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Impact of anti-counterfeiting trade agreement on pharma sector: a global perspective

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ABSTRACT

Drug counterfeiting is a worldwide issue and has damaging effects on patient health. Definition of counterfeit drugs, given by WHO, covers generic under the wrap of counterfeit drugs. The Anti-Counterfeiting Trade Agreement (ACTA) is a plurilateral agreement aims to establish international standards for enforcing intellectual property rights in order to fight more efficiently the growing problem of counterfeiting and piracy and to encompass intellectual property broadly including patents. On the other hand, ACTA continues to present risks for global access to medicines, including potentially restricting free transit of generics, imposing chilling effects on the medicines trade, and limiting flexibilities in intellectual property (IP) rules. This paper analyses the impact of IPR in scope of ACTA on pharma sector and public health.

Keywords: WHO, ACTA, IPR, pharma sector

1. DRUG COUNTERFEITING

1.1 Definition

According to the WHO definition, a medical product is counterfeit “when there is a false representation in relation to its identity (e.g. any misleading statement with respect to name, composition, strength, or other elements), its history or source (e.g. any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder)” (Dr Kopp et.al. 2010). This applies to the product, its container or other packaging and/or labeling information. Counterfeiting can apply to both branded and generic products. Therefore, counterfeit products may include:

- A. Products with the correct active ingredient(s), in the correct proportions;
- B. Products with the correct active ingredient(s), but with the wrong dosage;
- C. Products without active ingredient(s);
- D. Products with impurities or toxic ingredients (WHO factsheet 2010).

1.2 Generic Drugs under wrap of Counterfeit

A generic drug is identical to and bioequivalent of a branded drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. USFDA also confirms the most important advantage with generic drugs is that they are cheaper as no R&D investments are involved in comparison to new drugs. The prevailing fierce competition also makes the manufacturer to keep to low prices. Thus generic version helps patients by making the drugs available at affordable prices by retaining the quality. Fate of generic industry is at stake as per the definition of counterfeit drugs given by WHO, which covers generic under the wrap of counterfeit drugs. The genuine concern about the WHO definition is that it may end up negatively affecting the legitimate use of generic drugs (USFDA, drug@fda glossary 2010, K Outtersson et.al. 2006).

Counterfeit drug is worldwide issue. As per the estimation of the USFDA the counterfeits make up more than 10% of the global medicines market (USFDA, drug@fda glossary 2010). Similarly European statistics had shown a strong increase of drug counterfeit seizures at the European customs, with a total of 2.7 million of drugs seized in 2006, representing a growth of 38.4% compared to 2005 (European commission taxation & custom union 2006).

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Too many developing countries of Africa, parts of Asia, and parts of Latin America have areas where more than 30% of the medicines on sale can be counterfeit. It seems no country is free of drug counterfeiting. Most developed countries with effective regulatory systems and market control e.g. USA, EU, Australia, Canada, Japan, New Zealand etc. currently have a low proportion of counterfeit drugs, less than 1% of market value. However trends point to a shift and there has been an increase in the prevalence of counterfeit medicines even in these countries (http://www.fip.org/menu_counterfeitmedicines_policy).

Recently published WHO analysis shows that counterfeiting is greater in those regions where regulatory and oversight is weaker. The problem is further exacerbated by a number of other factors: scarcity and / or erratic supply of basic medicines, uncontrolled distribution chains, large price differential between genuine and counterfeit medicines, lack of effective intellectual property right protection, lack of regard for quality assurance and corruption in the health-care system. Today, the most counterfeit branded pharmaceuticals include innovative treatments for severe diseases (cancer, heart diseases, hypertension, psychological disorders and infections) whereas before, counterfeit had more to do with lifestyle drugs such as erectile dysfunction, tonics etc.

