United Nations
Interregional Crime and Justice
Research Institute

Counterfeiting,
A GLOBAL SPREAD, A GLOBAL THREAT

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advancing security, serving justice,
building peace

Counterfeiting

a global spread
a global threat

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Foreword

Counterfeiting, consumers' safety and the challenge posed by organized crime to the world economy

Counterfeiting has changed, dramatically and rapidly. This finding inspires the roadmap we will follow in this assessment report.

Counterfeiting has changed to become a terribly dangerous criminal activity. The numerous victims claimed by counterfeit products like drugs, beverages, and spare parts testify to the true nature of this crime. For those of us bound to the traditional view of counterfeiting as a typical craftsman activity, this truth could be shocking.

From luxury goods, music CDs and film DVDs to medicines, toys, food and beverages, spare parts and electronic equipments, everything can be forged. And quite well, we must admit. So well that even the producers themselves, sometimes, experience difficulties in telling the original product from its unauthorized copy.

Albeit the appearance is almost the same, the substance is dramatically different. Counterfeit drugs contain no active ingredients or poisonous substances; spare parts for automobiles and aircrafts do not possess the necessary durability and strength requirements; toys are produced using toxic lead paint while small parts are easily detachable and could be swallowed by a child.

Even more worrying, it is not only a matter of what is illegally reproduced; it is also a matter of who is behind the fraudulent imitation.

Organized criminals have since long grasped the opportunities that counterfeiting could provide them. The huge profits created by this crime, the weak penalties provided by the relevant legislation and the low level of awareness among the competent authorities and the civil society, rendered counterfeiting one of the most profitable and less dangerous activity for organized crime.

Moreover, counterfeiting is not only a golden mine for organized crime. It is also one of the preferred means by which money can be laundered and reinvested.

A part of the International Community – perhaps a too wide one – witnessed this process without fully understanding its implications. It is only in most recent times that we began to perceive that counterfeiting could kill us and that organized criminals could exploit our lack of awareness to increase their operating potential, infiltrate licit economy and flourish quite undisturbed.

Now the time to act has come. This assessment work will support the growth of awareness regarding the counterfeiting phenomenon, the distortions it creates for the world economy, the dangers it poses for the consumers' health and safety, and the profits it creates for organized crime. UNICRI is committed to lead with a sense of urgency new endeavors and new protagonists with the aim of finding common ground to improve the efficacy of our struggle against the major challenge posed by organized crime to the world economy and to the consumers' safety.

Sandro Calvani
Director, UNICRI

List of Acronyms

ACG	Anti Counterfeiting Group
CACN	Canadian Anti-Counterfeiting Network
CASA	Civil Aviation Safety Authority
CBSA	Canada Border Service Agency
CD	Compact Disk
CEBR	Centre for Economics and Business Research
CEIPI	Centre d'Etudes Internationales de la Propriété Industrielle
DEA	US Drug Enforcement Administration
EC	European Commission
EU	European Union
EUCD	European Copyright Directive
FAA	Federal Aviation Authority
FALSTAFF	Fully Automated Logical System To Against Forgery & Fraud
FDA	US Food and Drugs Administration
FBI	Federal Bureau of Investigation
GACG	Global Anti Counterfeiting Group
HIV	Human Immunodeficiency Virus
HP	Hewlett-Packard Company
ICC	International Chamber of Commerce
ICE	US Immigration and Customs Enforcement
IPRs	Intellectual Property Rights
IT	Information Technology
MEMA	Motor and Equipment Manufacturers Association
NAFDAC	National Agency for Food, Drugs Administration and Control
OECD	Organization for Economic Co-Operation and Development
PC	Personal Computer
PDMA	Prescription Drug Marketing Act
RAPO	Russian Anti-Piracy Organization
R&D	Research and Development
RCMP	Royal Canadian Mounted Police
SCICO	Central Service for the Investigation of Organized Crime
smi-ati	Italian Federation of Textiles Enterprises and Fashion
SUPs	Suspected Unapproved Parts
TAXUD	Taxation and Customs Union (European Commission)
TRIPs	(Agreement on) Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom of Great Britain and Northern Ireland
UN	United Nations
UNICRI	United Nations Interregional Crime and Justice Research Institute
US	United States of America
USA	United States of America
WCO	World Customs Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Executive Summary

Counterfeiting is a rapidly expanding criminal activity which poses serious threats to consumers' health and safety. An undeniable link today exists between counterfeiting and criminal organizations, as demonstrated by the results of various criminal investigations. Attracted by the profitability of this illicit activity, criminal organizations now control the actual production and trade of counterfeit goods.

The profitability of counterfeiting is not limited to the economic sphere. Given the fact that it is an illegal activity, the risk linked to the activity itself is of critical importance. This low risk level is potentially one of the most appealing elements for criminal organizations given the lack of adequate deterrents within the applicable legislations of various countries. This lack of deterrence is the result of a distorted perception on the part of legislators and competent authorities with respect to the effects of this phenomenon. Despite an increasing awareness of the scale of the problem, legislation has often been constrained by a purely economic analysis of the phenomenon whose negative effects are believed to exclusively affect producers from a financial point of view. First of all, this viewpoint does not take into account the significant consequences caused by the involvement of organized crime in the management of such activities nor the risks for the safety of citizens and public order. This perspective is also limited from another point of view: it not only neglects the elevated risk for the health and safety of consumers - as a result of certain counterfeit products - but it also ignores the damage caused to government revenues due to the existence of untaxed traded goods. Counterfeiting is far from being a victimless crime and international and national responses to the problem should take this into due account. Standards that only punish counterfeiting on the basis of economic damages or as a result of a violation of public faith are not sufficient.

The rapid diffusion of technology allows for a relatively easy replication of every kind of product on the market. Albeit the economic consequences deriving from counterfeiting constitute a *trait d'union* among the various types of the so-called "fakes", the replication of certain kinds of products is cause for a greater concern. Counterfeit medicines, toys, foods and beverages as well as spare parts for cars and aircrafts pose a great risk for public health and safety. Unscrupulous criminals are solely concerned with the high profits that can be derived by Intellectual Property Rights (IPRs) infringements.

Intellectual Property Rights have the peculiar function of protecting the author of a literary, scientific or artistic work; the manufacturer or inventor of a product; or the entrepreneur or company who trade their goods using a particular mark or sign as a badge of origin and quality, from any form of illicit reproduction of the results of their creative activity or of the good reputation acquired through the years. Dif-

ferent forms of IPRs are established, following the various forms through which human intellect can express its creative potential. For example: Copyright, Patents, Industrial Designs and Trademarks.

The growing importance of Trademarks, Patents and Industrial Designs in modern trade has led progressively to the increasing importance of the economic side of IPRs. However, the opportunity to exploit another's Name, Symbol or Product as well as the literary and artistic expression of another person's intellect at the same time began to attract the attention of criminals and led to the beginning of the counterfeiting activity, which subsequently grew immensely.

Providing precise data and information on the problem is extremely difficult. Counterfeiting is in fact linked to illegal markets and it is therefore difficult to quantify figures, given the problems associated with collecting and comparing data. However some estimates are available. The Organization for Economic Co-operation and Development (OECD) states that at least 200 billion US dollars of international trade in 2005 could have been in counterfeit or pirated products, while the World Health Organization (WHO) reports that between 7-10% of all pharmaceuticals products in the world are possible counterfeits, reaching a total of 30-40% in some African countries. Regarding the toy sector, the Toy Industries of Europe states than one toy out of ten would be a counterfeit in Europe; with regards to the automotive sector, the incidence of counterfeit spare parts could be quantified as a loss of 12 billion dollars per year. Following the data provided by the World Customs Organization (WCO) and the European Commission DG – TAXUD, on the seizures made by customs officers in the respective Member Countries, it is possible to affirm that the global trade in counterfeit goods is indeed growing. Considering the years 2000-2006, an 88% increase in the seizures of counterfeit goods was registered in the European Union, with almost 68 million goods seized in the year 2000 and more than 128 million in 2006.

Different causes lie underneath this exceptional growth. Counterfeiting is a very lucrative illicit activity, even if compared with other profitable ones like drugs trafficking or arms smuggling. Weak penalties and enforcement as well as lack of awareness regarding the involvement of organized crime among the civil society and the competent authorities led to an underestimation of the consequences it creates for the society as a whole.

In this regard it is possible to affirm that the economic damage caused to authors and producers is only one of the several negative effects of this illicit activity. From a merely economic point of view, in fact, decreased profits for producers imply a lower level of investments for product improvement as well as decreased innovation and, possibly, job losses. It estimated that - in the European Union alone - , more than 100,000 jobs are lost every year due to counterfeiting. In the United States of America, a study performed by the National Customs Service estimated 750,000 job losses caused by counterfeiting.

The diffusion of fake products sold as original ones to unwary customers, due to their low quality and high defectiveness, could lead to a lack of trust with respect to original manufacturers, with negative effects on their market share. Moreover, counterfeit products are produced and

traded within an unregulated market and this creates a lower level of taxes and revenues collected by States.

Counterfeiting poses more risks for all the civil society. The unauthorized replication of certain kinds of products like medicines, toys, foods and beverages, spare parts for automobiles and aircrafts creates serious threats for the public's health and safety. There are several cases that testify to how the use of counterfeit products could be extremely harmful, or even deadly, for consumers. The use of counterfeit baby milk-powder formula containing no nutritional value caused the death of at least 13 babies in China in 2004; counterfeit raki, a typical turkish alcoholic beverage, killed 23 people in Turkey in 2005; the use of diethylene glycol in counterfeit cough syrup, anthistamine tablets, calamine lotion and rash ointment killed 38 people in Panama in 2006; and a counterfeit drug containing diethylene glycol caused the death of 11 people in China in the same year.

Counterfeit medicines are today a point of great concern. Their diffusion is constantly growing, especially because of the role played by the Internet in their dissemination. The Internet has been appropriated by criminals and utilized as a giant and anonymous market that allows counterfeit products to be easily offered and purchased. According to the WHO, more than 50% of medicines purchased online from Internet sites concealing their URL addresses would be counterfeit. The US Food and Drug Administration (FDA) states that almost 10 million of postal parcels containing medicines enter the United States of America each year.

The Asian and African regions seem to be the most affected by counterfeit medicines. According to the WHO in Africa, more than 30% of medicines on sale could be counterfeits in parts of Asia and parts of Latin America while in the former Soviet republics counterfeit medicines could constitute more than 20% of market value.

Fake medicines will usually contain a lower level of active ingredients or no active ingredient at all, failing to cure the patient. Several cases have been registered in which the fake products contained poisonous substances, as the diethylene glycol previously mentioned – therefore even more dangerous for the patients' health.

Counterfeit medicines are usually sold to unwary customers. Counterfeiters are able to infiltrate their products into the legitimate commodities' supply chain exploiting the complexity of the production and distribution systems. The existence of a great number of outsourced producers as well as wholesalers, retailers and parallel traders - without correspondingly tight regulations regarding their roles and functions - creates serious impediments for controlling and securing the medicines' trade and distribution. As a result, counterfeit drugs have been discovered in local pharmacies even in European and North American countries.

The extreme profitability of counterfeiting attracted the attention of organized crime. Due to its involvement, the production and distribution phases of counterfeit products were greatly improved. Criminal organizations operating in different countries have established close ties and synergies. The same routes and concealment methods utilized to traffic drugs or firearms, for example, can be exploited for trafficking counterfeit goods while the great potential for intimidation and corruption of organized crime is another facilitating factor.

Counterfeiting represents a huge source of money for criminals – liquid funds which are readily reinvested in other illicit activities. The possibility to infiltrate the licit supply chain and sell fake products as original ones, allows counterfeiters to also utilize this activity to launder the proceeds deriving from other crimes.

