between the paper reality of the INTA study and the reality in the streets: people are dying because they do not have access to medicines. The INTA study aims too low, just meeting our international obligations on public health is by far not enough. We leave in place, and reinforce with ACTA, low-volume high-profit strategies. We also note some other health issues (development and availability of medical and diagnostic methods and instruments).

The world faces a major challenge: climate change. In a worst case scenario, climate change may cause serious public health issues. The INTA study does not assess the effects ACTA may have on green innovation and diffusion of green technology, needed to fight climate change. Our analysis shows ACTA hampers both green innovation and diffusion of green technology. Green innovation will inherit the problems in the software field. Not protected by the Doha Declaration, diffusion of green technology may face worse problems than access to medicines. Green technology for the happy few will not solve the problem.

The European Parliament Committee on Environment, Public Health and Food Safety should commission a study on the effects ACTA may have on public health, the environment and diffusion of food technology.

## 1. The basic problem: low-volume high-profit strategies

A few years after the ratification of the 1994 WTO TRIPS agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), the AIDS epidemic took millions of lives in Africa. Protected by TRIPS, pharmaceutical companies sold AIDS medicine in Africa for prices higher than in the US. They only served a very small part of the market. The death toll was enormous.

Despite the Doha Declaration on the TRIPS Agreement and Public Health, the problem still exists. Pulitzer Prize winner [Tina Rosenberg in the NY Times](#): “The new strategy is to treat people in Egypt, Paraguay, Turkmenistan or China — middle-income countries, all — as if they or their governments could pay hundreds or even thousands of dollars a year each for AIDS drugs. This low-volume high-profit strategy might make business sense. But in terms of the war against AIDS, it means surrender.”

The exclusionary pricing strategy is widespread. Relative to local incomes in Brazil, Russia, or South Africa, the price of a CD, DVD, or copy of Microsoft Office is five to ten times higher than in the United States or Europe. It is the same pattern, multinationals only serving a small part of the market. Some 90% of the people in emerging economies can only turn to illegal media copies. See the [Media Piracy in Emerging Economies study](#).

Patents also make medicines in the EU very expensive. Insurance systems are needed to make medicine affordable. The high prices lead to moral dilemmas: can the health service afford to pay for grandma’s expensive medicine?

Since the signing of TRIPS, a new problem has emerged: climate change. Here two problems come together. We both need green innovation and diffusion of green technology. Patents hamper follow up innovation and trade rules lead to exclusionary pricing. Green technology for the happy few will not solve the problem.

These problems already exist under the TRIPS agreement. ACTA will do nothing to solve these. ACTA’s strengthened enforcement measures will make it more easy to execute low-volume high-profit strategies. ACTA’s strengthened enforcement measures also hamper follow up innovation.

## 2. The need for impact assessments

Multinationals prefer world wide harmonised circumstances to operate in. Low-volume high-profit strategies work for them. They have a clear interest and agenda, and huge lobby power. Grandma, who risks losing her medicine, has limited lobby power.

The "[Hargreaves Review](#)" (pdf) — the UK government-commissioned study on the relationship between intellectual property and growth, urges the UK Government to ensure that in future, policy on Intellectual Property issues is constructed on the basis of evidence, rather than weight of lobbying. The UK government agrees with this.

The European Commission refused to commission independent assessments of the effects ACTA will have on access to medicine and the diffusion of green technologies needed to fight climate change. In an [Answer given by Mr De Gucht](#) on behalf of the Commission on Parliamentary questions 27 September 2010 E-4292/2010, De Gucht states: "Regarding the conduct of an impact assessment of the implementation of ACTA, the Commission notes that, since it is bound not to go beyond the EU acquis it has based its assessment of the impact of ACTA on the studies made for the 2004 Directive on the enforcement of Intellectual Property Rights (Directive 2004/48/EC(2)) and for the 2006 proposal for a directive on criminal enforcement of IPR (COM(2006)168 final) (not adopted)."

This answer is not convincing. The impact assessments the Commission refers to are of very poor quality. And they do not assess possible negative effects on ICT, access to medicine, green innovation and diffusion of green technology. Furthermore, the Commission disregards that the EU can change its legislation, but will depend on others to change ACTA. ACTA codifies provisions in international rules and consequently prevents domestic reform. For international agreements, scrutiny needs to be more strict. And according to prominent European academics, ACTA does go beyond the current EU legislation.