1.3 Damaging Effects

Counterfeit drugs can have damaging effects on patients' health, including death. For example in 1995, 89 people died in Haiti after ingesting cough syrup manufactured with diethylene glycol (a chemical, commonly used as anti-freeze). This particular product was made in China and transported through a Dutch company to Germany, before winding up on the Haitian market. A recent survey of seven African countries by WHO found that between 20% and 90% of all anti-malarials failed quality testing. These included chloroquine-based syrup and tablets, whose failure rate range from 23% to 38% and sulphadoxine/pyrimethamine tablets, up to 90% of which were found to be below standard. Counterfeit drugs are even more detrimental to public health efforts when health care resources of the country considered are limited (http://trade.ec.europa.eu/doclib/docs/2008/october/tradoc_140836_11.08.pdf).

Additionally the impoverished inhabitants of developing nations are prone to illnesses, such as malaria and HIV/AIDS, partially because of substandard living conditions; they are more likely to suffer from the adverse effects of counterfeit drugs. The harmful effects of counterfeit drugs include worsening of the condition, creation of new symptoms, prolonged treatment and sometimes death. The overuse of counterfeit drugs, such as antibiotics can lead to the growth of drug resistance strains which places entire populations at risk.

2. ACTA: A PLURILATERAL AGREEMENT WITH GLOBAL IMPACT

2.1 Background

The Anti-Counterfeiting Trade Agreement (ACTA) is a plurilateral agreement for the purpose of establishing international standards on intellectual property rights enforcement.⁸ The aim of the initiative was to bring together those countries, both developed and developing, that are interested in fighting counterfeiting and piracy, and to negotiate an agreement that enhances international cooperation and contains effective international standards for enforcing intellectual property rights. ACTA established a new international legal framework that countries can join on a voluntary basis (ACTA Discussion 2009). and created its own governing body outside existing international institutions such as the World Trade Organization (WTO), the World Intellectual Property Organization (WIPO) or United Nations(http://www.med.govt.nz/templates/ContentTopicSummary__34357.aspx).

Preliminary talks about such an anti-counterfeiting trade agreement took place throughout 2006 and 2007 among an initial group of interested parties (Canada, European Union, Japan, Switzerland and United States). After several negotiations, the participating countries had reached "Agreement in Principle", with only a small number of issues outstanding. The negotiating parties released a draft text of agreement on 2nd October 2010. Government participating in the ACTA negotiations (including EU member states) are Australia, Austria, Belgium, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy Japan, Korea, Latvia, Lithuania, Luxembourg, Malta, Mexico, Morocco, Netherlands, New Zealand, Poland, Portugal, Romania, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom, United States and European Union. The 'Agreement' only covers infringement of patents, which is counterfeit physical goods such as medicines, however the 'Treaty' also covers infringement of copyright in the context of "Internet distribution and information technology"(http://www.med.govt.nz/templates/ContentTopicSummary__34357.aspx).

Expertise, innovation, quality, and creativity are the main factors for success in knowledge based economies. Adequate protection and enforcement of intellectual property rights is a key condition for nurturing these factors. The proliferation of counterfeit and pirated goods in international trade poses an ever-increasing threat to the sustainable development of the world economy. Trade in these goods causes significant financial losses for the right holders and legitimate businesses. It also hinders sustainable economic development in both developed and developing countries and, in some cases, represents a risk to consumers.

In 2006, Japan and United States launched the idea of a new plurilateral treaty to help in the fight against counterfeiting and piracy known as Anti-Counterfeiting Trade Agreement (ACTA). The ACTA is aimed at tackling the trade in fake products from luxury watches and cosmetics to car parts and medicines and those persons infringing on intellectual property (IP) rights by strengthening powers of custom officials in signatory countries to seize counterfeit goods.

2.2 Objective

The ACTA aims to establish international standards for enforcing intellectual property rights in order to fight more efficiently the growing problem of counterfeiting and piracy. The agreement also helps in protection of consumers from the health and safety risks associated with many counterfeit products. (<http://www.reuters.com/article/idUSTRE6910AO20101002>).