In order to improve the global response to counterfeiting and taking into consideration the complexity of the phenomenon, a series of proposals have been elaborated.

- More importance should be given to data collection and analysis. The availability of more information and data is of crucial importance for the identification of more incisive actions against counterfeiting, while data elaboration would allow for the verification of their results. Both the public and private sector should contribute more actively to this end;
- Criminal law on counterfeiting should contain more severe penalties and their application should be more effective;
- All the different phases, from production to sales, should be taken into consideration. In particular, criminal laws should not make any distinction between those products intended for import and those intended for export or transit;
- Awareness raising activities for law enforcement agencies involved in the fight against counterfeiting should be promoted and organized, highlighting the involvement of organized crime and the risks created by this illicit activity;
- Codes of conduct as well as investigative protocols should be elaborated, with the aim of improving the efficacy of the law enforcers' actions. Training courses for police forces and prosecutors should be organized, presenting the most effective investigative techniques and providing a constant update on the relevant national and international legislative frameworks;
- Detection techniques of counterfeit goods and concealment methods utilized by counterfeiters constitute important topics upon which specific training activities for customs officers should be conducted;
- The adoption of integrated IT customs risk assessment systems should be promoted and supported. In these regards, technical assistance programmes could be planned and implemented as well as training courses for the systems' operators. More attention should also be given to the usage of postal parcels and postal couriers as a mean to dispatch counterfeit goods purchased via the Internet; and transshipment through Free Trades Zones;
- The security of shipping documentation should be enhanced, possibly through legislative action indicating security requirements that should be present in shipping documentation in order to avoid simple falsification;
- Methods to secure the commodities production and supply chains should be discussed, with the aim of protecting the consumers' health and safety without affecting free trade. In particular, producers and distributors should adopt specific codes of conduct aimed to secure the production (i.e. sources of raw materials or more controls with regards to outsourced production) and distribu-

tion (i.e. more controls regarding the different steps composing the commodities supply chain) of original products;

- The role of the Internet as a facilitating factor in the trade of counterfeit goods should be more deeply analyzed;
- The private sector should more actively contribute to the diffusion of information regarding the presence of counterfeit versions of their products on the market. This would support the activity of law enforcers while enhancing the safety of consumers;
- Awareness raising activities directed to producers and the public at large, explaining the severe consequences deriving from counterfeiting, should be planned and realized;
- National and international cooperation should be enhanced, with the aim of avoiding the duplication and waste of resources while improving the efficacy of the response to the problem. In particular, the private sector should be more involved.
- An International Permanent Observatory on Counterfeiting could provide services and facilitate a needed acceleration in the execution of the above mentioned proposals. Good practices that are now applied in some specific areas (i.e. medical products) might represent a good model of coordinated action for other sectors as well.

Methodological introduction

The research presented in this report was realized following a twofold principle for the collection and the analysis of information.

The aim is to present as much of an exhaustive perspective of counterfeiting as possible, considering this not only as an economic phenomenon but also as a criminal activity. The drafting of this action oriented research was guided by the purpose of providing a complete "diagnosis" that could allow those approaching this argument for the first time to better understand its complexity and the dangers it creates. At the same time, we intended the research to represent an important tool for those already experienced in the study of the phenomenon, especially for deepening the analysis and developing possible responses.

This work discusses the different aspects of counterfeiting in one single research project. It presents the economic damages together with the social consequences created by the problem and highlights the dangers it creates. Particular attention is given to certain kinds of counterfeit goods particularly "sensitive" for the consumers' health and safety while showing the interest of organized crime in managing this illicit activity.

An extensive analysis of the existing literature on the subject is offered to the reader as well the result of meetings/semi structured interviews with "key informants". The literature analysis highlighted the need of a multidisciplinary approach. While various studies discuss only the single aspects of the problem – intellectual property rights, medicines counterfeiting, organized crime – few are the sources from which an in-depth perspective of the relationship counterfeiting-organized crime can be obtained.

The interviews/meetings with "key informants" gave us the opportunity to discuss and verify different working hypotheses and to identify intervention strategies based on the experience of those people that work in this field.

In particular, existing studies have been analyzed, with the aim of presenting the importance and role of intellectual property rights to protect the creative activity of individuals, and the economic and social consequences created by counterfeiting.

The analysis of organized crime's involvement in counterfeiting activities enabled direct contact with those individuals and institutions actively involved in the fight against organized crime. Their experience provided us with important suggestions for the continuation of the research activity and allowed us to characterize the study with a less rigorous and more realistic approach.

The analysis of the already published available information has been integrated with the direct gathering of information obtained by various experts involved in countering the phenomenon.

The research was particularly focused on the European context, but the considerations made can be extended to other geographical areas. Various aspects of the phenomenon have been examined from an international perspective.

This is an action oriented research. As a result, and with the aim to provide a response to the phenomenon, different proposals have been formulated. The annexes are examples of information/instruments – a legislative analysis on the subject and a collection of particularly interesting counterfeiting cases – that could prove to be of great importance to conduct further studies in the future. The legislative annex presents the relevant international legislation on the subject as well as an analysis of the most recent normative instruments adopted by the European Community Institutions together with some examples related to their national implementation in the EU Member States. The analysis of the national implementation of the EU legislation was completed by direct consultations with some of the EU Member States.

The scarceness of available data regarding the extent and quantification of the counterfeiting - organized crime phenomenon and the difficulties experienced in comparing data rendered impossible any attempt to conduct a rigorous statistical survey on the development of this relationship. Notwithstanding this difficulty, thanks to the information on counterfeit products seized by customs officers collected by the European Commission – DG TAXUD, the World Customs Organization and the Italian Customs Agency, the silhouette of this evolution was outlined.

It is therefore certain that counterfeiting is an illicit activity linked with the existence of an unregulated and submerged market. The magnitude of this global emerging crime is threatening, especially if one considers that what we see is only the tip of the iceberg while the main part is still submerged.

1. Intellectual property rights

The term "Intellectual Property Rights" (IPRs) is often used – even in legal settings – in a rather broad manner; its meaning incorporates a range of concepts in which the legal system grants protection over the creative activities of individuals and organisations. Different types of protection are granted by law to the different forms through which creative work is expressed and implemented. These differing types of protection generally grant the entitled parties with the right to utilize – temporarily and in an exclusive manner – the results of their creative work; other parties are excluded from enjoying such rights and the work subject to protection is prohibited from being reproduced and marketed (if the work is marketable) unless explicitly authorized by the owner of such rights. This therefore reflects the idea that the results of creative and intellectual work by individuals are not only worthy of protection but are also susceptible to acquisition on the part of the creating party, in accordance with the right to private property over material goods. Intellectual Property Rights may therefore also be transferred, sold or licensed to third parties.

The protection of the creative work is based on the rationale that positive effects may be generated for the common good given the incentive that this protection provides with respect to research and innovation.

In addition to the protection of the creative activity of individuals and organisations, Intellectual Property Rights also protect the commercial activity of either individual entrepreneurs or commercial enterprises. The latter identify and market their products and services under a "symbol" or a "name" that they create to represent their commercial activity. This symbol or name has a fundamental importance in modern trade because it allows consumers to distinguish products and services offered by different entrepreneurs. Consumers evaluate the quality and the price of what is offered under that particular symbol or name and the entrepreneurs who invest to add value to the products and services offered and build their commercial reputations.

In order to more accurately define the area of influence of intellectual property rights, it would be opportune to initially classify the variety of creative and innovative activities that may be expressed by individuals, noting that intellectual property laws grant and specify a series of rights in relation to the creative idea itself or the form in which the latter is expressed (music – film, industrial products – inventions and brands, to name a few).

- **Copyright**: copyright protection grants the author of artistic, literary and generally creative work (music, film, paintings as well as software) with the exclusive right to control - for a certain period of time - the reproduction, marketing or adaptation of such works.
- **Patents**: the granting of a patent is the result of a new and creative invention

following the presentation of a special request, thereby providing the inventor with the right to exclusively but temporarily enjoy the fruits derived from marketing the invention.

- **Industrial designs**: guarantee protection to a particular form or style of industrial activity which characterizes a certain type of production of the party retaining such rights, thereby avoiding the replication of this form/style without authorization. Furniture or textiles as well as spare parts for automobiles and mechanical equipment are examples that would fall under this category.
- **Trademarks**: these refer to protection that is granted in favor of a distinctive sign characterizing a commercial or productive activity or the supply of a service, thereby preventing third parties from taking advantage of the reputation that is acquired by placing the trademark on their products or services. Trademarks become the symbol of the activity of entrepreneurs offering their goods or services on the market. They incorporate the reputation acquired by entrepreneurs through the years of activity and are an assurance of good quality for consumers.

Patents, trademarks and industrial designs are part of so-called "industrial property", while copyright protects the results of artistic and literary creation. Both forms of protection refer to information or knowledge which may be integrated in a tangible manner and supplied through an unlimited number of copies. Intellectual Property Rights are granted to the actual content that is shared by the copies and not the copy itself; the latter may be transferred, sold and distributed and represents a commercial consequence of Intellectual Property Rights.

Before considering specific cases of protection and their associated rights in more detail, it should be noted that intellectual property – or, more specifically, the rights deriving from the latter – often acquire a negative connotation by excluding unauthorized parties from enjoying their fruits and allowing the owner of these rights to act in an almost monopolistic manner.

These characteristics of intellectual property acquire additional significance when the property is linked to commercial activities on the part of the party retaining the associated rights, given that it allows this party to exclusively exploit their creation or invention as well as the reputation acquired over years and attributed to their trademark: the "creation" of "brand loyalty". There are therefore commercial elements linked to the protection of intellectual property rights – the influence of these elements has significantly grown over recent years at a rate that is almost directly proportional to the expansion of commercial trade and the expansion of markets.

The requirement for such protection has also grown as the result of another factor: the possibility of generating profit by exploiting a particular trademark or a particular product has resulted in the phenomenon of counterfeiting on the part of subjects which are not authorized to replicate the products or trademarks in question. These parties attempt to generate profit by exploiting the idea, image and reputation of others.

Although there are numerous consequences deriving from counterfeiting, it should be noted that specific concern is

caused by the evolution of the phenomenon itself; the target of the latter - and therefore the products being replicated - have been gradually changing. Luxury goods – initially considered by counterfeiters as one of the most profitable goods to replicate and market – have progressively been flanked by goods with much broader market penetration, such as musical CD's or DVD's and sportswear, but also toys, spare parts for motor vehicles and aircrafts, and particularly medicines. The unauthorized and uncontrolled production of these categories of goods, however, poses a significant risk for the health and safety of consumers.

Counterfeiting activities – and the shift towards goods that are more easily replicable and more difficult to recognize as copies – have become extremely profitable and widespread. These activities have attracted the interest of organized crime which today - without the shadow of a doubt - pulls the strings and weaves the webs in which this phenomenon is embedded.

1.1 Intellectual property

Intellectual property is typically subdivided into two categories reflecting the different ways in which the creative potential of the human intellect and enterprise is expressed: industrial property and copyright.

The difference underlying this distinction is essentially based on the idea of conceptually separating creative activity which results in an invention, an innovation or in the identification of a symbol representing a commercial activity, and that which yields an artistic, scientific or literary creation. In the first, the idea and the novelty expressed by the creation is protected, thereby ensuring protection against utilization on the part of unauthorized third parties. Within this category falls also the protection of those symbols or names which are created and utilized by entrepreneurs for commercial purposes and with whom they identify their commercial activity. The protection which is granted is limited in time - usually a twenty-year period. On the other hand, copyright doesn't protect the idea itself but rather the manner in which it is expressed, whether as a sequence of notes, words or images; the protection involves preventing others from copying this form of expression without authorization: hence the term copyright. Given that the target of protection therefore differs with respect to industrial property and given that copyright does not involve the possibility of creating a monopolistic use of information, the duration of the protection is longer than that granted for industrial property; copyright is generally granted for the whole duration of the author's life plus a period which generally ranges from 50 to 70 years.

