



INTERNATIONAL  
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**Criminal Law and the Public's Health:  
A Study and Guide to National Criminal IP Laws and their  
Use to Protect the Public's Health**



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MICHELE FORZLEY, JD, MPH  
DIRECTOR, FORZLEY & ASSOCIATES

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## ABBREVIATIONS

ACTA	Anti-Counterfeiting Trade Agreement
ASEAN	Association of Southeastern Nations
FDA	Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FSG	Federal Sentencing Guidelines
IMPACT	International Medical Products Anti-Counterfeiting Task Force
IP	Intellectual Property
IP Crimes	Intellectual Property Crimes
IPR	Intellectual Property Rights
NMRA	National Medical Regulatory Authority
OECD	Organization for Economic Cooperation and Development
PDMA	Prescription Drug Marketing Act
STOP	<a href="http://www.stopfakes.gov">www.stopfakes.gov</a>
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
USTA	Uniform Trade Secrets Act
WTO	World Trade Organization

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## **Executive Summary**

The global community has demonstrated its appreciation and commitment to combating counterfeit goods by numerous forums, initiatives and resources organized to find solutions. Among the solutions can be found legislative approaches and, in particular, the use of criminal law as a deterrent to counterfeiting. This study describes the use of substantive criminal intellectual property law, its definition in TRIPS, and what is permissible as additional substantive law. Specifically, it addresses how to tailor criminal IP law in cases where the counterfeit good poses a threat or actually causes harm to human health and safety, and it considers this aspect of counterfeiting for any and all goods that could harm humans rather than limiting the approach to drugs and medical products. Action steps and legislative guidance for legislators are provided, allowing readers to refer to this study during national implementation efforts, such as in legislative or inter-ministerial working groups in the process of considering national trade and health matters, the category in which such counterfeit goods fall. A self test and answers are included to further expand comprehension of the limitations and possibilities of criminal law as one solution in combating counterfeit goods that cause human harm.

## **About the Author**

Michele Forzley, JD, MPH, is the director of Forzley & Associates, a global public health law and consulting firm. The firm provides legal and consulting services on public health matters for which law and regulation are important determinants of health outcomes. It has been engaged in determining barriers to imported health products, in assessing and finding solutions to counterfeits and corruption in the pharmaceutical sector, designing pooled procurement mechanisms, on trade and health issues, drafting health, drug and health finance legislation and health sector governance. Michele Forzley is the public health representative to ITAC 15 on behalf of the Global Health Council and is a Visiting Distinguished Professor at the Health Law Institute at Widener School of Law. She can be reached by email at [mforzley@comcast.net](mailto:mforzley@comcast.net) or 1-202-459-1370 for comment or questions.

## Background

Counterfeit goods are a global public health and intellectual property rights problem affecting adults and children in all corners of the world. The global community has recognized this threat to the public's health and safety and is taking action to combat this problem in international, regional, and national forums.<sup>1</sup> By most definitions, a good is considered counterfeited when it bears a form of intellectual property right, such as a trademark or copyright that is infringed. All definitions of counterfeit goods include the most basic concept that the good is misrepresented as original whereby the purchaser or consumer is duped. Both civil and criminal laws are available but what is the case if a counterfeit product when ingested or used by humans could cause or in fact does cause harm or death to humans? Such jeopardy to human health and safety can only be considered a societal harm, particularly when principles of public health are applied to the potential dangers created by counterfeits. Given the traditional role of criminal law to define and punish offenses against society, this study considers existing legal criminal provisions relevant to counterfeit products that can or do cause harm to humans. Its goal is to explore existing and potential substantive criminal legal provisions so that these can become a part of a comprehensive national approach to combat counterfeit goods.

The matter of combating counterfeit goods and the public's health and safety is significant given the wide range of products counterfeited, the size of the market for these products, and the magnitude of resulting human injury. Many products commonly used or consumed daily by people around the world – such as foods, drinks, pharmaceuticals, chemicals, electronics, and household products – are easy and lucrative targets for counterfeiting. We consider goods used consumed or used by humans and include in this category animal, agricultural or other products if at some point human exposure to the product will occur veterinary products, fertilizers for growing foods, and similar products are included when this paper refers to goods used or consumed by humans that when counterfeited pose a risk to or cause actual harm. Global trade in manufactured goods was estimated in 2006 to be over USD8.2 trillion.<sup>2</sup> Of that amount, it is estimated in 2005, about USD 200 billion was counterfeit.<sup>3</sup> Thus it is easy to see how this market catches the attention of criminals looking to profit. Certain products such as tobacco, alcohol and pharmaceuticals are especially profitable. In the case of pharmaceuticals on which the largest portion of health expenditures in all nations is spent, the potential is enormous. For example, in the United States, national expenditures in 2005 on pharmaceuticals alone were in excess of \$200 billion.<sup>4</sup> In one case in Florida involving counterfeit Procrit, it is estimated criminals may have made a profit of approximately \$46 million from the sale of 110,000 bottles of the illicit drug.<sup>5</sup>

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<sup>1</sup> See international, regional and national activities including WHO IMPACT, OECD, ASEAN, the STOP Initiative and laws of Nigeria, Philippines, India summarized in Chart 1.

<sup>2</sup> [www.wto.org/](http://www.wto.org/) World Trade Report 2007, Chart 1 Growth in the volume of world merchandise trade and GDP, 1996- 2006, [http://www.wto.org/english/news\\_e/pres07\\_e/pr502\\_e.htm](http://www.wto.org/english/news_e/pres07_e/pr502_e.htm), accessed March 17, 2008.

<sup>3</sup> Economic Impact of Counterfeiting and Piracy, Executive Summary. <http://www.oecd.org/dataoecd/11/38/38704571.pdf>. Accessed March 17, 2008.

<sup>4</sup> National Health Expenditure Projections 2006-2016. Centers for Medicare and Medicare Services. <http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2006.pdf>. Accessed September 4, 2007.

<sup>5</sup> Testimony of Robert Penezic, Asst. Florida State Prosecutor to the House Committee on Energy and Commerce June 24, 2003. <http://energycommerce.house.gov/reparchives/108/Hearings/06242003hearings982/Penezic...> Accessed June 18, 2007. See



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Though incapable of precise measurement, there is no dispute that human injury and death result from exposure to counterfeit products, in addition to the economic damages. Despite numerous incidents, criminal prosecution is not always undertaken. One theory as to why prosecution is not pursued is that counterfeiting is a victimless crime, especially when counterfeit products are blocked from entering the stream of commerce and no actual human injury occurs. Perhaps more influential in prosecutorial discretion is that the potential harm counterfeit products can cause is not apparent to the eye, such as a counterfeit label on a box of genuine product. In such cases additional analysis of the product in question may be necessary to determine the toxicity or other risks of such products. Such tests are not commonly conducted, though these practices could be developed in conjunction with public health authorities, who are equipped to conduct such analyses.