Could ACTA be just as detrimental as TRIPS, or even worse? The Commission does not want to know.

### **3. The European Parliament INTA study**

In secret, the European Parliament Committee on International Trade (INTA) commissioned a study on ACTA. The INTA study highlights problematic aspects of ACTA and makes recommendations. According to the study, "unconditional consent would be an inappropriate response", and "There does not therefore appear to be any immediate benefit from ACTA for EU citizens". The study confirms ACTA goes beyond current EU legislation.

The study's weaknesses:

- uncritical of industry numbers on piracy and counterfeiting,
- uncritical of OECD numbers on piracy and counterfeiting which are based on the industry numbers,
- lacks to incorporate findings from the Hargreaves report and the Media Piracy in Emerging Economies study,
- fails to see the right approach with regards to fake inefficient or hazardous medicaments,
- the havoc patent trolls are causing is not mentioned,
- no assessment of the effects ACTA may have on the software sector, on availability of medical and diagnostic methods and instruments,
- no assessment of the effects ACTA may have on green innovation and diffusion of green technology, needed to fight climate change,
- no assessment of the effects ACTA may have on public health surveillance and crisis management,
- no assessment of the effects ACTA may have on diffusion of food technology,
- not all deviations from the current EU law are mentioned, or they are not mentioned in the summary and recommendations,
- fails to notice some fundamental rights issues.
- the huge EU deficit on IP is not mentioned in the text.

As a result, the INTA study's recommendations do not provide a solution to all issues, nor do they describe the remaining issues in full.

With regards to access to medicines, the INTA study concludes that adding some annotations will solve the problems. There is a huge gap between the paper reality of the INTA study and the reality in the streets: people are dying because they have no access to medicines.

The INTA study aims too low: "The first thing to note is that access to medicines is affected by two major IP categories: patents and trademarks. How these are treated by the ACTA therefore affects how the EU will manage its domestic market for access to medicines as well as how well it will meet its international obligations on public health."

Just meeting our "international obligations on public health" is by far not enough. We leave in place, and reinforce with ACTA, low-volume high-profit strategies.

The INTA study does not assess the effects ACTA may have on green innovation and diffusion of green technology, needed to fight climate change. It would be irresponsible to give consent to ACTA without an impact

assessment on these issues. The European Parliament Committee on Environment, Public Health and Food Safety should commission a study on the effects ACTA may have on public health, the environment and diffusion of food technology.

ACTA threatens the very foundation of the EU IP policy: to become more innovative. Note that ACTA is soft law for the US, hard law for the EU. The US president does not even dare to propose Congress to ratify ACTA, why should the European Parliament ratify ACTA?

With its high deficit on IP trade, the EU has a bigger need for flexibility than the US. While the US has a surplus, it still strives to be not bound by ACTA. While the EU has a deficit, the Commission still accepts being bound to higher damages and stronger measures that can be used against European companies. This approach does not seem rational.

#### 4. The INTA request to the European Parliament Legal Service.

The European Parliament Committee on International Trade requested the Parliament's Legal Service an opinion on ACTA. The request seems based on the summary of the INTA study. For instance, the deviations from the current EU law which are mentioned in the study's summary are mentioned in the request. The deviations that did not make it to the study's summary, are not addressed.

Compared with the request US Senator Wyden made, and seen the European academics Opinion on ACTA, the questions are very narrow. The questions seem carefully designed to minimize damage to ACTA. The INTA Committee did this work in secret.

Another quote from Tina Rosenberg in the NY Times: "Even In developing countries, health concerns are underrepresented in these negotiations. Trade agreements are not negotiated by health ministers, but by trade ministers, advised by powerful commercial interests. Their goal is access to foreign markets. They are often quite content to trade away health considerations."

Likewise, in the European Parliament, just two Parliament committees will issue an opinion on ACTA, the Committee on Legal Affairs and the Committee on International Trade.

Missing are the Committees on Environment, Public Health and Food Safety; Civil Liberties, Justice and Home Affairs; and Human Rights. They should issue an opinion on ACTA, after commissioning thorough impact assessments.