ACTA is not intended to interfere with a signatory's ability to respect its citizens' fundamental rights and civil liberties, and will be consistent with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and will respect the declaration on TRIPS and public health (<http://europa.eu/pressReleasesAction.do?referenceIP/10/437>).

ACTA would contribute to fighting counterfeiting in three ways:

1. Building international cooperation leading to harmonized standards and better communication between authorities,
2. Establishing common enforcement practices to promote strong intellectual property protection in coordination with right holders and trading partners, and
3. Creating a strong modern legal framework which reflects the changing nature of intellectual property theft in the global economy, including the rise of easy-to-copy digital storage medium and the increasing danger of health threats from counterfeit food and pharmaceutical.

2.3 Scope

The scope of ACTA includes

1. *Counterfeit goods*: A counterfeit is an imitation, usually one that is made with the intent of fraudulently passing it off as genuine. Counterfeit goods are often produced with the intent to take advantage of the established worth of the imitated product (Wikipedia 2011).
2. *Generic medicines* : According to U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties. Therefore as per FDA guidelines generics are considered identical in dose, strength, route of administration, safety, efficacy, and intended use (USFDA generic drugs question & answer 2010).
3. *Copyright infringement on the internet*: Copyright infringement is the unauthorized or prohibited use of any work under copyright, infringing the copyright owner's exclusive rights,

such as the right to reproduce or perform the copyrighted work, or to make derivative works (<http://www.wipo.int/copyright/en>).

2.4 ACTA and Counterfeit Medicines

The scope of ACTA reveals that counterfeit medicine will be addressed as part of ACTA. The EU press materials for ACTA persistently cite the "danger of health threats from counterfeit food and pharmaceuticals drugs" as one way that ACTA will contribute to fighting counterfeiting (<http://www.govtech.com/security/Major-New-International-Anti-Counterfeiting-Pact-in.html>) and Peter Mandelson, the EU Trade Commissioner, has said that "when people reach for chemicals that are fake or medicines that are not real, they are at a very great risk of killing themselves" (<http://www.ipwatch.org/weblog/2007/11/21/south-korea-urged-to-strengthen-ip-in-eu-trade-talks/>). Australia has expressly listed counterfeit medicines due to alarming impact of counterfeits on consumers (<http://www.dfat.gov.au/trade/acta/dis>). These reports confirmed that ACTA was negotiated as issue of health and safety amongst the member states.

The pharmaceutical industry has also offered important input on ACTA to governments involved in negotiations. For example, industry groups for pharmaceutical research and biotechnology companies as well as for generics companies made submissions to the office of the U.S. Trade Representative (USTR) and in Canada, both of Canada's Research-Based Pharmaceutical Companies and the Canadian Generic Pharmaceutical Association reported to the Minister of Industry. European Generics Association informed that the group has had considerably more access to the context of the agreement than what has been made public (<http://www.thestar.com/Business/article/468267>).

2.5 IPRs in Scope of ACTA

Article 61 of TRIPS makes an important distinction trademarks, counterfeiting and copyright piracy on one side and other IP right dispute on the other. But ACTA agreement blurs these distinctions between counterfeits and other legitimate medicines which are the subject of IP-related disputes – including parallel importing, compulsory licenses, and generics. Therefore such conflation could do more harm than good for public health (http://papers.ssrn.com/sol3/papers.cfm?abstract_id=926985).

Objectives and goals of ACTA focus broadly on intellectual property rights and do not show distinction between patents and other forms of IP such as copyrights and trademarks. This means ACTA is taking a much broader approach by generalizing measures to combat counterfeiting and piracy as applicable to all forms of intellectual property rights, including patents. The concerns here are raised for misapplication and misuse of common enforcement practices proposed by ACTA by intellectual property holders against competition in the area of patents.