In addition to the specific harm a counterfeit good could cause specific victims, certain counterfeit products can also cause a wider victim pool and increase the societal harm. A prime example is drug resistance. Studies considering counterfeit anti-malarial drugs circulating in five countries have documented the consequences of sub-therapeutic doses and development of drug resistance.<sup>6</sup> Drug resistance is a threat to society as a whole, particularly when no treatments are known to manage drug-resistant pathogens. Multi-drug resistance tuberculosis (MDRTB) is another example of a disease for which there is no cure. On yet another front, the evidence is growing that the sale of counterfeit products is being used to finance terrorism and, worse yet,

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also: US Food and Drug Administration. Counterfeit Drugs Questions and Answers.  
<http://www.fda.gov/oc/initiatives/counterfeit/qa.html>. Accessed November 14, 2007.

<sup>6</sup> Newton P, Proux S, Green M, et al. *Fake artesunate in Southeast Asia*. *Lancet* 2001; 357: 1948-9.

that counterfeits could become a vector for terror activities.<sup>7</sup> In these instances, a counterfeit T-shirt or handbag may be harmless to human health, but if the revenues are used to finance terrorism, untold public harm may occur.

Concern about the scope of human harm is so significant that stakeholders ranging from international governmental and trade organizations, governments, civil society, business communities, and patient groups have agreed that a multi-sector approach to combating counterfeit products is required.<sup>8</sup> Various approaches have been proposed for use by governments, industry, and civil society. These vary from legislation and regulatory infrastructure and implementation to enforcement to technology and communication. Within each category, an overwhelming array of detailed recommendations has been made. Though only some of the suggestions have been incorporated into national practice and legislation, all are worthy of consideration. One solution is found in the substantive law on intellectual property crimes, just two of which are required. Other crimes and most of the details of these two crimes are left to national discretion by TRIPS Article 41 and the direction of the Doha Declaration that TRIPS is implemented with a view to protection of public health.<sup>9</sup>



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Thus, a goal of this study is to focus on just one concise solution – the use of the substantive law of intellectual property crimes to protect public health – so that local practice can be changed to the extent necessary or desired and new regulations can be implemented. It is hoped that if this study and tool are effective in this one area that the successful exercise of its components will encourage countries to take further action. Moreover it is hoped that the structure and methodology of this study can be applied to other proposals so that the utility and feasibility of each can be economically and readily determined, easily adopted, and rapidly implemented.

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<sup>7</sup> Millar K. *Financing Terror- Profits from counterfeit goods pay for attacks*. Office of Public Affairs US Treasury, Customs and Border Patrol Today, (formerly known as Customs Today), November 2002, <http://www.cbp.gov/xp/CustomsToday/2002/November/interpol.xml>.

<sup>8</sup> See IMPACT, <http://www.who.int/impact/about/en/>.

<sup>9</sup> Doha Declaration on Public Health, 14 November 2001, [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

This study considers only substantive IP criminal law and related sanctions as key national measures to combat counterfeit goods that could verifiably cause harm or death to humans. First, this article examines current laws as they have been enacted, including their essential and optional elements. The study is followed by links to a multiple choice quiz and tools for use at the national level to support the legislative and regulatory infrastructure necessary for implementation and enforcement of criminal IP laws.

## The Definition of a “counterfeit”

There is no global consensus on what is a counterfeit good. Different definitions are found in health and safety, criminal and intellectual property laws between and within national laws. If global consensus could be achieved on the definition of a counterfeit good and this definition could remain constant throughout substantive law, the prospects for success in combating counterfeit goods would be greatly enhanced. In national laws, the definition of counterfeit often differs between differing areas of substantive laws and may include characteristics other than those relevant to IP enforcement. For example, Nigeria regards a drug that is not registered with its drug authority as counterfeit even if it is marketed by the authorized IP rights holder. The problem with this definition for criminal prosecution is that there is good reason to permit prosecution in cases in which there has been risk of or actual human harm even if no drug registration exists in the place of prosecution. (This is, of course, in addition to prosecution of infringers in cases where the IP right has been properly registered.) The corollary to this concept is permitting intellectual property seizures by border law enforcement of products that are counterfeit under the definition relied upon by health and safety codes even if a the suspicious good may not be infringing of a product for which IP rights are registered. This concept has been accepted customs border enforcement within the European Community. Whether or not national law should permit these extensions of the concept of counterfeit is an option to be considered, however without fail, defining counterfeit for all purposes under national law is a first and required step.

ACTION STEP 1: Conduct a comprehensive review of national substantive IP criminal law that includes a review all other laws in which the term counterfeit is used. Develop a primary definition and ensure that each time the term is used it has the same meaning.

To aid completion of ACTION STEP 1, current definitions of the term “counterfeit” need to be reviewed, followed by discussion of the Key Elements (below) of the definition that are recommended for not only substantive IP criminal law, but also any other area of substantive law.<sup>10</sup>

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<sup>10</sup> All references throughout this study to counterfeit goods are intended to include any and all products, and no effort is made to limit the scope of the use of criminal law to any particular class of goods or types of products, with the caveat that the focus of this study is on goods that when counterfeited can cause harm to humans.

With reference to trademarks, the World Trade Organization (WTO) Glossary defines “counterfeit” as the:

*Unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered, with a view to deceiving the purchaser into believing that he/she is buying the original goods.<sup>11</sup>*

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides two definitions of “counterfeit” in Part 111 “Enforcement of Intellectual Property Rights,” Note 14:

*For the purpose of this Agreement:*

*(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;*

*(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.*

These precise or similar definitions have been used in other national and international instruments. For example, similar language is used in the EC Council Regulation on goods when presented to Customs and are suspected of being or are counterfeit.<sup>12</sup> In particular Article 2.1 states: For the purpose of this Regulation, “goods infringing an intellectual property right” means:

*(a) counterfeit goods,” namely:*

*(i) goods, including packaging, bearing without authorization a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holder's rights under Community law... or the law of the Member State in which the application for action by the customs authorities is made;*

*(ii) any trademark symbol (including a logo, label, sticker, brochure, instructions for use or guarantee document bearing such a symbol), even if presented separately...;*

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<sup>11</sup> WTO Glossary [http://www.wto.org/english/thewto\\_e/glossary\\_e/glossary\\_e.htm](http://www.wto.org/english/thewto_e/glossary_e/glossary_e.htm).