Descriptions of copyright and industrial property will contain references to currently effective international agreements, particularly the *Berne Convention for the Protection of Literary and Artistic Works* and the *Paris Convention for the Protection of Industrial Property*. Both have been included within the *Agreement on Trade-Related Aspects of Intellectual Property Rights – TRIPs Agreement* initiated by the *World Trade Organization* (WTO).

Copyright

Article 2 of the Berne Convention defines and outlines the field of artistic and literary works, stating that the agreement covers all production within the artistic, scientific and literary domain, regardless of

the method or the form in which they are expressed[1].

The same article provides some examples of certain productions, including: books and written works in general; choreographic works and works with entertainment value; musical compositions, with or without words; film works; painting, design, sculptural, engraving and architectural works; photographic works; applied art works; translations, musical adaptations and arrangements; and collections of literary or artistic works such as encyclopedias and anthologies.

This list is obviously not considered exhaustive given that software is also included within the concept of artistic or literary work being the result of creative scientific work and therefore falling – by all effects – under the scope of Article 2.

Rights deriving from copyright and their duration

The copyright holder is granted exclusive rights from both the Berne Convention as well as from the majority of national legislations. The term "exclusive" notes that only the copyright holder may exercise these rights, thereby excluding all unauthorized third parties from exercising them. The copyright holder may also decide to not utilize any of the rights that are provided for, or to exercise them over a limited period of time, given that this is a right which fully falls under the provisions of the international and national legislative frameworks relative to copyright.

It is possible to distinguish between two different typologies of rights granted by copyright: economic rights, which allow the copyright holder to obtain profits if her/his work is utilized by other parties; and moral rights, which allow the copyright holder to act in order to maintain a connection with the results of her/his creative work.

The economic framework of copyright generally allows the author to prohibit or authorize a series of behaviors/actions in relation to her/his creative work, including: the reproduction of the work in various forms; the distribution of copies of this work as well as its public representation; broadcasting of the work by radio/television or through other media; translation into other languages; and adaptations of the work.

It should be noted that the ability of the copyright holder to prevent the reproduction, distribution, marketing and importing of copies of her/his work is potentially the central element on which the economic protection granted by copyright is based; the latter is reinforced by the other rights mentioned above[2].

The strictly commercial element of copyright is supported by an additional element whose specific goal is to guarantee that the origin of the work is always acknowledged and – in accordance with the provisions of Article 6 bis of the Berne Convention[3] – must be considered separate from the commercial component. In addition, moral rights may not be transferred – unlike economic rights – and their recognition is only granted to the individual author[4].

The rights analyzed thus far are generally attributed to the author of the artistic, scientific or literary work by the Berne Convention itself. It is, however, possible to state that – although moral rights are always retained by the author – commercial rights are subject to certain exceptions to

the general rule linking these rights to the author of the work[5].

Rights deriving from copyright are subject to limitations relative to the individual copies that are legally produced, marketed and acquired by a third party; the latter becomes the owner of the copy in question. In particular, the owner is not prohibited from re-selling the copy, with the exception of cases where the transfer of ownership occurs between parties operating in different countries where there are importing limits relative to such products[6].

The limitations mentioned above include a series of exceptions that are specified within the majority of national legislations of reference and which concern particular categories of goods. The Berne Convention itself, in any case, recognizes the free usage of certain categories of works within Article 9 (2) so long as this usage does not interfere with the legitimate rights of the author and does not lie outside the normal usage of the work in question. This free usage consists, for example, in the possibility of citing certain phrases of a book while obviously mentioning the source of the citation and the author as well as utilizing a work for illustrative, educational or even informational purposes[7].

The determination of a copyright's duration falls under the competence of national legislation. Within countries that are bound by the Berne Convention, the minimum guaranteed protection must, in any case and in accordance with Article 7, correspond to the life of the author plus fifty years after her/his death. National legislations differ as to when this protection should begin; in certain cases, the initial date corresponds to the date of creation of the work while other cases provide for the date in which the work has been concretely completed. Current trends have involved a lengthening of the period of granted protection in order for the author's heirs to more fully enjoy the fruits of the creative work[8].

Patents

Patents grant a series of rights that are exclusive and limited in time with regards to the creation of a product or an innovative productive process. This provides an outline of the primary characteristics of this form of protection of industrial property. Firstly – and unlike copyright – the attainment of a patent is the result of a regular procedure whereby the patent is requested, implemented by a private citizen or an employee of an organization with respect to the government – given that the latter is the entity which grants the rights that are provided for by protection regulations.

Secondly, this protection is only granted in connection with the creation of an innovation, whether a product or a productive process. The underlying rationale for granting this protection is based on a particular type of "exchange" that is implemented between the inventor and the government. The latter, in fact, grants the protection deriving from a patent on the condition that the creating party reveals the technology or the procedure underlying the invention; the technology/procedure is described during the request procedure and then recorded within state archives once the patent is granted. In this manner, the government reserves the right to assess the existence of the pre-requisites which form the basis for granting the protection and thereby acquires the "secrets" of the inven-

tion; the exclusive utilization of the latter will be protected for a limited period of time, typically twenty years. Given that the knowledge underlying the invention is, however, of public domain, other parties may create improvements of the technology itself and request a patent on such improvements.

The theoretic justification underlying the granting of a patent – despite being currently subject to criticism from several fronts[9] – involves the idea that the temporary protection serves as both an incentive for research, experimentation and innovation as well as a guarantee that the idea itself will be preserved within registries that are made public and finally available to the public at the end of the granted protection period.

In accordance with the provisions of Article 27 of the TRIPs Agreement, a patent may be granted for an invention – whether a product or productive process – if it not only represents a novelty but also incorporates a creative/inventive element in addition to being susceptible to industrial application[10].

The subsequent article specifies the exclusive rights that are granted to the patent holder following its granting. In particular, and if the subject of the patent is a product, the patent holder retains the right to prevent third parties from producing, utilizing, selling, marketing and importing the product in question without her/his consent. If, on the other hand, the subject of the patent is a productive process, the patent holder may prevent third parties from utilizing the productive process in question.

For this purpose, it should be noted that the granting of a patent does not automatically imply the possibility of marketing the product over which protection has been attained. The marketing of the product may only be implemented in compliance with all laws and authorizations regulating such matters. Consider, for example, protection concerning the production of a new type of medicine: the patent does not correspond to an authorization to market the medicine; marketing the latter will require complying with all required laws and procedures.

In accordance with the provisions of the Paris Convention – whose norms are moreover incorporated within the TRIPs Agreement – the application procedure for a patent within a member state is coupled with a priority right relative to the presentation of the same patent request in one or more other countries which have ratified the convention. In this case, the application procedure implemented in the second country is assigned the same date as the date of presentation of the first application. The priority right has a duration of twelve months from the date of presentation of the first patent application in any of the member states.

The Paris Convention and the TRIPs Agreement itself also stipulate limits to the sole rights deriving from the patent, thereby reflecting the balance between private and collective interest which characterizes regulations in this sector. Article 5, A, (2) of the Paris Convention, in fact, considers the case in which the patent holder decides to abuse her/his rights by not utilizing the invention. In this case, the granting of a right to a private citizen would not result in a real benefit for the community – at least not until the expiration of the patent. In order to prevent such situations, the article provides for the possibility of mandatory licenses relative to the usage of the

product or the productive process[11].

National laws regulating this area may also specify other cases allowing the utilization of a good subject to protection without the authorization of the patent holder. These cases generally refer to situations in which – due to the very nature of the product or productive process – priority is given to the collective interest or to utilization of the invention on the part of the government, thereby resulting in (typically rare) mandatory licenses in favor of government entities or structures[12].

At the end of the period of sole (exclusive) rights granted by the legal system, the invention becomes of public domain and the right to commercially exploit it becomes universal given that the original inventor no longer retains the exclusive rights.

Industrial designs

The protection of industrial designs is provided for in the Paris Convention and the TRIPs Agreement. While the former only establishes a generic commitment assumed by member states in this regard[13], the latter contains much more detailed regulations. Article 25.1 of this agreement affirms that member states must commit to granting protection to those industrial designs which present characteristics of novelty or originality although it is possible to deny protection to products whose design has been exclusively dictated by their designed function.

The definition found within the TRIPs Agreement serves as a good starting point for considering certain characteristic elements of protection that are granted to industrial designs by the legal system of the state. The design is considered to be a purely aesthetic or ornamental element that is incorporated within an object that is mass-produced. Reference is therefore made to products deriving from an industrial process whose aesthetic element serves a differentiating function with respect to other products of the same category and which are created for the same purpose. The aesthetic element – similarly to the quality, price and function of the marketed good – represents one of the potential selection criteria of the consumer. The need to protect this distinctive element derives from this ability to influence consumer choices.

This protection is only granted to a design relative to a good produced on an industrial scale that possesses certain specific characteristics. These characteristics – as noted moreover in Article 25.1 of the TRIPs Agreement – include the novelty or originality of the design and the fact that the latter is not exclusively imposed by the function for which the good is produced. Granting protection over the design of widely distributed products – such as a simple screw or a belt – would distort the market by creating monopolies in which only one producer would have the possibility of manufacturing and selling screws or belts. On the other hand, it is possible to protect a particular design applied to screws or belts if this design represents a novelty and characterizes the producer, thereby rewarding the latter for the effort and creativeness involved in the design and stimulating further research in this realm.

The identification of the good which is subject to the protection guaranteed by industrial design rights allows this protection to be differentiated from copyright protection. Copyright, in fact, protects an idea ex-

pressed in a particular form while in this case the idea itself is protected; the idea is defined as an abstract concept incorporated within the good but it is not the latter that is protected but rather the idea underlying the good.

The protection is granted following the completion of a procedure for the registration of the industrial design; its duration varies from country to country, ranging from a minimum of ten to a maximum of twenty five years. The rights are usually granted to the creator of the design[14].

The guaranteed rights are also exclusive in this case and serve the final purpose of preventing unauthorized third parties from commercially exploiting the registered industrial design. In particular, unauthorized third parties may not implement the following actions for commercial purposes: manufacture, import, sell or market goods which reproduce or incorporate the protected industrial design[15].

Trademarks

A trademark is a symbol and/or a name which identifies the goods or services of an entrepreneur and/or her/his company and allows consumers to distinguish goods or services from those supplied from other companies or entrepreneurs. The primary function of a trademark is therefore to differentiate manufacturers, suppliers of services and entrepreneurs in general and is obviously linked to the quality of what they offer and market. The rationale behind the existence of a trademark is based on a collection of interests given that it is important that the consumer can direct her/his purchasing choices towards products whose origin represents a quality guarantee and that the efforts implemented by the producer – in order to reach these quality standards – are protected.

In this case, protection for the consumer and the entrepreneur meld together, thereby creating the basis of trademark protection regulations contained within the legal system.

Article 15.1 of the TRIPs Agreement allows the trademark to be defined as any symbol, name or combination of the latter – given the restrictions described below – which allow the products or services of one company to be distinguished from those of other companies. The definition includes two correlated elements or functions. These elements or functions are contained within the distinguishing nature of the trademark; such a distinguishing nature is, moreover, required in order to register the mark itself and allows the consumer to identify the good/service.