This affects two main areas: the expansion of border measures and precautionary measures from other IPRs to patents; the application of IP criminalization to patent infringements. Both of these developments have a serious negative impact on the affordability of health care and generic pharmaceutical industry. If

counterfeit medicines are to be addressed effectively then the Agreement is required to distinguish counterfeits from alleged patent infringements (<http://www.tgdaily.com/business-law-features/51908-acta-draft-draws-cautious-welcome>).

Counterfeits should not be equated with patent infringements and concepts, definitions and measures designed to address counterfeits should not be extended to patents. The generics industry is worried about how the concept of counterfeits may be defined and applied within an ACTA enforcement regime. European Generics Association (EGA) released a position paper on counterfeiting and patent infringement which states that “patent infringement during the normal legitimate business development of a product” should not become a crime, and should remain a private civil matter. In addition, the EGA proposal also recommended that any definition of counterfeits adopted within ACTA, should not be addressed at patents or patent infringement (EGA position paper 2008). There are a number of situations in which patents themselves are contested in the pharmaceutical industry. The conflicting beliefs about the validity and scope of protection of trademarks and patents may arise many patent (and trademark) disputes. Such disputes are resolved by civil cases. In the absence of pre and post-grant patent opposition processes, civil cases are the only means by which the validity and scope of a patent is determined.

If product seizure is applied to a situation where medicines which are the subject of a patent dispute are wrongly characterized as “counterfeits” could result in additional costs to litigation than already exist and in liability for producers who legitimately believe that their product was not patent infringing. Additionally the threat of litigious action will discourage using IP flexibilities to their fullest for securing access to medicines.

For example, in 2007 the government of Thailand issued compulsory licenses for a number of medicines, including the HIV antiretroviral medicine, Kaletra (Kaiser Daily HIV/AIDS Report 2007). In response to this, the patent holder, Abbott, withdrew its application to register seven new drugs in the country and found such move as illegal (<http://wistechology.com/articles/3886/>). This case revealed that if the ACTA enforcement regime does not clearly distinguish the IP disputes from issues of “counterfeits” then a patent holder could trigger the enforcement mechanisms (especially border and precautionary measures) against the drugs produced under compulsory licensing. Seizures of medicines based on the allegation that they are “illegal” may restrict the ability of governments to make use of IP flexibilities such as compulsory licensing. If patent disputes are confused with counterfeits, then a more specialized regime will be needed to tackle the situation.

Cross-border flows of medicines will also be impacted by ACTA as its focus is mainly on border measures as a means of enforcement.²² For example, Thailand issued a compulsory license in 2006 for the HIV antiretroviral medicine Efavirenz and the medicine was sourced in India. These drugs made under

compulsory license will be prospect of border seizures because ACTA grants “ex officio authority to take action against infringers *i.e.* authority to act without complaint by right holders”.

ACTA-style enforcement will not be suitable for the drugs manufactured under IP flexibilities. It is required to note the difference between a counterfeit or “therapeutically harmful” medicine crossing a border, and a medicine manufactured under a compulsory license (which may be subject to allegations of patent infringement) crossing a border. Similarly the other IP flexibilities such as parallel importing are also affected by ACTA. The overall effect is on the access to medicines. The ACTA’s IP enforcement regime is also working against medicines that are therapeutically beneficial but that may be the subject of patent or trademark disputes.