<sup>12</sup> Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights. [http://eurlex.europa.eu/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&numdoc=32003R1383&model=guichett&lg=en](http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&numdoc=32003R1383&model=guichett&lg=en). Accessed January 23, 2008.

*(iii) packaging materials bearing the trademarks of counterfeit goods, presented separately...;*

*(b) "pirated goods", namely goods which are or contain copies made without the consent of the holder of a copyright or related right or design right, regardless of whether it is registered in national law...; [and]*

*(c) goods which...infringe [a patent, supplemental protection, national plant variety, or geographical indication of a Member State]."*

#### KEY ELEMENTS OF A DEFINITION

1. Any good or product.
2. Deception of buyer, consumer or anyone that goods are original.
3. Unauthorized representation of a trademark on similar or identical goods.
4. Unauthorized representation of a trademark symbol on packaging, packaging materials, label, sticker, brochure, instructions for use, or guarantee document (even if presented separately).
5. Deception that the trademark symbol and the packaging, packaging materials, label, sticker, brochure, instructions for use, or guarantee document (even if presented separately) is original,
6. Copyright piracy or copies made without the consent of the right holder
7. Any good which infringes a patent, supplemental protection, plant variety or geographical indication or other IP right recognized under national law.
8. With respect to criminal IP cases in which the counterfeit could have caused or did cause human injury or death, a clear recognition that criminal prosecution can proceed if the IP right is registered under the law of *any* WTO member state whether or not under national law in the place of prosecution.



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TRIPS definitions of a criminal counterfeit trademark or copyright refer to the country of importation and require registration in that place as an element of the two IP crimes nations must provide. Given that trade in counterfeit goods is global - such goods are imported, exported, are found in transshipment, in free trade zones and are locally produced. In order for criminal law to be effectively deterrent, prosecution must be possible where ever counterfeit goods are found. Thus, the administrative formality registration in the place of prosecution should not be included in the definition of IP crimes. Rather prosecution can proceed as long as the IP right in question is recognized by another WTO member. While this approach adds an additional fact for prosecutors to establish, this approach will limit the markets in which criminals can effectively distribute counterfeits. Thus Key Element # 8 above proposes applying an expanded definition of criminal counterfeit trademark or copyright piracy to cases in which the right is not registered in the place of prosecution if the counterfeit poses a risk of or causes actual harm to human life

Safeguards against erroneous civil or administrative procedures or measures and criminal prosecutions are contained in TRIPS Articles 48 and 56, which provide for indemnification by the payment of adequate compensation. Given that balance is a principle of TRIPS, protecting the public's health by expanding what can be criminally prosecuted as an IP crime (and including Key Element # 8, above) does not upset any balance, overly burden free trade or limit protection of individual rights holders. While amendments to TRIPS are neither likely nor suggested here, enacting such provisions in local laws and considering mandating such provisions in the proposed ACTA<sup>13</sup> is recommended.

ACTION STEP 2: Review the draft definition prepared in ACTION STEP 1 and compare to the KEY ELEMENTS OF A DEFINITION. Adjust differences to refine the definition.

## TRIPS, Intellectual Property Crimes and National Substantive Law

The Trade-Related Intellectual Property Rights Agreement (TRIPS) provides WTO Members mandatory minimum legislative standards for enforcement of intellectual property rights, as well as optional measures for their consideration. Part III of TRIPS sets out the requirements for mandatory civil, administrative, and criminal law procedures for effective actions against any IP rights infringements.<sup>14</sup> Only one section – a single paragraph – is devoted to criminal procedures:

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<sup>13</sup> Remarks by U.S. Trade Representative Susan C. Schwab Anti-Counterfeiting Trade Agreement (ACTA) October 23, 2007. [http://www.ustr.gov/assets/Document\\_Library/Transcripts/2007/October/asset\\_upload\\_file110\\_13428.pdf?ht=](http://www.ustr.gov/assets/Document_Library/Transcripts/2007/October/asset_upload_file110_13428.pdf?ht=)

<sup>14</sup> Part III: Enforcement of Intellectual Property Rights, Articles 41- 61. [http://www.wto.int/english/docs\\_e/legal\\_e/27-trips.doc](http://www.wto.int/english/docs_e/legal_e/27-trips.doc).

## Article 61

*Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture, and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.*

The implementation of TRIPS within national law can be accomplished with full regard to the protection of public health, a principle established in the Doha Declaration and in GATT Article 20b, as long as other basic trade principles are respected. Thus, there is nothing in TRIPS or other trade accords that prevents the use of criminal penalties for infringement of IP rights to protect public health. Given that counterfeit goods do affect public health, it essential that IP laws be implemented in a manner that protects public health.

ACTION STEP 4: Understand the required and optional Key Elements of IP Criminal Laws and Penalties in TRIPS Article 61.

### KEY ELEMENTS OF IP CRIMINAL LAWS AND PENALTIES

#### *What Must and May National Substantive Criminal Law Provide?*

“Members shall provide for criminal procedures and penalties to be applied at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale....

Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed willfully and on a commercial scale.”

It is mandatory for Members to provide substantive criminal law in the case of trademark counterfeiting or copyright piracy. This standard is the minimum that must be met. There is no maximum indicated in terms of substantive criminal law. In fact, TRIPS makes clear that Members may provide criminal law in other cases of IP rights infringement. Thus criminal counterfeit laws can be enacted for cases in which a patent, geographical indication, supplemental protection, national plant variety, or any other IP right recognized under local law is counterfeited in connection with a good or service.



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TRIPS imposes two qualifiers for the crimes of trademark counterfeit and copyright piracy: the counterfeiting must be done (1) willfully and (2) on a commercial scale. These concepts are not defined in TRIPS. However, a few remarks will demonstrate that the lack of definition should not be a barrier to legislating or amending national laws to provide for these crimes. The intent requirement of willfulness is well understood as deliberate, conscious, and voluntary under national criminal law, and in the case of IP crimes, the same intent requirement generally should be applied. That a defendant was deliberately involved in counterfeit trademark or copyright piracy activity seems simple enough. However, in cases in which there is also a risk of or actual human harm, it is important to avoid a definition of willfulness that also requires intent to harm the consumer. Such intent may not be in the mind of all defendants involved in counterfeiting activity, like those providing transport or packaging, but these defendants are just as responsible when harm occurs. This simple intent approach is especially important in cases in which a counterfeit label or packaging material is associated with a product that in itself is not harmful. However for certain products, labeling, packaging, and other visual materials that are often the subject of an IP right are also important components of safety systems such as product recalls, pharmacovigilance, and quality controls.