The existence or inexistence of the distinguishing function of the trademark allows the variety of symbols and names existing in nature to be placed within a hypothetical *continuum*; the latter is limited by clearly distinctive or arbitrary symbols or names at one end, and generic symbols or names at the other. The more a symbol is arbitrary or distinctive or comes close to having such characteristics, the more it will tend to be considered representative of a particular producer of goods and services, thereby allowing it to be used as a trademark. On the other hand, an excessively generic name or symbol does not sufficiently guarantee the distinguishing function of the trademark and its usage for this purpose will not be recognized by the legal system. Consider, for example, the usage of the Hewlett Packard (HP) trademark for

the production of electronic devices for PCs, such as printers, scanners and even digital cameras. HP is a sufficiently arbitrary or distinctive name and thereby allows the consumer to differentiate a printer produced by Hewlett Packard, for example, from other printers that are marketed by other producers. The same can not be said, however, for a manufacturer which intends to use the word "printer" as a trademark, given that this term is clearly generic and does not serve any distinguishing function. This argument may also be extended to cases where the trademark is not a name but a symbol.

Further limitations involve the utilization of certain categories of symbols such as country flags or symbols of international organizations or other symbols which may be ethically wrong or could negatively affect public order[16], in accordance with the Paris Convention. The said convention also specifies that national authorities which are entrusted with the task of registering trademarks may oppose a registration in the case that the trademark in question is a reproduction, imitation or translation of a previously known mark in that country[17].

The protection granted to trademarks by the legal system may result from: a) the registration of a trademark or, if required, b) the prolonged utilization of the latter. The Paris Convention, in any case, requires that all member states – even those which grant protection on the basis of usage – create a registry of trademarks. Registration is implemented by means of an application; the purpose of the latter is to allow the government to verify the existence – or inexistence – of the characteristics that are required for the symbol or name to be utilized as a trademark. This application procedure is currently the most widespread while usage primarily acquires a certain level of significance in common law jurisdictions.

The rights which this protection grants to the owner of the registered trademark are linked to the exclusive usage of the latter, given that the owner may prevent unauthorized third parties from commercially exploiting the mark or a similar one for similar products or services. This prevents consumers from being deceived or in any case prevents confusion with regards to the registered trademark[18]. The duration of the protection varies from country to country, but this limitation is essentially based on the bureaucratic formalism of the administrations which are entrusted with trademark registration – given that it is possible to renew the protection term for an equivalent duration on the expiration date of each term. This not only ensures control over continuity in the utilization of the mark but also ensures a revenue stream for the government given that both the renewal and the initial registration include a charged fee. In any case, the TRIPs Agreement states that the minimum duration of a granted protection term - from both the initial registration as well as subsequent renewal dates - may not be less than seven years[19].

The owner of a registered mark may therefore utilize the latter in order to distinguish the registered products or services; the actual marketing of these products will, in any case, be subject to further regulation and may require specific authorizations, for example. This is the active element of the protection which operates in conjunction with the merely negative and exclusive element. Once the goods or services have been marketed, the owner of the rights loses, however, the possibility of con-

trolling their subsequent sale, in accordance with the principle that the right to control the sales of goods or services ends after the first sale. All of the above is certainly applicable within the national territory of a country but there may be limitations within international commerce where there are different norms limiting parallel imports, i.e. those which are not directly authorized by the producer[20]. In any case, the producer retains the right to apply her/his trademark on the products or services which she/he markets as well as on packages containing these products. The producer may oppose any destruction of the mark or any re-packaging or alteration of the product[21].

Given that the purpose of the protection granted by the legal system is closely linked to the commercial activity and the ability to distinguish the origin of products or services, it follows that the registration of a trademark assumes a utilization of the latter. An unjustified failure to utilize the registered trademark will, first of all, allow other parties to take action in order to cancel the trademark so that the latter may be newly registered but with a different owner. This obviously does not apply in the case that the failure to utilize the trademark is justified, such as in cases of uncontrollable circumstances. It should, however, be noted that – in the case of legal action initiated for the purposes of canceling the trademark – the burden of proof is reversed and falls upon the party owning the trademark who must prove the utilization of the latter or provide evidence of causes that prevented its utilization[22].

The loss of the trademark's distinguishing function would serve as an additional case where cancellation is warranted. Consider, for example, the case in which a producer's mark or a name attributed to a product becomes synonymous with the product itself, as occurred in the case of aspirin. In these cases, the mark is defined as having acquired a generic nature.

Ownership of the trademark – similarly to other intellectual property rights – may be sold. It may also be subject to specific licensing agreements which authorize third parties to utilize the trademark for commercial purposes while simultaneously allowing the owner of the trademark to control the quality of any marketed products.

Notes

1 "The expression 'literary and artistic works' shall include every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression…". *Berne Convention for the Protection of Literary and Artistic Works*, Art. 2.

2 World Intellectual Property Organization (WIPO), (2004a), *Understanding Copyright and Related Rights*, page 10.

3 "Independently of the author's economic rights, and even after the transfer of the said rights, the author shall have the right to claim authorship of the work and to object to any distortion, mutilation or other modification of,…, the said work, which would be prejudicial to his honor or reputation." *Berne Convention* cit., Art 6 *bis*.

4 Given the above, a movie director or producer may retain economic rights linked to a work but only the creator may retain moral rights with regards to the work. WIPO, (2004a) *Understanding Copyright* cit., page 13.

5 It is interesting to note that copyright laws in certain countries allow certain commercial rights - if derived from the activities of an author employed by third parties for the sole purpose of producing the creative work - to be granted to the employer and not the material author. WIPO, (2004a), cit., page 15.

6 The owner of the individual copy may modify the contents or destroy the latter if resident in a country where copyright legislation does not recognize moral rights.

7 *Berne Convention* cit., Art. 10.

8 Within the United States of America and the European Union, this protection extends for seventy years after the death of the author. WIPO, (2004a), cit., page 14.

9 Similarly to that noted with respect to copyright, the most frequent criticism that is also applied to patents refers to the negative connotation characterizing the rights deriving from the protection; these rights exclude non-patent holders from utilizing a technology or a productive process.

10 "...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." *TRIPs Agreement*, Art. 27.

11 Each Country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example failure to work." *Paris Convention for the Protection of Industrial Property*, Art. 5, A, (2).

12 "The conditions regarding the granting of compulsory licensing are regulated in details by laws that provide for them. The decision to grant a compulsory license must provide for an adequate remuneration of the patentee." WIPO, (2004a), cit., page 8.

13 "Industrial designs shall be protected in all the Countries of the Union." *Paris Convention* cit., Art. 5 *quinquies*.

14 Exceptions include, for example, designs created as a result of an order or by an employee hired for this purpose. In both of these cases, it is not the creator of the design who retains the rights guaranteed by the protection but rather the party who ordered the work or the employer which is granted the design rights. WIPO, (2004b), *WIPO Intellectual Property Handbook: Policy, Law and Use*, page 116.

15 *TRIPs Agreement* cit., Article 26.1.

16 WIPO, (2004b), *WIPO Intellectual* cit., pages 76 – 77.

17 *Paris Convention* cit., Art. 6 *bis*, 1 and 6 *ter*, 1.

18 *TRIPs* cit., Art. 16.1.

19 "Initial registration and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely." TRIPs cit., Art. 18.

20 These limitations are often linked to consumer protection given that consumers may be deceived with regards to the quality of products or services. WIPO, (2004b), cit., page 84.

21 "Altering the product and selling it under the same mark has the same effect as affixing the mark to goods, that is, it gives the consumer the impression that the genuine product has been marketed by the trademark owner under his mark. If that is not true, the trademark owner has a right to intervene." WIPO, (2004b), cit., pages 84 – 85.

22 This reversal of the burden of proof is justified by the excessive difficulty facing an affected third party in trying to prove that a trademark has not been utilized. WIPO, (2004b), cit., page 78.

2. Counterfeiting

2.1 General elements

Intellectual property rights, as previously noted, include an economic element. In certain cases - such as copyright – there is an additional moral component which, in any case, does not undermine the possibility that these rights are commercially exploited by the respective parties holding such rights. It is this component – and the profits that may be derived from it – which serves as the deepest cause of the counterfeiting phenomenon and the roots to the latter; over time and in conjunction with the evolution of the social-economic environment of reference, other causes have been added.

A note within Article 51 of the TRIPs Agreement specifies and distinguishes between the concepts of counterfeiting and piracy by referring to *counterfeit trademark goods* and *pirated copyright goods*.

The first meaning includes violations relative to the unauthorized affixing – on a product or on its package – of a trademark identical to a trademark that is validly registered for the products in question or of a trademark that can not be distinguished from the latter[1]. The concept of *pirated copyright goods*, on the other hand, refers to usurping goods, i.e. those products which are unauthorized copies of products protected by intellectual property rights[2].

The terms counterfeiting and counterfeit goods will be used with a broader meaning throughout this report, in accordance with a trend emerging in the majority of the international reports and studies, whereby the two cases provided for by the agreement of the *World Trade Organization* (WTO) are included within these umbrella terms[3]. This choice is not only based on an increased ease of analysis and description but is also due to the possibility of discussing the counterfeiting and piracy phenomenon together – given that both involve causes and effects that are often linked. Specific care will obviously be given to highlighting, if necessary, any specific elements of these two categories.

The term counterfeiting is hereby defined as the illegal reproduction or imitation of products, given that this illegality is the result of a violation of any type of intellectual property rights. In addition, specific emphasis will be placed on attempting to provide a criminological interpretation of counterfeiting, dissecting its links with organized crime and analyzing its complexities; the phenomenon is essentially a process whereby an illegal product is supplied to a conscious or unconscious final user involving a production step which only represents the spark initiating the engines of a complex and branching chain of illegal distribution.

Having noted that counterfeiting always involves an infringement of the intellectual property rights of the respective parties retaining such rights, it is now possible to better understand the phenomenon in question as well as the evolution of the lat-

ter in recent years. It is natural to note – even for someone tackling this problem for the first time – that counterfeiting is a phenomenon in constant growth with evolving "targets". This statement may serve as a potential starting point for analyzing the problem; the causes underlying this expansion, its negative effects, the problems resulting from the involvement of organized crime in counterfeiting as well as the risks linked having certain types of replicated products on the market, will be analyzed subsequently.

2.2 Counterfeiting: a growing phenomenon

The variety of studies implemented with respect to this phenomenon, as well as the various reports of international organizations that are involved in analyzing the latter for various reasons, almost always contain commentary on the growth of this activity.

The growth in question should be analyzed from at least two perspectives. The increase in volumes of "fakes" and their penetration of legal markets must, in fact, be interpreted 1) as an increase in the type of products which are counterfeited and 2) as an increase in the number of parties involved in these illegal activities. These two perspectives also include other factors: an improvement in the quality of replicated products – quality referring to the difficulty in distinguishing the fake from the original – as well as an increasing trend in managing the production and trade of such goods at increased levels of organization.

In order to provide some estimates on the current size of the phenomenon, reference can be made to certain international studies and reports. It should, however, be noted that these estimates refer to a phenomenon linked to illegal markets and it is therefore difficult to quantify figures given the problems associated with collecting certain data. The possibility of accurately quantifying the problem faces several obstacles. One obstacle is related to the time of production: given that these products are generally distributed and marketed within a non-regulated market, no recordings or archives are kept and therefore an accurate estimate is impossible.

For the same reason, the exact incidence of illegal commerce with respect to its legal counterpart is difficult to quantify. The estimates which are hereby reported must therefore serve as useful indices in order to understand trends relating to the phenomenon but the nature of the latter prevents exact estimation. Let's now turn to the estimates: according to the Commission of the European Communities counterfeiting would total between 5-7% of the total legal market[4] while the *Organization for Economic Cooperation and Development* (OECD), which was previously supporting this figure, prefers now to rely on a numeric value instead of a percentage, affirming that at least 200 billion US dollars of international trade in 2005 could have been in counterfeit or pirated products[5]. The *World Health Organization* (WHO) reports that between 7-10% of all pharmaceuticals products in the world would be counterfeits, reaching a total of 30-40% in certain African countries[6].