## 5. Strengthened enforcement measures reinforce low-volume high-profit strategies

ACTA goes beyond TRIPS, this will make it more easy to execute low-volume high-profit strategies. The INTA study formulates it like this: “[ACTA] is significantly more stringent and rightholder friendly than the TRIPS Agreement”.

A group of prominent European academics published the [Opinion of European Academics on ACTA](#). They note: “However, certain ACTA provisions do not ensure a balance between the interests of different parties, since they either eliminate safeguards existing under international law or, after strengthening enforcement measures, fail to introduce corresponding safeguarding measures.” Strengthened enforcement measures without corresponding safeguarding measures endanger access to medicines. The academics provide illustrations of strengthened measures.

## 6. ACTA goes beyond current EU legislation

ACTA is not only TRIPS plus, it is even EU legislation plus (acquis plus). See for this the [FFII analysis \(pdf\)](#) and the [Opinion of European Academics on ACTA](#). The European academics conclude: “Contrary to the European Commission’s repeated statements and the European Parliament’s resolution of 24 November 2010, certain ACTA provisions are not entirely compatible with EU law and will directly or indirectly require additional action on the EU level.” They invite “the European institutions, in particular the European Parliament, and the national legislators and governments, to carefully consider the above mentioned points and, as long as significant deviations from the EU acquis or serious concerns on fundamental rights, data protection, and a fair balance of interests are not properly addressed, to withhold consent.”

In April 2011, the [European Commission’s services put on-line comments to the European Academics’ Opinion on ACTA](#). The Commission denies that ACTA is incompatible with EU law. The European Commission gave a nonsensical response to the European Academics’ Opinion on ACTA. See our blog post: [The EU Commission lacks basic reading skills](#) and [ACTA Still Open To Interpretation, Legal Experts Say: Transparency Fight Ongoing](#)

The European Parliament [INTA study](#) acknowledges there are inconsistencies. Not all deviations from the current EU law are mentioned, or they are not mentioned in the summary and recommendations. Only those that made it to the summary and recommendations of the study made it to INTA request to the Legal Service.

We will discuss examples of heightened measures. Note that rights holders may use civil measures (injunctions, provisional measures) to attain the same effect as border measures provide. Governments can wash their hands in innocence, the problems are not solved.

The INTA study notes: "In fact, a Party may exclude patents from the civil enforcement sections as well, which may go a long way to removing access to medicines concerns within the EU." But the Commission does not want to exclude patents from the scope of ACTA. It is unclear whether excluding patents has to be done at the time of ratification. Footnote 2 on page 5: "A Party may exclude patents and protection of undisclosed information from the scope of this Section."

## 7. Excessive damages

Damages beyond the actual prejudice have a disproportional negative effect on competitors. In the TRIPS agreement, damages are based on adequate compensation. The EU IPR Enforcement Directive (IPRED) provides damages appropriate to the actual prejudice suffered, including lost profits. Companies confronted with damages beyond the actual prejudice would suffer great harm. Patentee overcompensation hampers desired freedom to act in the market and leads to excessive license prices, transaction costs and consumer prices.

ACTA's damages are higher than the damages in current EU legislation, the *acquis*. ACTA's damages may include the value of the infringed goods or services measured by the market price, or the suggested retail price (Art 9.1, ex Art 2.2). Suggested retail price damages are higher than actual prejudice. The entire market value rule (EMVR) systematically results in the overcompensation of patent owners relative to their inventive contributions to society.

From a KEI letter to the European Parliament: "Patent experts increasingly see the EMVR as a deeply defective approach to patent damages, and call for 'more rigorous, empirical approaches' that 'provide adequately detailed evidence of consumer-driven demand,' as well as a realistic analysis of the importance of a particular patented invention in a product that may contain dozens, hundreds or even thousands of inventions, not to mention significant investments and outlays entirely unrelated to the patented invention."

Products that may contain dozens, hundreds or even thousands of inventions may rather refer to equipment containing software than to medicines, but may include medical equipment, like scanners. See below, ACTA and Public Health.