The second qualifier for mandatory IP crimes is that they are committed on a commercial scale, another term left undefined by Article 61. Defining what constitutes “commercial scale” can be done by inference from Article 60 –*De Minimis Imports*, which allows an exclusion from the application of enforcement measures in general to small quantities of goods of a “non-commercial nature” contained in travelers’ luggage or sent in small consignments. Given the global agreement on this exclusion, commercial scale has acceptably been defined by implication to mean quantities that one could or would not carry in a suitcase; that is, goods not intended solely for personal use. Caution is recommended, however, when selecting qualifiers for other IP crimes to avoid limiting such crimes to those committed on a commercial scale or to fixed quantities, such as amounts that would not fit into a suitcase if there is the potential for or actual injury to human health. The difficulty of successful prosecution is that definitions that are so limiting could preclude prosecution for certain products that are very small, such as drugs, and of which a suitcase could contain a large enough quantity for commercial-scale distribution. Thus, national practice and definitions of crimes should provide for analysis of the quantity, the product itself, and reference to the number of recipients that might use or consume the counterfeit product. Another approach could be to simply define commercial scale to be *actual*

*or intended distribution to more than one person or legal entity.* The attempt or actual commercial distribution might have relevance to the imposition of penalties and the severity of the crime.

#### *What Penalties Must National Law Provide?*

Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity.

Penalties are mandated by TRIPS for IP crimes in Article 61. These are described as remedies, although clearly they are punishment and are prescribed to be sufficient to inflict a deterrent to infringers. The severity of these remedies is only limited by the level of penalties applied to other crimes of corresponding gravity. The penalties for the crimes of conspiracy, smuggling, racketeering, money laundering, and criminal fraud are all relevant guidelines and may even be appropriate as the basis of additional charges against defendants who counterfeit. Other crimes such as murder and assault – the penalties for which could be as severe as life imprisonment, substantial monetary penalties, and even capital punishment in countries in where acceptable under local practice – should be applied in cases of counterfeits that pose a risk of or cause actual harm to humans and would be entirely appropriate. The payment of damages to the rights holder adequate to compensate for the injury in cases of willful or careless infringement, similar to what is provided for in Article 45 could be included in any calculation of monetary penalties. This punishment, while payable to the rights holder, would add a TRIPS compliant sting to the punishment.

Other penalties are required “in appropriate cases.” The list of other penalties includes seizure, forfeiture, and destruction of infringing goods and materials and implements used predominantly in the commission of the offence. TRIPS does not prevent the adoption of other measures such as injunctive relief to prevent the entry of an infringing product into the channels of commerce, according to article 44, a procedure which can be *ex parte* under Article 50. The details of these penalties are described in several Part III articles and are generally in common practice in most countries and are not explored here in detail. Discretion is left to national law to determine what is appropriate; thus it is possible to apply all penalties where practicable to criminal cases. In any case where the counterfeit good poses a risk of or causes actual harm to humans, national law can likely presume such cases are “appropriate.” To fully deter criminal behavior, courts and prosecutors should be armed with a full arsenal of penalties and measures, and no discretion should be permitted in such cases.

Nothing in TRIPS precludes the application of both civil and criminal procedures to the same defendant or the cumulative application of penalties. Moreover, TRIPS does not prevent the enforcement of other laws of members in general. Thus, any local criminal laws – such as murder, battery, and assault – or health and safety code violations could be charged in addition to the IP crime. Finally, a key to the success of such measures is not only to adopt them, but also to educate the judiciary and prosecutors on the issues of public health in general and how

counterfeit goods and services can cause harm to health and safety. This education is important to eliminate the misrepresentation that counterfeiting is a victimless crime.



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## Intellectual property crimes and the Use of Other Laws

### IN WHAT BRANCH OF THE LAW ARE IP CRIMES FOUND?

The law of IP crimes is generally found in national or federal law rather than state or local law due to preemption by national law of the substantive area of IP rights. Such is the case in the United States, where the U.S. Constitution grants to the federal government the exclusive role to recognize and regulate such rights. A key step, therefore, in implementing IP criminal law is to determine at what level of government these crimes are to be regulated and in what branch of substantive law. The division of authority and jurisdiction over IP crimes recognized by national law will usually mirror the division of civil IP law and criminal law in general, as in the United States where federal statute 17 U.S.C. § 301 provides that "... no person is entitled to any such right or equivalent right in any such work under the common law or statute of any state." The role of regulating the area of intellectual property rights is thus reserved by the Constitution to the executive branch of government, and further, to the U.S. Dept. of Commerce's Patent and Trademark Office. Thus, there are no specific common law crimes under state law that directly addresses IP infringement. For the purpose of proper TRIPS implementation, it is recommended that IP crimes are governed by the same national law that governs intellectual property in general. This is especially important for the uniform application of definitions, penalties, measures, and other remedies.

ACTION STEP 5: Identify the branch or department of government that has authority over intellectual property rights and implement IP crimes within this body of the law.

As is clear, national law may recognize all types of intellectual property rights including copyrights, patents, trademarks, industrial designs, national plant rights, geographical indications, and trade secrets. For each, it is theoretically possible to describe a crime in which one or more right is counterfeited. TRIPS does so in terms of copyright and trademark infringement, but does not do so in terms of protection of public health. Thus, the task is to ensure that current and amended laws include sufficient elements to encompass crimes that, in addition to the rights infringement, recognize harms to public health.

ACTION STEP 6: Review existing IP crimes, list the specific IP rights recognized, and determine if current crimes include sufficient elements to encompass harms to human health and whether other IP rights should also be included in substantive crimes.

Finally, it is not unusual that national health and safety laws prohibit food, drug, and consumer product counterfeiting. However, these laws are not created from an IP perspective. In countries such as the United States, Nigeria, India, and Ethiopia, national health and safety laws prohibit unwholesome, adulterated, substandard, or unregistered products. Since counterfeit goods are generally always substandard and often adulterated, they would likely violate national health and safety laws. The goal of these laws is to prevent unhealthy products – rather than goods that infringe IP rights – from entering commerce. The ultimate benefit to society is the same, and fortunately these health and safety laws can be used cumulatively with IP crimes.

## COPYRIGHTS

This section will detail copyright, trademark and trade secret crimes, and briefly discuss other forms of IP rights and how each, when counterfeited, could cause harm to humans. The purpose of this section is to aid in the development of a national language that will encompass sufficient elements to encompass behavior that is offending to the health of the public.