In more detail, the counterfeiting report of the European Commission states that one out of every five French industries with more than fifty employees reported at least one case of infringement of Intellectu-

al Property Rights, while the US Copyright Industry estimates that 12-15 billion US dollars are lost in this sector as a result of such violations. The report of the European Commission also states that the sectors which are most affected by the phenomenon include the data-processing sector – in which the trade of counterfeit products reaches an incidence of 35% of all commerce – as well as the audiovisual sector (25%), the toy sector (12%), the perfume sector (10%), pharmaceuticals (6%), the clock sector (5%)[7], as well as the phonographic sector and that relative to the production of spare parts for vehicles.

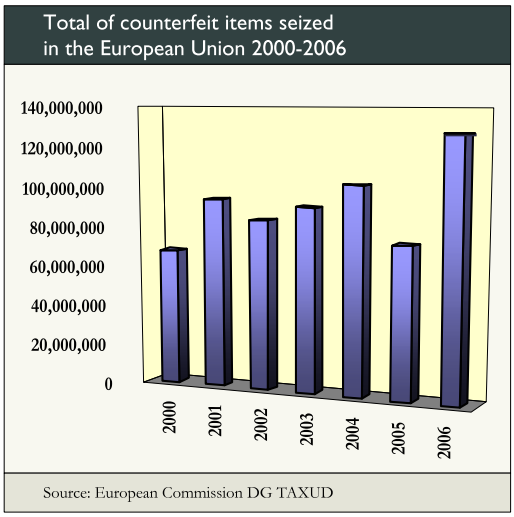
Graphic no. 1 more accurately illustrates the extent of the problem and presents the result of processing data relative to official statistics on counterfeit goods seized at the borders of the European Union[8].

The seizure of counterfeit goods within the EU in the year 2000 totaled almost 68 million goods and reached 95 million goods in 2001. The years 2002 and 2003 reported almost unvarying figures – 85 and 92 million goods, respectively – while 2004 and 2006 reported a significant increase in seized goods: more than 103 million goods in 2004 and more than 128 million in 2006 following a slight decrease in 2005, totaling 76 million goods.

The data collected in 2001 by customs authorities report a disturbing figure: a 39% increase in seized goods with respect to 2000, a trend which is also confirmed when the years 2000 and 1999 are compared. 2004 and 2006 also reported significant increases with respect to their preceding years – 12% and almost 70%, respectively. The total increase in goods intercepted at EU borders over the 2000-2006 period equaled to 88%.

This dramatic increase in seizures should be interpreted not only as the result of the growth of the phenomenon but also as a consequence of a more efficient legislation adopted within the European Union regarding customs controls[9].

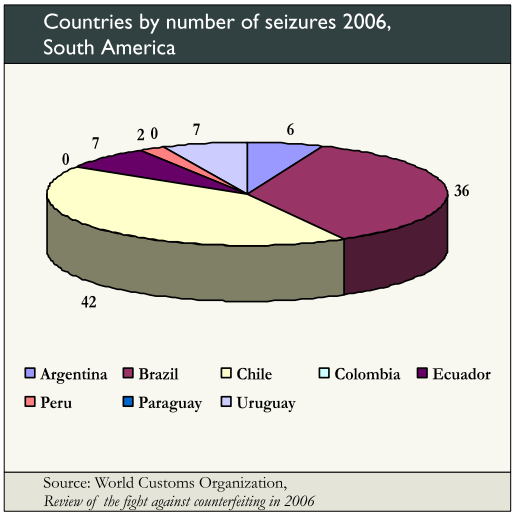
Graphic 1



The Report presented by the World Customs Organization (WCO) for the year 2006[10] allows considerations made so far for the European Union to be extended to other geographical areas. In the year 2006, the United States of America witnessed an increase in seizures of counterfeit goods of 83% over the previous year. In South America more than 200,000,000 counterfeit items were seized at the States borders in 2006. Of these, a considerable amount came from a noticeable seizure of pirated CDs and DVDs reported by Ecuador customs officers. Graphic no. 2 shows an interpretation of the enforcement activity undertaken by national Customs Agencies in South America, expressed by number of seizures while Graphic no. 3 shows the rel-

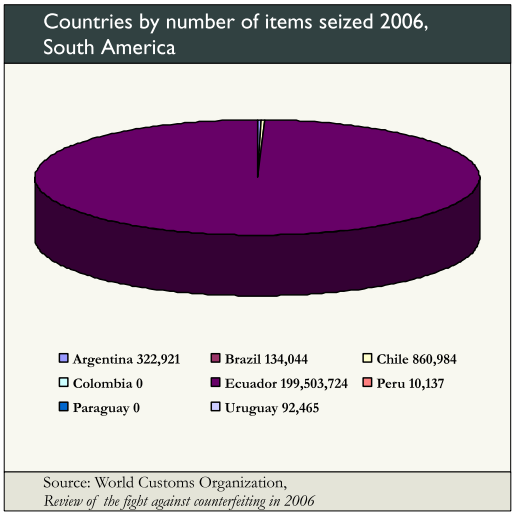
ative weight of the before mentioned seizure of CDs and DVDs in Ecuador with respect to the Area results.

Graphic 2



Source: World Customs Organization, *Review of the fight against counterfeiting in 2006*

Graphic 3



Source: World Customs Organization, *Review of the fight against counterfeiting in 2006*

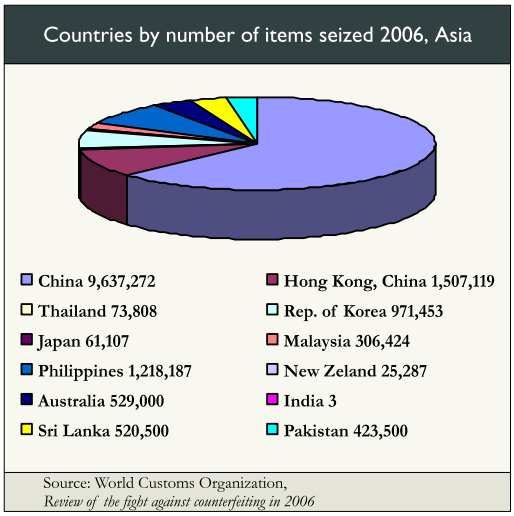
In 2006, only four African Countries reported to the WCO the seizure of counterfeit products: Senegal, South Africa, Mozambique, and Uganda. For South Africa and Mozambique seizures made by Customs were related to counterfeit cigarettes while in Uganda a cargo containing boxes of fake shoe polish was seized. In Senegal the customs officers intercepted several counterfeit "Pfizer Viagra" tablets and pirated DVDs.

Graphic 4

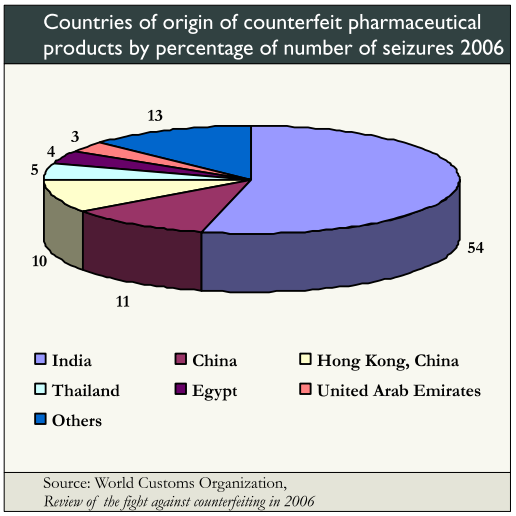
Source: World Customs Organization, *Review of the fight against counterfeiting in 2006*

In the Asian region, Customs' activity experienced an increase of 39% seized items in comparison with the previous year, totaling over 15,000,000 units intercepted. China is the most interested and active country, with 676 seizures and more than 9 million items intercepted. Graphics no. 4 and no. 5 show the geographic allocation of seizures and items seized for the Asian region.

Graphic 5



Graphic 6



Regarding the Commonwealth of Independent States, Russian Federation is still the country most affected by the problem totaling in 2006 15 seizures and more than 37,000 items intercepted.

Turning the attention to the different types of commodities intercepted, and with particular regards to those categories that are potentially more threatening for the consumers' health and safety, the year 2006 witnessed an increase in seizures of counterfeit pharmaceutical products over the year 2005 in several Member Countries of the WCO. The United Kingdom (710,083 items intercepted), France (328,144) and Belgium (161,040) registered in 2006 the most incisive action of their respective Customs Agencies in these regards, while India was confirmed as one of the most important sources of counterfeit pharmaceutical products followed by China, Hong Kong (China) and Thailand, as Graphic no. 6 clearly shows.

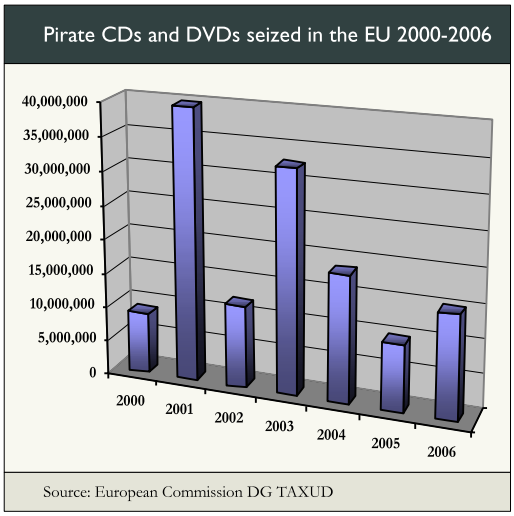
Italian Customs in 2006 intercepted the highest number of counterfeit spare parts for the automotive sector (121,229 items intercepted), followed by the Philippines Customs (49,328) and by the Customs Agencies of Lithuania (30,517) and Germany (27,252). The Italian Customs also registered the highest number of counterfeit toys seized in the years 2005 and 2006 (10,051,781 items intercepted in 2006), followed by the Dutch (1,243,777) and German (468,062) Customs.

Considering only the territory of the European Union and the statistics published by the European Commission – DG TAXUD in the period 2000-2006, the CD-DVD sector (Graphic no. 7) has been particularly affected; although the graphic illustrates data which are not constant across the analyzed time period, this sector represents 40% and 35% of total products seized at EU borders in the years 2001 and 2003, respectively. In addition, a significant increase in counterfeit clothing items (Graph-

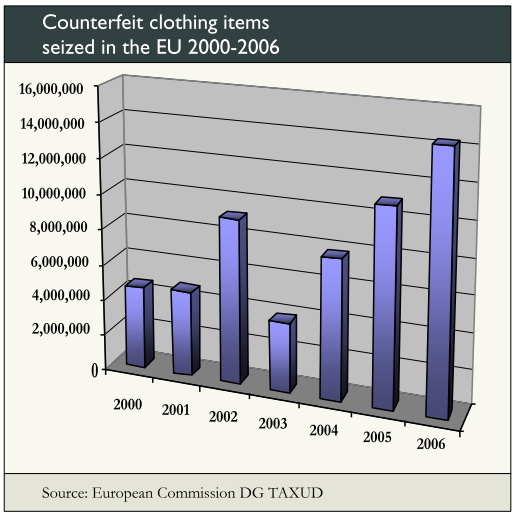
ic no. 8) was reported as of the year 2005; in the years 2000 and 2001, these items were equal to 7% and 5% of total seized goods while in the year 2005 they were equal to 15% of the total. This figure slightly decreased in 2006 but remained relatively high, representing more than 11% of all products seized at EU borders.