The INTA study notes regarding damages:

“Two issues arise with respect to damages. The first is that damages apply not only to a knowing infringement but also to infringement due to negligence. Thus those who could be considered to have reason to know they were or might be infringing, would be liable for damages even if they did not intend to infringe. While it seems clear that so-called innocent infringers are not covered by this provision, the standard may encroach on the behavior of competitors in knowledge-based markets who may be aware of a potential risk that a product may be considered an infringement (e.g. computer-related inventions), but who cannot be certain due to the nature of the right. This is particularly true for trademarks and patents where the existence of trademark confusion or scope of a patent cannot be fully determined except through litigation.

The second issue is the way in which damages are to be calculated. The focus is not on objective tests but on any “legitimate” measure of value the rightholder puts forward. Article 9.1 ACTA requires that judicial authorities have the authority to consider these measures, but are not necessarily required to take them into account. The judicial authorities may still be able to reject them. Indeed, this may be necessary as that list of measures to be taken into account contains two novel approaches which are problematic and not within the EU IPR Enforcement

Directive: namely market price of infringing goods based on the concept that each infringing product constitutes a lost sale; and suggested retail price, another proxy for the concept that each infringing product represents a lost sale. Article 9.3 ACTA also foresees that judicial authorities can order the infringer to pay his profits to the right holder, to pay pre-established damages, a presumption of the harm caused by the infringement or additional damages. This applies, “at least” to all copyright and related rights infringements as well as trademark counterfeiting.<sup>190</sup> However, this latter authority is only mandatory for cases of copyright and trade mark infringement, not for the infringement of designs, patents or geographical indications.”

See also below, Problems shared with ICT. The damages issue is also mentioned in the INTA Committee request to the Legal Service.

## **8. Injunctions**

ACTA contains injunctions in civil cases (Art 8.1, ex Art 2.X.1). When abused, injunctions are a tool that can be used to prevent market entry. With an injunction a competitor or patent troll can force a company to withdraw a product from the market.



ACTA also contains injunctions against third parties (Art 8.1, ex Art 2.X.1). ACTA adds “inter alia” and has a broader formulation of third party than the current EU legislation. ACTA includes third parties who are not intermediaries, like suppliers of raw materials and software. This may impact access to medicines and the ICT sector. The INTA study does not mention that ACTA has a broader definition of third parties than current EU legislation.

In the analysis part of the INTA study, the authors agree with the Academics Opinion that ACTA may go beyond the *acquis* with regards to injunctions. “Nothing in ACTA forbids the provision of authority for judicial authorities to order pecuniary compensation as an alternative. But recourse to this option may be called into question by other ACTA parties should this provision of ACTA be enacted in its present form.” But that did not make it to the summary, and then did not make it to the INTA request to the Legal Service.

The INTA study does note: “The provision therefore needs to be clarified to ensure that at no time should products produced under compulsory license be subject to injunctions. The issue of whether such licenses are valid or in compliance with TRIPS should be a separate issue and not a condition for the exercise of the exclusion in Article 8.2 ACTA.”

#### 9. Provisional measures lower burden of proof

ACTA contains effective provisional measures, *inaudita altera parte*, against a party or third party to prevent an infringement of any intellectual property right from occurring (Art 12, ex Art 2.5).

Before an infringement is proven, provisional measures allow actions to interrupt or suspend competition. A suspicion of infringement is enough to invoke these measures. The potential for abuse of provisional measures is high, as all provisional measures can be implemented even “without the other party having been heard”.

Interlocutory (provisional) injunctions used as an enforcement remedy, are particularly damaging. Provisional injunctions have a lower threshold of evidence. As the costs of a subsequent court case may be too high, the interlocutory injunction will often be a definitive judgment. This, in effect, lowers the burden of proof necessary to carry out enforcement measures against a suspected infringement.

Regarding provisional measures, the study INTA remarks: “It is not clear, therefore, whether the lack of specific procedural safeguards in case of provisional measures *inaudita altera parte* may be inconsistent with the *acquis*. It can be argued that, to the extent that the provisions of Article 6 allow EU Member States’ authorities to maintain

and apply the procedural safeguards envisaged in the EU IPR Enforcement Directive, there appears to be no inconsistency between the provisions of ACTA and the EU acquis.”