Most counterfeiting tends to occur in the area of trademarks, with or without any alteration of the actual product concerned. Available statistics, while not precise, point to this conclusion. Though this is presently the case, as countries adopt the principles and practices of intellectual property protection, other forms of infringement will possibly increase. Thus, nations would be well-advised to ensure that their laws are prepared. One area of extensive counterfeiting is copyright piracy. A copyright is defined as “pictorial, graphic, and sculptural works” to include “... works of fine, graphic, and applied art.”<sup>15</sup> The most obvious examples of the harmful effects of copyright piracy on human health are product labeling, packaging, and other marketing materials, such as instructions and information inserts. Copyrighted DVDs or other visual art materials might be harmful if, for example, the contents are disturbing to the emotional balance of some viewers, such as minors. The provisions of 17 U.S.C. § 506 define criminal copyright infringement as the act of a person willfully infringing a copyright if the infringement was committed for the purpose of commercial advantage or private financial gain.

### KEY ELEMENTS FOR PROSECUTIONS OF CRIMINAL COPYRIGHT COUNTERFEITING OR PIRACY

*NOTE: All items in brackets [ ] are subjects for national choice. Selections in brackets are common practice and can be adopted.*

1. That the works Defendant is alleged to have [reproduced] [distributed] were protected by copyright; however in the case of risk to or actual harm to human health, no formal registration of the copyright is required in the place of prosecution as long as the copyright is registered in any one WTO member;
2. That the Defendant infringed the copyrights of the works by [reproducing] [distributing to the public] one or more copies of [each of] the copyrighted works;
3. That the Defendant willfully infringed the copyrights; [and]
4. [optional] That the Defendant, during a [180]-day period, reproduced or distributed [ten (10)] or more copies of one or more copyrighted works which have a total retail value of more than \$[2,500]; or in the event the total retail value is less than \$2,500 the counterfeited work posed a risk to or caused actual harm to human health and safety; [and]
5. [optional] That the act of infringement was for the purpose of commercial advantage [or private financial gain.]
6. [optional] That the Defendant distributed the works by making them available on a computer network accessible to members of the public.

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<sup>15</sup> 17 U.S.C. §101

### *Elements for misdemeanor or felony*

Element 4 above can be adapted to characterize infringement of copyrighted works with a retail value totaling less than \$2,500 as a misdemeanor. However if there is potential or actual harm to human health, then the crime is automatically a felony without regard to whether an actual harm to human occurred or the degree of harm.

**ACTION STEP 7:** Compare the substantive law of existing criminal copyright crimes to the key elements checklist above and draft language to make any necessary adjustments. Or if there is not currently copyright crime in your law, then draft the law to include these key elements.



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### TRADEMARKS

A trademark is a mark used in connection with a good or service and is identified with the product by the public. The names of many products have been trademarked. Even generic companies rely on trade names to enhance market share, even if the trade name is that of the company itself, such as the Indian company Cipla or the Italian tire maker Pirelli. According to the study “Counterfeit Goods and the Public’s Health and Safety”<sup>16</sup> and national customs seizure statistics, trademarks are the form of intellectual property most often counterfeited. Typical offender constellation and *modus operandi* extend across more than one country, with several defendants each engaging in some portion of the range of activities to accomplish the distribution of counterfeit products.

A case involving counterfeit Lipitor and the printing and distributing of counterfeit labels is one example in which convictions for IP crimes and health and safety law violations resulted in jail

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<sup>16</sup> M. Forzley, Counterfeit Goods and the Public’s Health and Safety, July 2003. [www.iipi.org](http://www.iipi.org).

time for the defendants – a Cuban and three Americans, all residents of Florida. Each defendant played a part separately to accomplish the multi-million dollar counterfeit drug smuggling, manufacturing, and labeling operation that resulted in convictions for each on separate charges and for all on conspiracy. Criminal activities included sale of counterfeit drugs; theft of drugs; misbranding; illegally importing drugs; acquiring the tools, materials and dies to manufacture counterfeit Lipitor; illegally importing legal Lipitor; creation of false pedigrees; warehousing counterfeit prescription drug both in the United States and in Nicaragua; repackaging; printing counterfeit labels; and transporting counterfeit prescription drugs. The operation spanned many countries; Nigeria, where fake Lipitor was manufactured; Nicaragua, where fake and stolen drugs were stored; Costa Rica, where counterfeit product was manufactured; and the United States, where the counterfeit drugs were distributed. This case demonstrates the importance of IP crimes that empower prosecutors to charge criminals for activities that are potentially injurious to human health with substantive crimes that can be prosecuted anywhere. Also essential to the successful prosecution is the development of IP criminal substantive law that broadly defines criminal activity in counterfeit trademarks by criminalizing both the trafficking of goods and services using a counterfeit trademark and the trafficking of counterfeit labels or other materials bearing a counterfeit mark, such as a an emblem. In the United States, the relevant law reads, in part:

Whoever intentionally traffics or attempts to traffic in goods or services and knowingly uses a counterfeit mark on or in connection with such goods or services, or intentionally traffics or attempts to traffic in labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging of any type or nature, knowing that a counterfeit mark has been applied thereto, the use of which is likely to cause confusion, to cause mistake, or to deceive...<sup>17</sup>

US law typifies a useful manner in which criminal trademark behavior can be described. It includes the infringing mark, the intent to deceive, and either or both of the use of the mark in connection with goods or the making, sale and/or distribution of the mark in connection with that to which it is affixed such as a label. In this manner, the criminal can include those that sell goods with infringing marks and those that must sell the marks and their holders. The elements are described in the seven listed as follows.

#### KEY ELEMENTS FOR PROSECUTIONS OF CRIMINAL TRADEMARKS

1. That the defendant trafficked, or attempted to traffic, in goods or services;
2. That such trafficking, or attempt to traffic, was intentional;
3. That the defendant knowingly used a counterfeit mark on or in connection with the goods or services or defendant knew that counterfeit mark had been applied to the labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging;
4. The mark was used on or in connection with labels, patches, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation,

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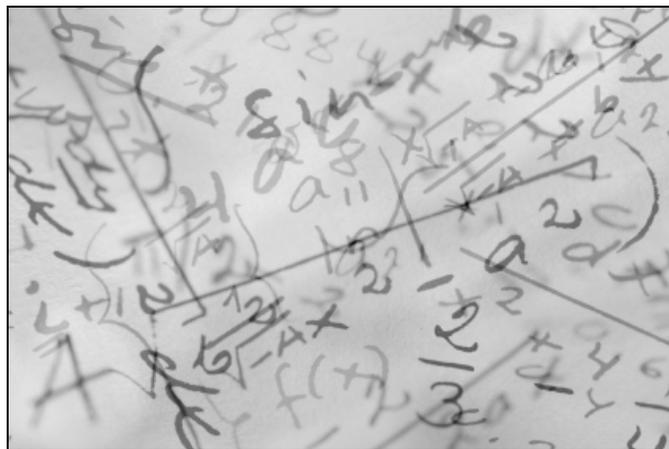
<sup>17</sup> 18 U.S.C. § 2320