3. IMPACT OF ACTA

3.1 On Generic Drugs:

3.1.1 Chilling Effects

A particular area of concern in ACTA’s proposed norms is intermediary liability. An EU/Switzerland proposal provided for general availability of injunctive relief against intermediaries whose services are used by a third party to infringe an intellectual property right (Baker B et al 2010) In the context of pharmaceuticals, such injunctions might include, for example, orders to cease sales to a generics firm. Intermediaries might include shippers and the manufacturers of active pharmaceutical ingredients, and potentially reach or influence the medicines procurement decisions of agencies such as the Global Fund (www.laquadrature.net/wiki/ACTA_Draft_Internet_Chapter). The effect of these injunctions makes a chilled market for medicines. The recently proposed U.S. legislation to establish lists of importers that have a history of attempting to import goods that infringe intellectual property rights and of low-risk importers has raised the concerns about the provision of ACTA’s Article 2.4 on Information Related to Infringement (<http://digitalcommons.wcl.american.edu/research/1>). If such EU/Switzerland or US proposals are applied broadly to civil infringements, as is currently proposed, contractors in the medicines supply chain would not like working with generics firms because of its lots of negative effects they might be more willing to work with the rights holders *i.e.* brand holders. If ACTA’s scope remains broad, generics firms will have to account for uncertainty and new potential costs, including shipping delays, storage and perhaps destruction fees and litigation, which will ultimately lead to negative effects on generic market and/or subsequent monopoly by brand holders.

3.1.2 Restricted International Transit

Under some early proposals, ACTA would have required countries to empower customs agents to seize medicines on mere suspicion or rights holder allegation of patent infringement, ahead of judicial process, even if the medicines were simply in transit through the port. Indian generics have already started courting trouble with the seizures of generic consignments

by EU from India which were *en route* to destinations like Brazil, Columbia and Peru, where they could be legally sold, while they infringed patents in EU member states. EU enforced EC Council Regulation No. 1383/2003 to seize drugs in transit via its territory (Shukla N et.al. 2009). On 4 December 2008; the Dutch authorities seized a cargo of generic medicines en route from India to Brazil. The cargo consisted of 570 Kg. of Losartan Potassium an active ingredient used in the production of medicine for arterial hypertension. It was sent by an Indian Company, Dr. Reddy's laboratory to the Brazilian Importer EMS. The cargo was held by Dutch authority for 36 days after which, it was released and directed back to India. Losartan Potassium does not enjoy any IP rights in India and Brazil. The confiscation generated considerable controversy regarding the status of generic vis-à-vis counterfeit drugs. Such seizures adversely affect the patient who eagerly wait these life saving drugs and for whom interruption the therapy might be dangerous (Seuba X et. al. 2010).

India and Brazil have since initiated procedures at the WTO to review the TRIPS compliance of Council Regulation 1383/2003, and some legal scholars argue the regulation may violate principles of territoriality and the General Agreement on Tariffs and Trade (Mara K. et. al. 2010).

Enforcement measures automatically triggered by right holders and customs authorities take on their own initiative, *ex officio*, are prone to abuse, inaccuracy and over enforcement. Generics firms are smaller firms than patent-based pharmaceutical firms, and operate on lower margins of return. Special border measures could affect not only shipments of generic medicines, but the business of the relatively small-scale generics industry and the access to medicines interests that rely on it. In response to the medicines seizures, several Indian generics producers have altered economical transshipment through Europe and preferred the alternative and more costly routes. Diversion of medicines from Europe could also risk the storage and distribution in transit.

The boarder measures is spoiling the image of generic drugs and making them of the type of counterfeits which require the police action for removal and prohibiting their entry into market (Mara K. et. al. 2010).

Article 52 of TRIPS speaks of seizure only if the final importation violates intellectual property in member state such excessive and inappropriate interpretation of IP rights, granting extraterritorial effects, runs counter the objectives and purposes of the TRIPS agreement. ACTA, as a flagship IP enforcement proposal, discourage rather than encouraging the generic market (<http://spicyipindia.blogspot.com/2009/01/indias-trips-case-against-eu-how-strong.html>).

3.1.3 Outsourcing Location

Generic companies export products worldwide. It is essential for generic companies to be able to access international markets as soon as they open up. Due to such stricter domestic intellectual property requirements, generic companies will simply be unable to compete on the international stage. Production would move to countries that do not have such a heavy-handed and excessive intellectual property regime (<http://www.canadiangenerics.ca/en/news/anti-counterfeiting.asp>, ACTA and the Drug Monopoly Enforcement Agenda 2009).