The authors of the INTA study are then pleased enough with the argument, the issue is not mentioned in the summary and recommendations, nor did it make it to the INTA request to the Legal Service. Furthermore, if the EU would in the future not only like to have procedural safeguards, but also limitations to provisional measures, ACTA seems to foreclose this.

#### **10. Other civil measures**

The INTA study also does mention the difference between “in appropriate cases” and “except in exceptional cases” (ACTA 10.1 destruction of goods).

An alleged infringer has to provide information (Art 11, ex Art 2.4).

#### **11. Parallel importation**

Parallel importation does not involve copying at all: genuine products are sold after being imported from a country where they are already being offered to the public. Parallel importation is not counterfeiting. Parties do not have to apply ACTA’s border measures to parallel importation. The civil and criminal measures do not have such an exclusion.

The INTA study notes: “As Chapter 5 pointed out many of the parallel importation disputes revolve around the question of whether there is consent, or a contractual breach, so that ACTA may enable criminal sanctions to be applied to parallel imports purely because of a contractual difference.”

This goes way beyond the European Parliament position on the 2006 proposal for a directive on criminal enforcement of IPR (COM(2006)168 final) (not adopted).

#### **12. Border measures**

In 2008 and 2009, claiming to follow EU rules, Dutch customs seized essential medicines. Generic AIDS medicine not patented in India, nor in, for instance, Nigeria, was seized while in transit in the EU. After these seizures became front page news, the then Dutch Minister for Development Cooperation Bert Koenders said that the EU rules have to change. ACTA’s border measures do not extend to patents. As noted above, rights holders may use civil measures to attain the same effect as border measures provide.

Border measures against trade marks infringements cause problems as well. The INTA study notes: “The issue of in-transit goods can be addressed simply by not applying ACTA’s optional provision on transit goods. There may however, still remain a concern with respect to access to medicines for the EU’s own citizens that can only be fully addressed by an interpretation of Article 13 ACTA that excludes pharmaceutical products from the scope of border measures. ACTA requires that border measures be extend to all acts of actual importation into the EU, in which cases, the issues regarding similar or confusing trademarks identified above would also arise.”

ACTA’s trade mark border measures include confusingly similar goods. This may impact access to medicines. Only fraudulent imitations should be regarded as counterfeiting, like fake Gucci handbags (a trade mark infringement). Ambiguous cases of trademark confusion are not counterfeiting, they do not involve fraudulent imitation. In September 2010, the Dutch minister of Economic Affairs admitted ACTA’s border measures are problematic for access to medicines. Furthermore, these border measures, which go beyond the current EU legislation, are anti-competitive.

### **13. ACTA and Public Health**

We identify five health issues with ACTA other than access to medicines.

#### **13.a. Hazardous Medicaments**

Regarding pharmaceuticals, the INTA study refers to Commission’s statements: “The Commission has made clear the two-fold risk for public health that counterfeit medicines pose. First, such medicines may not contain the proper active ingredient in the proper quantity and so result in a patient’s condition going untreated. Second, counterfeits may contain toxic materials that result in a patient being poisoned.”

But, the INTA study has to conclude: “At this point it is important to recall that the impact of ACTA in addressing the problems discussed above is likely to be limited. (...) Its main impact will likely come from how it influences the spread of more effective enforcement through other agreements such as bilateral FTAs that include IPR protection.”

But it is clear that ACTA meets opposition, even from negotiating partner Mexico. The INTA study fails to see the right approach.

Serious crimes such as making and selling fake inefficient or hazardous medicaments are not primarily IP infringements, but criminal acts jeopardizing public health and safety. ([pdf](#))

Resources are limited, especially in developing countries. Developing countries are better off with a focus on fighting dangerous products, whether IP rights are involved or not. The populations of developed countries too are better off with a focus on fighting dangerous products, whether IP rights are involved or not. For example, up to 80% of the active ingredients in US drugs are now made overseas, many in countries where regulatory oversight does not meet US standards. Most probably, both developing and developed countries could easily agree on a focused approach if the IP issues are left out.

As a policy instrument against hazardous medicaments, ACTA fails completely.