- or packaging of any type or nature or part thereof in which the defendant trafficked, or attempted to traffic;
5. That the use of the counterfeit marks was likely to cause confusion, to cause mistake, or to deceive; and
  6. The counterfeit mark is identical with, or substantially indistinguishable from, a mark registered for those goods or services on the principal register in the [name of national office where such marks are registered] and in use, whether or not the defendant knew such mark was so registered; except
  7. That in cases in which the goods or services in which a counterfeit mark is involved and the good or service poses a risk of harm to or causes actual harm to human health and safety, the mark must be registered on the principal register where such marks are registered in any one WTO member but it is not required to be registered in the place of prosecution.

ACTION STEP 8: Compare the substantive law of existing criminal trademark crimes to the Key Elements checklist above, and draft language to make any necessary adjustments. If there is no trademark crime yet established in local national law, draft the law to include the elements above.

### TRADE SECRETS

A trade secret is information including a formula, pattern, compilation, program device, method, technique, or process originating from the owner's intellectual work and is used for a competitive advantage in commerce. The famous example is the formula for Coca Cola syrup, which has never been patented. Rather it is kept in a safe place such as a vault. The company ships the syrup to bottlers who mix it with carbonated water, but never make the syrup itself, which is the product of the Coca Cola trade secret. It is not hard to find cola drinks throughout the world, which strive to be viewed as equivalent to Coca Cola, evidencing the strength of a trade secret as providing a competitive advantage.



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A trade secret is not registered and, as a result, claims of infringement are difficult to pursue since demonstrating the trade secret would be necessary for success. The adoption of model laws

such as the Uniform Trade Secrets Act<sup>18</sup> (USTA) by 45 states and the District of Columbia in the United States is expected to strengthen businesses' claims on their trade secrets. Thus for trade secret infringement crimes, it is essential to permit prosecution based on a standard that recognizes the use of the trade secrets in business, but without requiring the divulging of the secret information. For example, the U.S. Code on trade secrets identifies as crimes actions by a person who:

- “(1)... with intent to convert a trade secret, that is related to or included in a product that is produced for or placed in interstate or foreign commerce, to the economic benefit of anyone other than the owner thereof, and intending or knowing that the offense will, injure any owner of that trade secret, knowingly steals, or without authorization appropriates, takes, carries away, or conceals, or by fraud, artifice, or deception obtains such information;
- (2) without authorization copies, duplicates, sketches, draws, photographs, downloads, uploads, alters, destroys, photocopies, replicates, transmits, delivers, sends, mails, communicates, or conveys such information;
- (3) Receives, buys, or possesses such information, knowing the same to have been stolen or appropriated, obtained, or converted without authorization;
- (4) Attempts to commit any offense described in paragraphs (1) through (3); or
- (5) conspires with one or more other persons to commit any offense described in paragraphs (1) through (3), and one or more of such persons do any act to effect the object of the conspiracy,”<sup>19</sup>

This approach provides the elements of a taking of the secret and its sale or transfer or attempt thereto and adds conspiracy to do so. Conspiracy is an additional crime that can be added to IP crimes in order to increase the level of misdemeanor offense to felony and the associated penalties.

#### KEY ELEMENTS OF A TRADE SECRET CRIME

1. That defendant intended to convert a trade secret to the economic benefit of anyone other than the owner, by
  - a) Knowingly stealing or otherwise without authorization takes, carries away, or conceals, or by fraud, artifice, or deception obtains such trade secret, or
  - b) without authorization copies, duplicates, sketches, draws, photographs, downloads, uploads, alters, destroys, photocopies, replicates, transmits, delivers, sends, mails, communicates, or conveys such trade secret, or
  - c) receives, buys, or possesses such trade secret, knowing the same to have been stolen or appropriated, obtained, or converted without authorization; and
2. The trade secret is related to or included in a product that is produced for or placed in interstate or foreign commerce,
3. Defendant intended or knew that the taking of the trade secret will, injure its owner,

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<sup>18</sup> Text of Uniform Trade Secrets Act. <http://nsi.org/Library/Espionage/usta.htm>.

<sup>19</sup> 18 U.S.C. § 1832

4. Attempts to commit any offense described in paragraphs (1) (a) through (c); or
5. Conspires with one or more other persons to commit any offense described in paragraphs (1) (a) through (c), and one or more of such persons do any act to effect the object of the conspiracy,

ACTION STEP 9: Compare existing criminal trade secret crimes substantive law to the Key Elements checklist above and draft language to make any necessary adjustments. If there are no trade secret crime provisions in local law, then draft the law to include these Key Elements.

## Penalties for IP Crimes that pose risk or cause actual harm to human health

The penalties for criminal infringement of an IP right that poses a risk or causes actual harm to human health should be no less than the least penalties for other crimes and should be more if actual injury occurs. As this study will be viewed by readers from many countries, exact monetary amounts will not be suggested. Rather, some general principles are provided to guide local decision-making on penalties. TRIPS mandate that penalties must include monetary penalties and imprisonment to be sufficient to be a deterrent to infringers and be as severe as the level of penalties applied to other crimes of corresponding gravity. Thus, a general rule is to refer to the penalties for traditional crimes of murder, attempted murder, assault, and attempted assault. Just as assault may be found even though the defendant does not actually touch the victim, the counterfeit good can be seen as a vector of harm that does not physically ‘touch’ the victim, yet causes injury nonetheless.



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There may be other crimes recognized under national law and custom that are correspondingly similar and should also be considered.

**ACTION STEP 10:** Collect and review the sentencing requirements and monetary penalties for non-IP crimes in which a human victim is involved, including victims who are injured or killed and who could have been by the actions of the defendant. Include attempt crimes. Identify lengths of imprisonment, and apply the same to IP crimes.

With regard to monetary penalties, setting the amount must be sufficiently high to be significant to the defendant. It is important to refer in this calculation to amounts far in excess of national living standards. It may be advisable to provide the judiciary or prosecutor discretion in setting the amount with reference to the size of the market for the genuine product that has been counterfeited and the quantity involved in the circumstances. No limits should be placed on the total fines that can be imposed, especially when more than one offense is charged and conviction is had.