The food and beverages sector (Graphic no. 9) as well as the toy sector (Graphic no. 10) report inconstant trends for the 2000-2006 period, but their presence within the EU market is a sign of the widespread presence of products which are very risky for the health and safety of consumers.

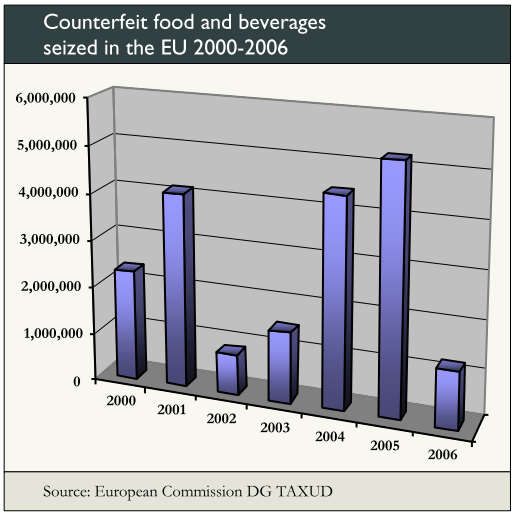
Graphic 7



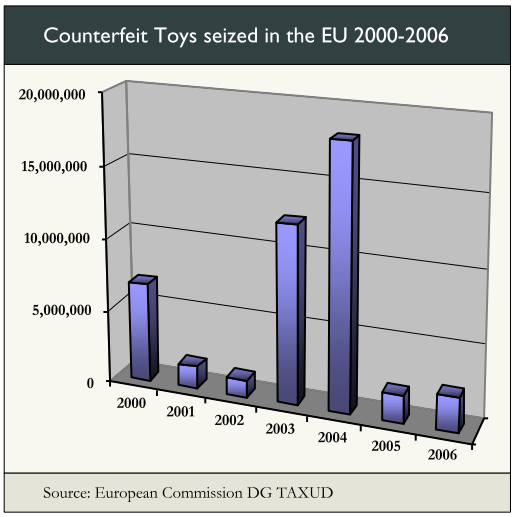
Graphic 8



Graphic 9



Graphic 10

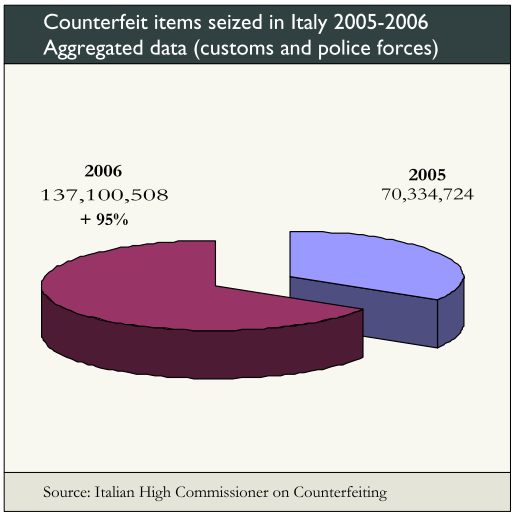


For the European Community area the considerations regarding counterfeit pharmaceuticals are more limited; data for this category has only been analyzed separately by EU authorities – entrusted with the statistical analysis of border seizures – since 2005. This category was previously included within the category "other products", which today still includes the sector for spare automobile parts. The reported increase in seized counterfeit medicines during the 2005-2006 period is, in any case, significant since it totaled 383%. Seizures of such goods, in fact, increased from almost 570,000 products in 2005 to more than 2,700,000 in 2006.

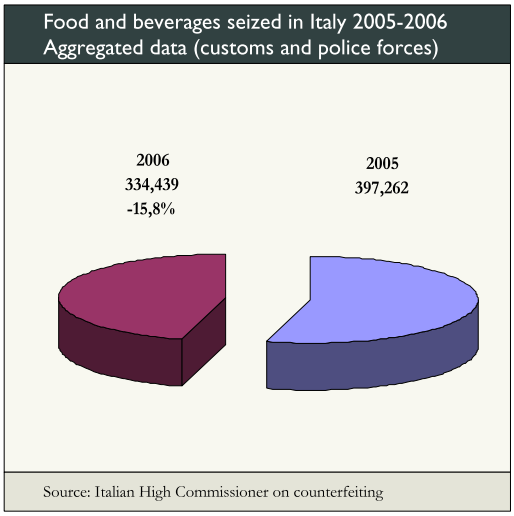
The exponential growth of the problem has been reported in the European territories for some time. As of 1996, German customs offices recorded an increase in seizures of non-original products that was eight times greater than that of the previous year; over the same period, French customs officials intercepted 45% more counterfeit goods[11].

Italy is confirmed as one of the European Union member countries most affected by counterfeiting, with more than 22 million items seized in 2004 by the customs, and more than 18 million in 2006[12]. Aggregated data considering the activity of customs and police forces in Italy show a constant or increasing trend for some specific merchandise sectors as well as for the phenomenon in general, as visible in Graphics no. 11, 12 and 13.

Graphic 11



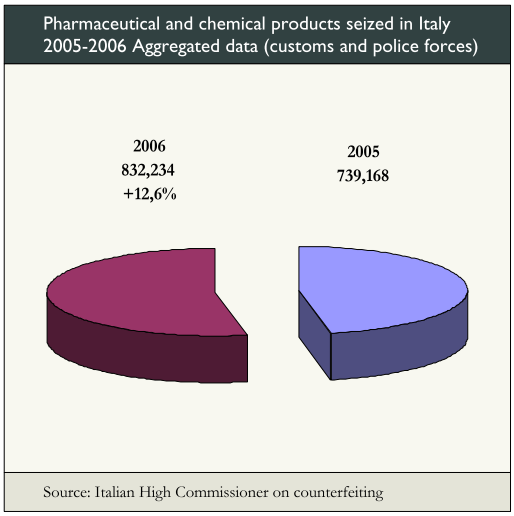
Graphic 12



Italy represents also an important entry point for various categories of counterfeit products destined to other EU countries. The greatest part of them originates from

China. Considering the years 2004, 2005 and 2006 the incidence of Chinese counterfeits with respect to the total number of items seized by the customs in Italy was of 82.5%, 91.5% and 93.4% respectively[13]. However, due to its geographical location, the Italian territory represents also a bridge for infringing products originating from – or transiting through – countries like Greece and Turkey. In some cases the merchandise was intended for the markets of other EU member states, like Spain or the United Kingdom[14].

Graphic 13



The growth levels of counterfeiting are associated with the significant development of international commerce, the internationalization of the economy, the large-scale distribution of new technologies, the opening of new markets and the gradually increasing importance of exploiting Intellectual Property Rights (especially the marketing of 'brands' or 'status' goods) in multiple sectors. As previously noted, the type of counterfeit goods itself has significantly expanded due to the rapid distribution of new technologies which allow for relatively simple and accurate replication of most products present in current markets while not complying with the elevated qualitative standards of original goods. It is often stated that there are no products today on the market which could not be counterfeited; this statement is true for most cases.

The counterfeiter himself is no longer a simple "artisan" committed to accurately reproducing luxury goods and re-selling them within a relatively limited market of reference. This form of counterfeiting has, in fact, become less profitable and there is a current trend towards large-scale consumer products. These products, in fact, exhibit two characteristics: 1) they have an elevated market demand and 2) they are easily reproducible. This results in a significant advantage for counterfeiters who can leverage a reference market that is much larger than that of luxury goods and can replicate goods without requiring specific technologies[15]. The phenomenon has thus developed from a small-scale activity to an industry that is highly organized and not only has an international market of reference but also incorporates an international network of productive-distributional structures. This network is currently one of its strong points, making it comparable to a global industry.

Market strategies which are applicable to current modern entrepreneurial structures – whereby the decentralization of productive activity is considered a competitive edge – are also fully applicable to the counterfeiting industry. Approximately speaking and given exceptions, this industry tends to center production in developing countries while distributing its products in industrial-

ized nations[16]. The widespread and global nature of the phenomenon must therefore be analyzed from the dual perspective of the replicated good as well as the differentiation between production and distribution locations.

A recent document stating the official position of the *Canadian Anti-Counterfeiting Network* (CACN) on this issue confirms the above, noting the explosive growth of the phenomenon in Canada over the last ten years. This explosive growth was characterized by a gradual expansion of the type of counterfeit goods and a shift towards large-scale consumer products. The document also confirms the growth of an organizational element involved in managing the production and trade of these products in addition to the difficulty in distinguishing the fakes from the originals. This difficulty highlights the greater emphasis placed on production by the counterfeiters as well as the widespread use of technology, as further confirmed by seizures of counterfeit goods on the part of competent authorities[17].

2.3 Causes underlying the growth of the phenomenon

The underlying causes of the "counterfeiting phenomenon" are multiple and should be considered in more detail.

Modern trade allocates increasing importance to the trademark as a direct expression of producer quality and reputation. These characteristics represent some of the reasons guiding the formation of a consumer basket. Manufacturing companies – being aware of this fact – have implemented significant investments to ensure greater quality for their products in order to attract a greater number of buyers. Quality controls are a natural consequence of this process given that the compliance of marketed products with pre-determined standards is an element that is directly linked to the reputation acquired by the producer and consequently the market share attained by the latter.

The importance of the "brand" and its impact on consumer choices is, however, of considerable appeal to counterfeiters: there is an opportunity to exploit the position attained by an entrepreneur by replicating the latter's trademark or the latter's products and marketing them under her/his brand without having to sustain the costs of the legal company. These costs are derived from compliance with elevated qualitative standards as well as product advertising and the payment of taxes and authorizations.

The opportunity to exploit the reputation of an entrepreneur in a given market is not, however, sufficient to explain such a widespread distribution of the phenomenon, particularly its significant growth and evolution. There are, however, additional elements which have served as catalysts for a process which has currently reached an enormous scale.

As previously noted, the significant expansion of international markets and trade should be taken into account; the trading of replicated products has benefited from this growth. In addition, significant profit opportunities have emerged from new markets following the collapse of highly regulated economic regimes – such as ex-Soviet countries – or the partial introduction of market economies, such as in China. The collapse of centrally planned and state-controlled economies and their transformation

into forms that are comparable to market economies was very sudden and insufficient controls were implemented with respect to this process. As a result, processes were initiated that resulted in the centralization of wealth in the hands of a minority and prevented redistribution in relation to profit opportunities. In addition, there was a failure to adequately replace the control that was previously ensured by the state-controlled model with other forms of monitoring over market rules and the parties engaging in the market itself. These markets unfortunately today represent fertile ground for counterfeiting production in addition to providing large consumer basins for such products. The ex-Soviet countries and China, for example, are still working to counteract the enormous distribution of counterfeit products[18] in their territories; these countries are currently considered the largest producers and consumers of counterfeit goods.

The broad range of counterfeit products is therefore determined by a number of causes which essentially allow counterfeiting to be a highly profitable activity. The concept of profitability should be analyzed further within this statement, particularly the meaning ascribed to this term by parties which are involved in illegal operations. The concept is, in this case, composed of two fundamental elements: 1) the profit attainable from the sale of an individual unit of counterfeit goods compared to that attainable from the sale of a different type of illegal product, and 2) the risk derived from this activity in comparison to other illegal activities. A brief analysis of this concept highlights the high level of profitability that is inherent within counterfeiting – an element which, as will be more fully described below, has attracted the interest of organized crime.