### **13.b. Problems shared with ICT**

The "[Hargreaves Review](#)" notes that for sequential inventions "higher welfare and more innovation may be more likely to result from the absence of patenting opportunities. Over time, as digital technology becomes pervasive across the economy, this represents a serious concern. (...) Given the pace of change in the digital world and the strongly sequential nature of innovation in computer programs, the problems arising from thickets in this environment are particularly severe and it is essential that changes do not worsen the situation."

The [Economist](#) notes: "At a time when our future affluence depends so heavily on innovation, we have drifted toward a patent regime that not only fails to fulfil its justifying function, to incentivise innovation, but actively impedes innovation."

ACTA threatens the very foundation of the EU IP policy: to become more innovative. Note that ACTA is soft law for the US, hard law for the EU, see below. For more on the problems ACTA will cause in the ICT sector, [see the FFII analysis](#). The above mentioned higher damages (entire market value rule, EMVR) is particularly damaging for the ICT sector. Medical equipment, like scanners, often contain software. ACTA's heightened measures may hinder development and availability of medical equipment, diagnostic methods and instruments.

### **13.c. Public health surveillance and crisis management**

Unconsidered in ACTA is the situation presented in matters of public health surveillance, crisis management, civil and environmental response and related situations where cross-jurisdiction information exchange and the data associated therewith could constitute "infringing" activities. Under ACTA, both information and technology associated with data collection, aggregation, assembly and transmission and analysis could be impaired greatly enhancing the complexity of responding to events like SARS, the Avian Influenza and crisis response to natural and manmade disasters.

#### 13.d. Green innovation and diffusion of green technology

In a worst case scenario, climate change may cause serious health problems. Here two problems come together. We both need green innovation and diffusion of green technology. Green innovation will inherit the problems in the software field. In a general way, like trivial patents, amassing of patents, patent trolls, frivolous lawsuits, hampering of follow up innovation and high transaction costs. And in direct ways, there are green software and business patents, e.g. on regulating traffic toll fees based on traffic volume/pollution. And many modern products, like hybrid cars, contain software.

Much less documented than issues with access to medicines are issues with diffusion of green technology. It is a more recent and diffuse issue. Not protected by the Doha Declaration, diffusion of green technology may face worse problems than access to medicines. Low-volume high-profit strategies do not diffuse green technology well enough. Green technology for the happy few will not solve the problem.

ACTA's high damages will drive up the costs for diffusion of green technology. While the funds are already limited, for instance, the fight against AIDS may be lost, due to lack of money. The same may happen with diffusion of green technology. The other earlier mentioned heightened civil enforcement requirements will restrict government flexibility, impede innovation and slow the development and diffusion of green technology as well. The heightened damages may invoke an accelerated patent arms race, making the problems worse.

ACTA also evidences a clear lack of awareness on the manner in which green technology in the energy and infrastructure sectors operate. The majority of systems (for example, wind turbines, water turbines, and solar collectors) rely on cross-border up-time-management software and systems. ACTA explicitly and adversely impacts the ability to transmit grid and local data, operate feedback mechanisms to energy suppliers, and operate security protocols across international rail, air, and shipping infrastructure applications. Once again, in an effort to be responsive to the media industry, a far larger component of the global IT infrastructure is being overlooked. This, in the short term, will create unintended liabilities and, in the long term, like we've seen in the flow of energy from Russia into Europe, may be the source of highly politicized controversy and impairment.

#### 13.e Food

Food technology is covered by patents as well and diffusion of food technology, to fight hunger in the world, and also to solve problems caused by climate change, will be impacted by the inclusion of patents in ACTA. Diffusion of food technology has different characteristics than diffusion of green technology and medicines. It deserves its own assessment.

#### 14. ACTA Committee

ACTA will create an ACTA Committee, which anticipates future amendments to ACTA. Requests to include language that the ACTA would operate in an open, inclusive and transparency manner were ignored.

#### 15. A huge EU deficit

A table on page 35 of the INTA study illustrates which countries have a total net surplus or net deficit in IP transactions – royalties and license fees – in 2008. The US had a 65 billion surplus, the EU a 25 billion deficit. The text of the study only notes: “In terms of the distribution of “rents” from trade in IP-related goods and services, there is therefore a clear tension between “north” and “south.” ” – as if the EU deficit is not important enough to mention. It does not play a role in the narrative of the study. Assuming that a major goal in trade policy is to have a high surplus, the EU policy does not work.