### Use of non-IP crimes to protect life/health

National health and safety laws refer to counterfeit, adulterated, and substandard products (which counterfeits are generally) and are not framed in terms of intellectual property rights infringement but these should be applicable cumulatively in IP crimes. Having such laws can be advantageous in the overall national approach to combating counterfeit goods that are injurious to human health. Even if national laws continue to require national registration of intellectual property in order to prosecute infringers for IP crimes, action can still be taken on non-IP crimes when the intellectual property has not been registered.

Even if the requirement remains under national law that national registration is required for prosecution, action can be taken. Given that many products regulated by health, safety, and consumer protection laws are counterfeited because they either have high value or there is a large market existing for such products, the interplay between these laws and IP crimes is important to the overall effectiveness of national policy on counterfeits. Products such as drugs, foods, alcoholic beverages, tobacco, and many consumer products (including shampoos, baby products, and toys) are counterfeited. Criminal law on counterfeit products is also found in national health, safety, and consumer protection jurisprudence – some aspects of which will be reviewed briefly as they relate to IP crimes.

Ensuring that prosecutors who are responsible for the enforcement of IP crimes are authorized to also enforce the criminal laws found in health, safety, and consumer laws should be a priority. In the United States, the U.S. Food and Drug Administration (FDA) oversees the safety of food, drugs, and cosmetics exclusively, but it is the U.S. Justice Dept. that prosecutes crimes, including those enacted under FDA statutes.<sup>20</sup> By limiting who has the ability to prosecute these crimes, strength and capacity can be developed in the prosecutorial office authorized under national law.

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<sup>20</sup> 21 U.S.C. 337

ACTION STEP 11: Consider and limit who can prosecute criminal behavior under national health, safety, and consumer laws. Ensure that the same prosecutors of IP crimes also prosecute health, safety, and consumer protection law crimes.

*Definition of a counterfeit good for the purpose of health, safety and consumer products laws:*

The definition of a counterfeit good for the purpose of health, safety, and consumer products should include a wide scope of activities so as to encompass every possible criminal defense and clarify words that may have multiple meanings. Yet, such definitions do not have to refer to registration of the IP right or the importation of the product, allowing statutes to become strong companions to IP crime prosecution and a tool in combating counterfeit products. An example of a definition of a counterfeit product under national health, safety and consumer laws is:

A product which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such product and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other product manufacturer, processor, packer, or distributor.<sup>21</sup>



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Health, safety, and consumer laws can also of course refer to registered trademarks or other IP rights and in fact mirror IP crimes. An example is the U.S. FDA law on counterfeiting, which prohibits:

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<sup>21</sup> Modeled on 21 U.S.C. § 321 (g) (2) which defines “counterfeit drug”.

“(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by [Law]...

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.”<sup>22</sup>

Further facilitating prosecution are laws specific to particular types of counterfeited products. For example, the Prescription Drug Marketing Act of 1987 (PDMA), signed into law in 1988, was enacted (1) to ensure that drug products purchased by consumers are safe and effective and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, sub potent, or expired drugs.<sup>23</sup> The legislation was necessary to increase safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs and is enforced by the FDA.<sup>24</sup> The Federal Food and Drug Cosmetic Act prohibitions are extensive and cover a broad range of activities that easily can be associated with the counterfeiting of prescription drugs, including alteration, misbranding, and obliteration of labeling.

A common approach to criminal law and counterfeit goods is to have both IP crimes and crimes within the food, drug and consumer product safety and health laws. This complementary approach can be found in the laws of countries as diverse as Nigeria, India, the Philippines, and Ethiopia. Chart 1 below contains some of the laws of this nature and the maximum penalties for their violation. . It is recommended that while enacting criminal IP laws, crimes for violation of health and safety laws are considered at the same time so as to ensure there are no conflicts and that these laws work together successfully. This is the goal of Action Step 12 and its related KEY ELEMENTS.

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<sup>22</sup> 21 U.S. C. §331

<sup>23</sup> Prescription Drug Marketing Act of 1987, Public Law 100-293 and amendments of 1992 Public Law 102-353.

<sup>24</sup> Id at 22. .

**Chart 1**

<b>COUNTRY</b>	<b>Nigeria</b>	<b>India</b>	<b>Philippines</b>	<b>Ethiopia</b>
<b>APPLICABLE LAW(S)</b>	<u>Decree No 25 of 1999</u> – Counterfeit and Fake Drugs and Unwholesome Processed Foods <u>Decree No 20 of 1999</u> –Drugs and Related Products (Registration etc.)	<u>Act 71 of 1995</u> – Drug and Cosmetics Act	<u>Republic Act No. 8203</u> – Special Law on Counterfeit drugs; <u>Republic Act No. 3720</u> – Food Drug and Cosmetic Act	Drug Administration and Control Proclamation No. 176/1999
<b>SANCTIONS</b>				
Fines (maximum)	\$4000	\$130, \$260 <sup>a</sup>	\$11, 500	\$5,500
Prison term (maximum)	15 years	3 to 5 years Or life term	10 to 12 years	20 years

**ACTION STEP 12:** Compare and harmonize all definitions of “counterfeit” in health, safety and consumer products laws with the final definition selected for IP crimes.

**KEY ELEMENTS OF WHAT HEALTH, SAFETY, AND CONSUMER PRODUCTS LAWS SHOULD PROHIBIT**  
What activities can and should health, safety, and consumer protection laws prohibit and thus support the overall policy to combat counterfeit products that can cause harm to humans? The following activities can be prohibited:

1. The introduction of any counterfeited or misbranded health, safety and consumer products into interstate commerce;
2. The receipt and/or delivery of counterfeited or misbranded health, safety, and consumer products;
3. The making, sale, and distribution of counterfeit health, safety, and consumer goods and services;
4. The act of placing expired products into the market after changing the date on the label or the entire label.

**ACTION STEP 13:** Compare and harmonize existing health, safety and consumer protection laws with these key elements and draft amendments where necessary. Also compare proposed drafts with newly drafted IP crimes to ensure compatibility.

## CONCLUSION

There is an increased appreciation of the dangers of counterfeit goods to the health and safety of citizens and substantial efforts devoted to find ways to combat counterfeit goods. This study selected the use of IP crimes as just one aspect of the many solutions under considerations. Its purpose is to provide a basis for comprehension of the key elements and legal requirements and more importantly define the steps to implement the solution. TRIPS, the basic legal document governing the solution, provides some direction, but in effect it relegates to national decision-making much discretion in the areas of other possible IP crimes and penalties. Moreover, it does not provide legislative guidance on how to draft local substantive law. This study aims to deliver details and legislative drafting guidance.