The first element that should be considered is the cost of production of a replicated good. From this point of view, counterfeiters utilize the cheapest available materials and are not concerned with the level of toxicity of such materials or their inconsistency with respect to the function of the counterfeit good. The goods which are produced in this manner are then marketed at prices that are significantly higher than their cost of production. The margin between the sales price and the cost of production depends on the type of replicated product, the type of targeted consumer and the method which the counterfeiters have chosen to penetrate the market. If the targeted consumers are "conscious" buyers, then the sales price – despite still being significantly higher than the cost of production – will typically be lower than the price of the original good. If, on the other hand, there is an attempt to deceive potential buyers by penetrating the legal market and reselling the products to "unconscious" consumers by means of the same sales channels, prices will be equal to those of the originals. This technique is especially used in the sale of certain types of counterfeit products which, due to their very nature, would rarely be knowingly acquired due to the risk associated with their utilization on the part of the final user. This category includes, for example, spare vehicle parts, toys and even medicines.

Regardless of which method is employed, it is interesting to compare the profits derived from such activity in comparison to that of other illegal activities in order to understand the level of profitability of counterfeiting attainable by criminal

organizations. The advantage of counterfeiting with respect to other activities is due to both the actual economic margin attainable from each sold unit as well as the risk associated with exercising the activity. This latter component involves the probability of being discovered by law enforcement as well as the severity of penalties that are applicable in the case of conviction.

A similar comparison could be made, for example, with respect to illegal drug trafficking. Experts in this sector, particularly the managers of anti-counterfeiting agencies and customs controls, estimate that the trade of replicated goods at the international level is at least as profitable as illegal drug trafficking[19], although numerous other authorities believe that counterfeiting is significantly more profitable[20] and is capable of generating profits that are up to eight times greater than that created by drug trafficking. The cost of production of a replicated computer program, for example, is estimated at 0,20 Euro while its sales price can reach 45 Euro – a profit margin that is much greater than that generated by a gram of cannabis whose cost of production is circa 1,52 Euro with an average sales price of 12 Euro[21].

A purely economic and particularly interesting study on this topic was implemented by Pierre-Jean Benghozi and Walter Santagata; the study considered the economic elements which determine the propensity to produce counterfeit goods. The latter is a function of the value of the material utilized to implement the good as well as the economic value of the Intellectual Property Right incorporated within the good, its market share and the number of licenses granted by the party retaining the rights[22]. According to the interpretation of Benghozi and Santagata, the variables mentioned above would quantitatively affect the propensity to counterfeit a good, increasing or decreasing the probability as a result of changes in its performance. In particular, costly production materials would decrease the profitability of reproducing the good due to the lack of clear competitive advantages while the opposite would apply to an easily replicable good. The economic value of intellectual property rights inherent to the product is another element that directly affects the probability of counterfeiting, similarly to the relationship between counterfeiting propensity and the number of licenses granted by the producer. The latter is due to the fact that increasing the number of licensees increases the probability that one of the latter may decide to abuse the license and develop an illegal activity. Finally, as the market share of a product increases, the potential demand for the replicated good also increases and controls over the more extensive market become more arduous[23].

The profitability of counterfeiting, however, is not limited to the economic sphere. Given the fact that it is an illegal activity, the second element described above – the risk linked to the activity itself – becomes critical. It is potentially one of the elements which has had the most appeal for criminal organizations given the lack of adequate deterrents within the applicable legislations of various countries. The lack of deterrence is the result of a distorted vision on the part of legislators and competent authorities with respect to the effects of this phenomenon. Despite an increasing awareness of the scale of the problem, different legislative frameworks have been constrained by a purely economic ana-

lysis of the phenomenon whose negative effects are believed to exclusively affect producers from a financial point of view. First of all, this viewpoint does not take into account the significant consequences caused by the involvement of organized crime in the management of such activities as well as the risks for the safety of citizens and public order. This perspective is also limited from another point of view: not only is it unaware of the elevated risk for the health and safety of consumers – as a result of certain counterfeit products - but it also ignores the damage caused to government revenues due to the existence of traded goods which are not taxed.

The result of an incorrect, perhaps anachronistic, perspective on this phenomenon – linked to the existence of illegal reproduction activities that are conducted at the artisan level – has led to the adoption of inadequate standards in different countries or to the lack of rigorous application of the latter. As a result, there is a widespread failure in terms of legal prevention and deterrence, thereby creating the strong profitability – defined in both of its meanings – which characterizes counterfeiting and increases the attention that organized crime reserves for it. Counterfeiting has thus become one of the preferred channels through which black money is laundered[24].

A few concrete examples will illustrate how counterfeiting is considered a second class crime in many legal systems. Although legislation has recently changed, the sale of counterfeit products in France in 2003 was punishable with a fine of € 150,000 and two years of prison while the sentence for drug trafficking included a fine of € 7,500,000 and ten years of prison[25].

In accordance with Decree of the President of the Republic no. 309/90, the Italian legal system provides for penalties of eight to twenty years for the production and trafficking of narcotics. In addition and in the case of criminal association, the sentence may not be less than twenty years for the party promoting the association while parties participating in the association may not receive less than ten years. The same sentences are increased if the association is composed of ten or more participants. The standards relative to counterfeiting are included within various articles of the penal code. According to articles 473 and 474, the counterfeiting of distinguishing signs and industrial products is punished with a prison term of up to three years, while trading of such products is punished with a prison term of up to two years. The counterfeiting of food and pharmaceutical products is, on the other hand, punished with prison terms ranging from three to ten years. Article 517 punishes the use of counterfeit names or trademarks for commercial purposes and with the intent of deceiving the public in relation to the origin or quality of the product with a prison term of up to one year and a 1,000 Euro fine. Moreover article 4 of the law 350/03 extends the application of article 517 of the penal code to the false indication of origin of agricultural products.

The significant difference in sentences between these illegal activities may then be combined with the previously analyzed economic profitability to ensure that counterfeiting is a decidedly more appealing illegal activity.

Finally, an additional element characterizing the existence of this illegal trade – and formed from the reasons underlying demand – must be mentioned. The creation

of this element does not obviously include the unconscious buyer who has no intention of buying a non-original product and is subject to deceit on the part of counterfeiters. The latter exploit the fact that certain distributors will acquire goods at very low cost in order to increase profit margins but will not verify the origin of the products and are not aware that they are marketing counterfeit goods.

The additional element mentioned above is that demand for goods is generally linked to the price and availability of the goods in question. The existence of easily accessible sales points for such products has a beneficial effect on the market created by replicated goods. The emergence of the Internet has also created the possibility of easily and anonymously acquiring different types of products, regardless of the location of the buyer – thereby allowing counterfeiters to exploit or create actual online "bazaars" that are specialized in the sale of replicated goods.

Such a widespread distribution and availability of replicated products can only be opposed by creating a negative attitude towards counterfeiting within the social community, particularly amongst buyers. This attitude can only be created by condemning all forms of counterfeiting, even those relative to goods which are not dangerous in themselves but whose sale and purchase – if tolerated and not punished – would contribute towards generating a "positive" attitude with respect to counterfeiting and would support the belief that the latter is a "victimless crime".

The demand for counterfeit goods is often determined by the status value associated with ownership of a certain type of product; this is particularly true in the case of luxury goods. This constitutes an added value that should be considered when evaluating the difference in price between the two types of goods: original and replicated. Similarly to their analysis of propensity towards the production of replicated products, Benghozi and Santagata implemented another study on the reasons which cause the creation of demand for counterfeit goods on the part of a conscious consumer. This interpretation is valid for products such as designer clothing items, watches or sunglasses. In this case, the buyer sacrifices the quality of the original product and is tempted to buy as a result of other characteristics: the price and the status value associated with owning the good in question[26]. Consumer behavior and choices depend on consumer knowledge – or lack thereof – relative to the quality of the two goods, original and replicated. Benghozi and Santagata formulated four different hypotheses. The first hypothesis is of greater interest and provides for a conscious consumer who has knowledge of the quality level of both products. In this case, the consumer will choose the counterfeit product if the loss deriving from the different quality/price ratio is less than the advantage associated with the improved image/status created by owning the luxury good. In this case, the status value therefore plays a key role in guiding the choices of the conscious buyer[27]. In addition to luxury goods, this hypothesis also seems capable of explaining the purchase of replicated audio-visual materials. The second and third hypothesis provide for a consumer who is aware of either the quality of the original or the replicated product. In this case – and given the assumption of a rational consumer – the latter will want to acquire information on the quality of these

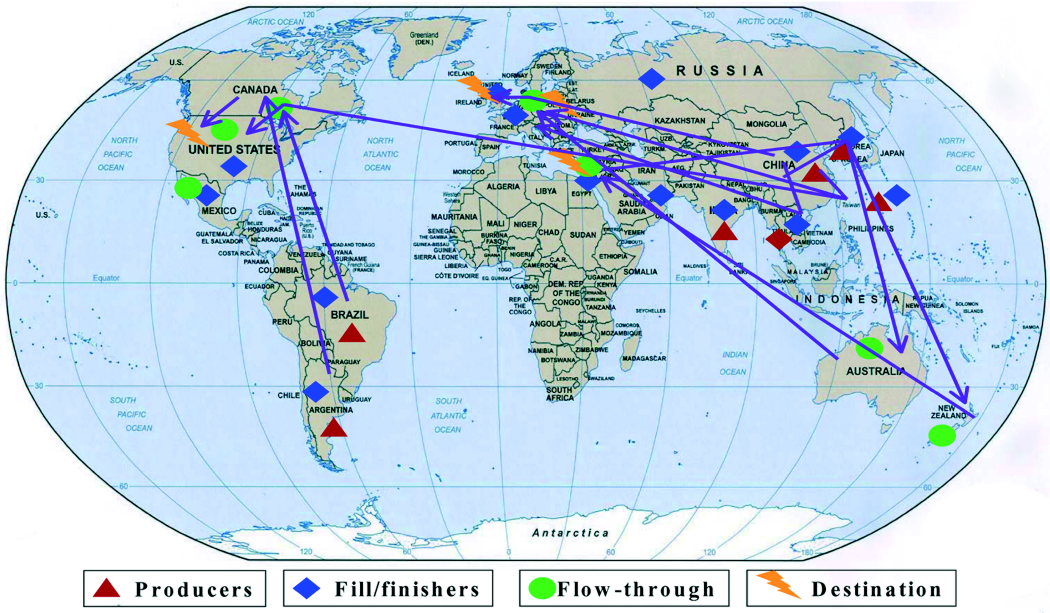
products and will sustain some costs which are added to the quality loss deriving from the purchase of a non-original product – thereby decreasing the appeal of the counterfeit good. The last hypothesis provides for a consumer that is not conscious of the quality of either of the products. This would therefore entail research on the quality of both goods and even higher costs than those involved in hypotheses two and three[28], thereby further decreasing the propensity to acquire the non-original goods.

2.4 Organization and trade routes

The elevated profitability of counterfeiting – as noted above – has not only attracted the attention of occasional criminals but also, and particularly, organized crime. Although the links between these activities and organized crime will be analyzed in more detail below, it is helpful to illustrate the current complexity of the phenomenon and the logistical organization supporting its implementation.

Counterfeiting has been depicted as a problem that is linked to the growth of international trade and international markets; it is now possible to state that the management of counterfeit trade is very similar to a normal supply chain of legal products, involving producers, assemblers, distributors and finally buyers[29]; the main difference between the two is the difficulty in identifying the various players in the counterfeit supply chain.

This supply chain benefits from the existence of actual networks that connect the various market players and which tend to cross over the thin line separating a legal and illegal supply chain. Commerce of this nature – particularly on such a large scale – can only be managed by large organizations which are also involved in other types of il-



Source: Lilly, (2005), Combating Pharmaceutical Counterfeiting

legal trade; the latter primarily include narcotics and weapons. The illegal distribution of counterfeit products therefore benefits from the existence of trade routes that have been previously and successfully exploited for other activities; this illegal distribution also utilizes additional methods to avoid customs controls and thereby penetrate the market.