The INTA study refers to the Innovation Union Scoreboard, the first edition of which was published in 2010. “This study used new indicators to better capture the performance of national research and innovation systems. The study confirmed that the US and Japan are maintaining an innovation lead over Europe. It also reinforced the view that Europe’s innovation lead over countries such as China and Brazil was closing (though it noted a holding of the lead over India).”

ACTA threatens the very foundation of the EU IP policy: to become more innovative. The EU has a deficit which may not go away, but rather may become worse. It would be more logical to strive for flexibility.

#### 16. ACTA’s binding nature: soft law for the US, hard law for the EU and others

In the US, the Congressional Research Service (CRS) found inconsistencies with US law. The CRS also observes that ACTA, as an executive agreement that reportedly will not be submitted to Congress for approval, does not reduce, constrain , or otherwise impact the authority and prerogative of Congress to enact measures that change federal law. The US considers itself not bound by ACTA, while the EU will be bound by ACTA.

The INTA study notes: “The apparent lack of intent to seek congressional approval and thus actually implement the treaty in US law begs the question of what, if anything, the EU gained from the US. There are serious concerns regarding whether ACTA will have any effect under US law and thus be able to be treated as a treaty under international law. On what subject will the EU hold bilateral consultations with the US regarding its implementation

of ACTA if there is no implementing legislation that authorises action by US administrative and regulatory agencies?"

With its deficit, the EU has a bigger need for flexibility than the US. While the US has a surplus, it still strives to be not bound by ACTA. While the EU has a deficit, the Commission still accepts being bound to higher damages and stronger measures that can be used against European companies. This approach does not seem rational.

The US president does not even dare to propose ACTA to Congress, Why should the European Parliament ratify ACTA?

### 17. The need for transparency

According to the Commission ACTA will fall under the Vienna Convention on the Law of Treaties. The Vienna Convention on the Law of Treaties stipulates that the history of a treaty plays a role in the interpretation of that treaty. Without full publication of all versions and positions (pdf), ACTA may have hidden interpretations.

Pedro Velasco Martins, EU ACTA negotiator, answered FFII's 30 December 2010 questions on the initialling of ACTA. ACTA was initialed on 25 November 2010, through an electronic procedure. The Commission chief-negotiator initialed all the pages of the text, including the criminal measures.

The Commission added negotiators' notes in the course of the negotiations. The EU did not publish its negotiators' notes. Negotiators' notes may influence the interpretation of ACTA. The notes should be published, as should all the earlier versions of the text.

The European Parliament Committee on International Trade requested the Parliament's Legal Service an opinion on ACTA. The questions seem carefully designed to minimize damage to ACTA. The INTA Committee did this work in secret. We believe ACTA is too important to discuss behind closed doors.

The European Parliament loves secrecy?

The Trade Committee operates like Navy Seals

### 18. European Court of Justice

The Parliament (and EU Member States) should seek an opinion of the European Court of Justice on the compatibility of ACTA with the EU Treaties.

Open legal questions:

- Does ACTA deviate from the EU acquis?

In January 2011, European academics issued an "Opinion of European Academics on ACTA". The academics invite the European institutions, in particular the European Parliament, and the national legislators and governments to withhold consent of ACTA, "as long as significant deviations from the EU acquis or serious concerns on fundamental rights, data protection, and a fair balance of interests are not properly addressed".

In April 2011, the European Commission's services put on-line comments to the European Academics' Opinion on ACTA. The Commission denies that ACTA is incompatible with EU law. The Commission's services' comments met criticism. (The EU Commission lacks basic reading skills and ACTA Still Open To Interpretation, Legal Experts Say: Transparency Fight Ongoing)

The European Parliament Committee on International Trade request to the Parliament's Legal Service is too narrow.

- Was the agreement to keep ACTA negotiations confidential in violation with the Treaties?

Art 1 TEU: "This Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen."

The article suggests transparency is a *conditio sine qua non* for the Union's competence.