The proposals set forth herein demonstrate how IP crimes can be used to combat counterfeit goods that are dangerous to health and safety in a TRIPS compliant manner and suggests that for such IP crimes, nations adopt limited exceptions to the requirement of local IP rights registration as a necessary element of the crime and that IP crimes apply to exports, goods in transshipment, in free trade zones, and to locally produced goods in addition to imported goods and services. Furthermore, these proposals are offered for consideration in the pending Anti-Counterfeiting Trade Agreement (ACTA) to be included in a special section on counterfeits and public health. This approach is one example of how trade and health policy and national law can be harmonized to serve both objectives.

## Legislation Checklist for Criminal Law to Control of Counterfeit Goods and the Public's Health <sup>25</sup>

### **POLICY**

1. Is there a cohesive national policy and plan of action on the protection of public health and intellectual property rights? Is this policy part of a larger cohesive national policy on how to balance trade and health objectives?
  - a. If yes, does the national policy provide for the control of counterfeit goods?
  - b. If yes, was the policy developed in consultation with all relevant stakeholders including and involving government agencies (NMRA, Customs, police, consumer products safety department and Judiciary), medical and consumer product manufacturers, wholesalers and other distributors, retail outlets, health professionals and their associations, consumers, non-governmental and relevant international organizations?
2. Are there legal provisions for the control of corruption in the country?
3. Does the policy require the NMRA, consumer products safety department and the criminal legal system to cooperate and collaborate with their counterparts within the region and internationally in the control of counterfeit products that endanger health and safety?

### **LEGISLATION**

1. Is there national legislation to support and authorize the national policy and plan of action on the protection of public health and intellectual property rights?
2. Does the legislation include IP crimes?
3. Does it provide for crimes occurring in the manufacture, importation, exportation, distribution, supply, and sale of counterfeit goods?
2. Are there specific provisions for the control of counterfeit medical and consumer products in the legislation? Are counterfeit medical and consumer products defined in the legislation?
3. Are the definitions of...

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<sup>25</sup> This tool is based in part on World Health Organization Guidelines for the development of measures to combat counterfeit drugs, 1999 and the WHO Tool for Assessment of Medicines Regulatory Systems, 2006.

- a. Counterfeit medical products in line with that of the WHO?
  - b. All other counterfeit goods in line with that of TRIPS?
- 4. Are there penal sanctions against criminals of counterfeit products that can cause harm to humans in the legislation?
- 5. Are the sanctions deterrent enough to prevent frequent occurrence of the problem?
- 6. Even though this study does not cover criminal procedure, it does stress the importance of a procedure for the reporting and referral of civil counterfeit case to the appropriate justice system office (e.g., attorney general or state prosecutor) for consideration of whether an IP crime has occurred. .
- 7. To support the determination that a counterfeit good does in fact pose harm to humans, a system of sampling or testing must be provided which can be conducted by the food and drug regulatory agency with laboratory capacity and can include visual inspection and other non-analytical checking such as basic tests on suspected counterfeit products.
- 8. Basic Elements
  - a. **Scope** of legislation and jurisdiction of courts.
  - b. **Definitions** – counterfeit, counterfeit trademark, copyright, other IP rights and counterfeit consumer product, counterfeit good, broker, distributor, exporter, importer, wholesaler, retailer, consumer, patient, victim. Is the definition of counterfeit consistent across all areas of the law (but most importantly, in the health, drug and other safety laws; consumer product safety laws; and criminal law?)
  - c. Does the law establish as criminal offenses under domestic law:
    - 1. The production, manufacture, preparation, sale, offering, offering for sale, distribution, delivery on any terms, importation, or exportation of any counterfeit good harmful to human health.
    - 2. The manufacture; transport; or distribution of equipment, materials or components used in the production of counterfeit goods harmful to human health;
    - 3. Participation in; association or conspiracy to commit; attempts to commit; and the aiding, abetting, facilitating, and counseling in the commission of any offenses described in the laws.
    - 4. Make the intent to counterfeit an element of the crime, which may be inferred from the facts and circumstances.
    - 5. Make the attempt to commit any one of the IP crimes a crime.

6. Make the fraudulent labeling of a counterfeit product or the trading of fraudulent labels a crime.
- d. **Sanctions** – In order to effectively combat the counterfeiting of goods that could or do cause human harm, all the sanctions described below should be available and mandatory without prejudice to those additional remedies and/or sanctions which are available under relevant criminal, civil, or administrative legislation.
1. Custodial sentences;
  2. Fines; Payment of damages to the IP rights holder and to the victim.  
Pecuniary sanctions can extend to the identification and seizure of bank records and accounts, proceeds of the crime, property, or other instrumentalities for the purpose of eventual confiscation.
  3. Confiscation of assets;
  4. Confiscation of instruments used to commit the crime;
  5. Total or partial closure, on temporary or permanent basis, of the establishment(s) involved in the commission of the offence;
  6. Permanent or temporary ban to engage in product-related activities;
  7. Destruction of the goods involved in the offences;
  8. Ban on the access to public assistance or subsidies;
  9. Placing under judicial supervision;
  10. Judicial winding-up;
  11. Indemnification of affected/damaged parties (including, inter alia, affected victims, affected operators, and manufacturers of genuine products);
  12. Publication of judicial decisions (including dissemination of information to international organizations and to national competent authorities of other countries);
  13. Withdrawal of licenses.
  14. Recall from the market
  15. Use of illegal gains: Without prejudice to other compensation mechanisms, money derived from confiscation of assets should be placed in a public fund for the purpose of compensating victims and financing anti-counterfeit operations.
  16. National criminal procedures may include provisions on extradition, mutual legal assistance in the investigation, prosecution and judicial proceedings in relation to criminal offenses established in the treaty, and the transfer of proceedings.
  17. Other topics related to offenses and sanctions can include provisions on a statute of limitations, release and parole of persons convicted of these crimes, limitations on discretionary powers relating to the prosecution of these crimes, no limitation on the exercise of criminal jurisdiction under domestic law and rights of bona fide third parties.

9. Aggravating Conditions: Aggravating conditions are a basis for the determination of the class of offense and severity of penalty. Any product ingested or used by humans when counterfeited should be defined as a per se threat of harm to persons. The following are examples of and can be considered aggravating conditions:
- a. Death or serious injury to persons affected,
  - b. Affecting the health of a large number of persons,
  - c. Risk for endangering the health of a large number of persons,
  - d. Risk of death or serious injury to persons affected,
  - e. Acquisition of considerable pecuniary gain,
  - f. Perpetrator is an authorized operator (manufacturer, retailer, other)
  - g. Perpetrator is a health professional
  - h. Repeated offence
  - i. Organized crime