3.1.4 Global Competition

Generic companies operate in a highly competitive global environment. Companies would be left with no choice but to re-examine their significant investments in comparison to other, more competitive jurisdictions. This could have a negative impact on employment, R&D spending along with current and future investments in the world economy.

3.2 On Cost of Drugs

3.2.1 Extension of Brand Monopolies

The absence of timely generic competition may increase brand market monopolies, even when the only active patents covering a product are invalid. The extended monopoly could last from a few years to more than a decade for each product. Therefore ACTA will serve as a gift to the brand-name pharmaceutical industry and may not have any role in achieving the goal of combating counterfeit medicines.

3.2.2 Increased Drug Costs

Generic drugs play an important role in the affordability of the health care system and increasing patient access to life saving treatments. Delays in generic competition would unnecessarily cost provincial governments, taxpayers, employers that sponsor drug plans and patients millions of dollars each year. The final impact of ACTA will be not only on generic competition but also on the patient's pockets.

3.2.3 Lower Access to Cheaper Medicine

Market competition plays a key role in improving global access to medicines. The generics are essential for competition. They not only lower the cost of the treatment but also make the medicine and treatment available to patients. For example, over the last ten years, global competition and generic medicines have produced a revolution in HIV/AIDS treatment, reducing prices from \$10,000 to \$100 per person per year in developing countries, and enabling more than five million people worldwide to access

Life saving antiretroviral therapy. Competition remains every bit as vital today to expand access to new drugs, including among many others expensive second and third-line HIV/AIDS treatments. Any negative effect posed by ACTA on generics will definitely affect the competition and as a result will have negative implication on access of medicine.

3.3 On Public Health

3.3.1 Public Safety

The member states have described ACTA as a means to protect the public from unsafe counterfeit products. But it is observed that most of the cases of patent infringement do not raise health and safety concern by their nature. Criminal trademark counterfeiting can be exception to this and it can be targeted by TRIPS Agreement. Therefore it is important to distinguish criminal trademark counterfeiting from patents and other class of intellectual property including the civil trademark infringement. Thus the broader scope of ACTA will outweigh the public health costs over its benefits (Maybarduk P. et al 2010).

3.3.2 Increased Attractiveness to Counterfeiters

The extension of monopoly prices for brand companies through unchallenged invalid patents will definitely increase the drug cost. Such higher cost and more earning will attract counterfeiters to greater extent. Counterfeiters will find increased opportunities to target consumers, which may risk public health.

3.4 Conflicts in Intellectual Property Rules

Knowledge Ecology International has described ACTA's evolving, as inadequate, allowance for flexibility on damages rules and the availability of injunctions. Under TRIPS Article 44.2, countries are not required to make injunctive relief available in all circumstances, because other important national interests, such as reducing medicine costs through the government use of patents or keeping health products on the market, could be compromised (Love J. et al 2001). The innovations will be limited by rigid damages and injunctions rules, because they are uniformly seeking to prevent or punish infringement, rather than providing adequate compensation in those particular cases where use of a proprietary invention might advance technological development. ACTA's provisions on damages and injunctions may conflict with numerous national laws affecting many economic sectors. The limited scope of ACTA may reduce the number of potential conflicts.

4. CONCLUSION

Any enforcement approach that ACTA takes to remove counterfeit medicines should be tailored such that it does not negatively affect the use of safeguards such as compulsory licensing and parallel importing by governments that aim to secure access to medicines. The counterfeits must be distinguished from alleged patent infringement and the generics. The best way to address the public health and safety issues raised by therapeutically

harmful medicine is to strengthen regulatory regimes in a manner which allows them to carry out full and regular testing of all products prior to market entry, random testing of the products in the market and the ability to pull away counterfeits from the market. ACTA should be developed as an agreement which is globally accepted and its IP protection should create a proper balance between innovation and access, and private rights and public interest.

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