Art 15.1 TFEU: "In order to promote good governance and ensure the participation of civil society, the Union institutions, bodies, offices and agencies shall conduct their work as openly as possible"

The Commission agreed on secrecy while ACTA contains norm setting, even, according to academics, FFII and INTA study, beyond the acquis.

- Does ACTA endanger fundamental rights, including the right to life?

A few years after the ratification of the 1994 WTO TRIPS agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights), the AIDS epidemic took millions of lives in Africa. Protected by TRIPS, pharmaceutical companies sold AIDS medicine in Africa for prices higher than in the US. They only served a very small part of the market. The death toll was enormous. This was an unforeseen effects of TRIPS. We now know the



devastating effects that intellectual property enforcement may have on societies. The Doha Declaration on the TRIPS Agreement and Public Health does not solve all problems. Since TRIPS, a new problem has emerged: climate change. Not protected by the Doha Declaration, green innovation and diffusion of green technology may face worse problems than access to medicines. Impact assessments of the effects ACTA will have on access to medicines, green innovation, diffusion of green technologies needed to fight climate change, production and diffusion of food and fundamental rights within and outside the Union are missing.

The European academics noted serious concerns on fundamental rights. UN Special Rapporteur on freedom of expression Frank La Rue warned that fearful Governments are increasingly restricting the flow of information on the Internet.

- Is the EU competent to ratify ACTA's criminal measures?

The EU power to negotiate criminal measures in trade agreements is not unlimited. The criminal measures in trade agreements are limited by the same rules that limit the power to make internal EU legislation (Art 207.6 TFEU). Criminal IP measures have to be based on art 83.2 TFEU, the criminal measures have to be proven essential. This proof is missing.

- Does ACTA comply with the UN International Covenant on Economic, Social and Cultural Rights and art 3.3 TEU (second paragraph)?

The Media Piracy in Emerging Economies report observes that relative to local incomes in Brazil, Russia, or South Africa, the price of a CD, DVD, or copy of Microsoft Office is five to ten times higher than in the United States or Europe. Exclusionary pricing promotes piracy. As long as IP protected goods – whether they be medicines or media products – are priced in middle income countries as luxury goods affordable only to the rich, there will be a strong pull of the majority of consumers toward competitively produced products.

Some 90% of the people in emerging markets can only turn to illegal media copies to enjoy cultural media products. This is already the case now, under the TRIPS agreement. ACTA makes this worse, ACTA confronts these people with criminal and high civil measures. ACTA norms are meant to become global norms. The UN International Covenant on Economic, Social and Cultural Rights recognizes the right of everyone to take part in cultural life; and to enjoy the benefits of scientific progress and its applications (art 15.1 (a) and (b)).

Art 3.3 TEU: [The Union] “shall combat social exclusion and discrimination, and shall promote social justice and protection (...)” (second paragraph)

- Does ACTA comply with art 3.3 TEU (first paragraph)?

Art 3.3 TEU: "The Union shall establish an internal market. It shall work for the sustainable development of Europe based on balanced economic growth and price stability, a highly competitive social market economy, aiming at full employment and social progress, and a high level of protection and improvement of the quality of the environment. It shall promote scientific and technological advance." (first paragraph)

The Commission did not make an impact assessment on the effects ACTA may have on access to medicines, green innovation, the diffusion of green technology, needed to fight climate change. The lack of impact assessments makes it impossible to establish whether ACTA complies with art 3.3 TEU.

- Does ACTA comply with art 3.5 TEU?

Art 3.5 TEU: "In its relations with the wider world, the Union shall uphold and promote its values and interests and contribute to the protection of its citizens. It shall contribute to peace, security, the sustainable development of the Earth, solidarity and mutual respect among peoples, free and fair trade, eradication of poverty and the protection of human rights, in particular the rights of the child, as well as to the strict observance and the development of international law, including respect for the principles of the United Nations Charter."

The issues noted above may indicate that ACTA does not comply with art 3.5 TEU.

- Does the ACTA Committee comply with the Treaties?

There is no guarantee the ACTA Committee will operate in an open, inclusive and transparency manner. This may compromise the transparent and democratic nature of the Union.

- Does ACTA comply with art 5 TEU, the principle of proportionality?

ACTA's intrusive criminal measures and other articles may not be proportional.

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