Due to a greater number of controls caused by the increasing awareness on the part of competent authorities with regards to the extent of the problem and its associated risks, one of the techniques that is most frequently utilized by counterfeiters in order to pass through customs controls involves disguising the origin of the counterfeit goods. This is usually accomplished by avoiding any evidence that suggests an origin from "sensitive" locations which are known as sites of counterfeit good producers. Cargoes of goods are therefore diverted several times in order to pass through different transit points for the purpose of deceiving the authorities with regards to their actual origin[30]. The transfer of goods and their final entry into the market will also depend on currently effective legislation in a given country, given that it is common practice to select a transit or entry point on the basis of the severity of local legislation as well as the degree of application of these norms on the part of law enforcement. A clear example of this practice was reported in connection with the interception of a cargo of counterfeit batteries in the spring of 2002 on the part of customs authorities in Vancouver, Canada. The batteries reported an origin in the United States despite the fact that the cargo had arrived from China. Several months earlier, US officials implemented a similar operation that involved the same type of counterfeit batteries, suggesting that the cargoes of goods were diverted to Canada. The latter was chosen as an entry point due to the lower number of border controls compared to the USA[31]. This problem has recently also become a key factor within the European Union where differing legislations between member states could serve as an element that counterfeiters would exploit in their trafficking[32].

The complexity of the distribution network makes it extremely difficult to identify exact counterfeiting supply chains[33]; this is also due to the fact that criminal groups which manage the counterfeiting trade are capable of quite deftly modifying the trade routes. As a result of this difficulty, it is currently only possible to identify a few of the major collection points: the ports of Antwerp, Hamburg and Amsterdam or the airports of Schipol and Roissy in Europe. Outside of Europe, Dubai, Hong Kong and certain American ports serve as important transit points[34].

Tracing these trade routes is quite arduous. The existence of a "commercial" flow of replicated goods linking certain Asian countries such as China and India with European and North American markets by means of complex trade routes is, in any case, undeniable. The existence of unscrupulous European or North American importers – who exploit the opportunities offered by a parallel market in order to re-import goods for other markets – is also undeniable. These importers thereby create dangerous openings for the entry of counterfeit goods within legal supply chains.

The same manufacturing or assembly process may be subdivided into several

countries in order to increase the complexity of the distribution as well as reduce the probability that the trade routes are traced. A famous example in Europe concerning a counterfeit medicine may serve as a clear example of this phenomenon. The raw materials – which can in turn be counterfeited – originated in Turkey while the product was manufactured in Greece. The drug was marketed through a Dutch importer and by means of a Swiss "broker".

The next level of sophistication involves another distribution method which consists in mixing counterfeit goods with original or with parallel traded and grey market products within a single cargo of goods. This method is widely used today and is the result of improvements in the productive technology of counterfeiters who are capable of supplying products that are externally very similar to the originals. This practice is adopted on a large scale and may affect cargoes of goods that are delivered to final distributors which in turn supply the goods to retail outlets. Although the apparent similarities with the original products may serve as an extenuating factor for the distributor which acquires the cargo of goods, it should be noted, however, that the counterfeiter will have to supply the cargo of goods at lower cost in order to be inserted within the supply chain. This lower price level should at least generate suspicion on the part of the distributor and convince the latter to utilize more secure supply channels that are authorized by the producer. This method of entering the market, in fact, exploits the opportunities of a parallel market; this topic will be subsequently analyzed in more depth. This parallel market creates commercial channels that are not directly authorized by the producer and – although legal in many nations, such as the member states of the EU – carry a strong shadow due to the absence of real controls over goods and their origin.

Despite the increasing role played by the Internet as a distribution channel of counterfeit goods, counterfeiters benefit from the existence of shadow companies that are solely created for the purpose of providing cover for illegal trafficking. An example of such a practice was reported in Italy: following a detailed investigation, the authorities of Florence discovered that two clothing distribution companies which operated in the city, and were managed by a couple of Chinese citizens, actually only served to cover the distribution and sale of counterfeit clothing items that were directly imported from China[35].

2.5 The dangers and effects of counterfeiting. An introduction

Data derived from the analysis of seized goods – relative to both European as well as international markets – report other serious causes for concern. The expansion of the type of replicated products has gradually led to the marketing of counterfeit products of particular delicacy which are dangerous for the health and safety of consumers. The counterfeiting of medicines and pharmaceutical products as well as spare parts for airplanes, automobiles and toys is, in fact, very widespread. Far from being a "victimless crime", counterfeiting involves a series of costs of significant entity and varying nature. The most obvious involves the economic losses affecting the market and producers in general while the more worrisome are those linked

to risks generated for consumers. In addition, the enormous competitive advantages for a counterfeiter should be noted: the counterfeiter is not subject to taxation; is not required to comply with any regulations on worker compensation or safety; is not required to comply with quality control processes; takes full advantage of the research implemented by the producer of the original product; does not sustain research and development costs; utilizes low quality raw materials which are attainable at very low cost; and attains a high level of profitability allowing for significant sums to be re-invested in other operations, legal or illegal.

The replication and marketing of a non-original product, regardless of its type, clearly results in significant damages to the producing industries. The creation of a product is, in fact, preceded by multiple studies and Research and Development (R&D) investments as well as the development of market positioning strategies and promotions. In addition to these costs, there are actual production costs which are largely linked to predetermined qualitative standards.

In the short term, losses sustained by producers are therefore caused by decreased sales of original goods due to the presence of counterfeit products in the market. Additional long-term losses may, however, arise as a result of the purchase of counterfeit products on the part of unconscious buyers. The lack of quality in the replicated goods may, in fact, generate dissatisfaction with respect to the producer amongst the buying consumers who may be unaware of the swindle and may ascribe the low quality level to the producing company[36]. The decreased revenues, in turn, may create a lack of confidence within the company which – due to the decrease in turnover – has fewer incentives for investing in R&D. Taken to the extreme, it is also possible that the income loss may compromise the actual stability of the industry and could result in the loss of numerous job positions.

Another form of economic damage would affect national governments which may sustain losses in terms of reduced tax revenues given the impossibility of taxing an illegal product. The government is not even aware of the existence of the latter due to the lack of records. These losses are, in any case, considerable and are estimated to be circa 3 billion dollars per year for the Chinese government and 2.4 billion dollars for the United Kingdom[37].

Counterfeiting primarily involves elevated costs for the public as a result of the dangers inherent in certain types of counterfeit products such as medicines, toys or spare parts for airplanes and motor vehicles. The connection between organized crime and counterfeiting is an additional social cost: it allows criminal groups to not only finance other illegal activities by using proceeds from counterfeiting but also to use the latter to launder black money derived from such proceeds.

The negative effects of this phenomenon – particularly its associated dangers – deserve a more detailed analysis in connection with its links to organized crime. These topics will therefore be subject to further analysis; specific elements associated with the counterfeiting of particular categories of goods and the factors which promote the development of the phenomenon will also be considered.

Notes

1 "'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." *TRIPs Agreement* cit., Art. 51, note 14, (a).

2 "'pirated copyright goods' shall mean any goods which are copies made without the consent of the rights holder or person duly authorized by the rights 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." *TRIPs Agreement* cit., Art. 51, note 14, (b).

3 "Technically the English term *counterfeiting* only refers to specific cases of trademark infringement. However, in practice, the term is allowed to encompass any making of a product which so closely imitates the appearance of the product of another as to mislead a consumer that it is the product of another. Hence, it may also include the unauthorized production and distribution of a product that is protected by other intellectual property rights, such as copyright and neighboring rights. This is in line with the German term *Produktpiraterie* and the French term *contrefaçon*, which both cover a broader range of intellectual property infringement." Organization for Economic Co-operation and Development (OECD), (1998), *The Economic Impact of Counterfeiting*, page 5.

4 Commission of the European Communities, (1998), *Green Paper – Combating Counterfeiting and Piracy in the Single Market*, page 4; OECD,(1998), *The Economic* cit., page 23; Noble R. K., (2003), *The Links between Intellectual Property Crime and Terrorist Finance*, text of public testimony before the United States House Committee on International Relations.

5 The OECD clarifies that this figure does not consider "domestically produced and consumed counterfeit and pirated products and the significant volume of pirated digital products being distributed via the Internet." The OECD further specifies that "if these items were added, the total magnitude of counterfeiting and piracy worldwide could well be several hundred billion dollars more." However, the "200 billion dollars figure" was chosen because it can be supported without any doubt on the part of the OECD. OECD, (2007), *The Economic Impact of Counterfeiting and Piracy, Executive Summary*, pag. 2.

6 World Health Organization (WHO), (2006a), *Counterfeit Medicines: an update on estimates*, www.who.int.

7 Commission of the European Communities, (1998), *Green Paper* cit., page 4.

8 For more information on estimates on goods seized within the European Union and the data reported in these graphs. TAXUD, http://ec.europa.eu/taxation_customs/taxation/index_en.htm.

9 In these regards mention has to be made of Regulation 1383/2003 of the Council of the European Union aimed at strengthening customs cooperation to more effectively counter the trade in counterfeit and pirated products, enhancing the efficacy of customs controls, and harmonizing the procedures for filing an application for customs action by the right holder.

10 World Customs Organization (WCO), (2007), *Review of the fight against counterfeiting in 2006*.

11 Hetzer W., (2002), *Godfathers and Pirates: Counterfeiting and Organized Crime*, in European Journal of Crime, Criminal Law and Criminal Justice, volume 10/4, page 307.

12 Italian Customs Agency, undistributed material.

13 Italian Customs Agency, undistributed material.

14 Italian Customs Agency, undistributed material.

15 "As regards the sectors hit by the phenomenon, infringers are no longer targeting luxury goods with a prestigious reputation (perfumes, watches, leather goods and other accessories). Custom operations have revealed that the phenomenon may also affect such highly diverse sectors and goods as spectacles, fountain pens, garden gnomes, garden furniture, playing cards, biscuits, circuit breakers and even saucepans." Commission of the European Communities, (1998), cit., page 8.

16 "The trade in such (counterfeit) items is now organized on a global scale with known producers in countries such as China, Taiwan, India, Turkey, Singapore, Iran, Latin America, Belgium, Denmark, France, Spain, Italy, Germany, the United Kingdom and Portugal. Products are distributed through extensive networks of importers-exporters in countries such as Belgium, Italy, the Netherlands, Spain, Argentina and the Czech Republic." Majid Yar, (2005), *A Deadly Faith in Fakes: Trademark Theft and the Global Trade in Counterfeit Automotive Components*, in Internet Journal of Criminology, page 7.

17 "In February 2003, Peel Regional Police seized counterfeit Epson and Hewlett-Packard computer ink and Laser Jet cartridges with packaging so close to the genuine products, including security holograms and lot numbers, a police detective involved in the case could not tell the difference". Isaac B., Osmond C., (2006), *The Need for Legal Reform to Address Intellectual Property Crime*, Canadian Anti-Counterfeiting Network, Position Paper, pages 7 – 8.

18 "…Eastern Europe and the former Soviet Union…are now emerging as both large producers and consumers of fakes. Although counterfeiting occurs more or less throughout the world, East Asia, including China, is still pinpointed as the main source for fakes." OECD, (1998), cit., page 26.

19 "According to Detective Superintendent Alain Defer, Head of the French anti-counterfeiting unit, the profits are similar to drugs trafficking, about €10 per euro invested." Union des Fabricants, (2003), *Counterfeiting and Organized Crime*, page 9.

20 "According to Jorn Rise Andersen, chairman of the Danish customs and excise association, counterfeiting brings in more money than drugs trafficking." Union des Fabricants, (2003), *Counterfeiting* cit., page 9.

21 Union des Fabricants, (2003), cit., page 10.

22 The function is as follows:

if $0 \leq ([Ipv*Ms+L]/ Mv) \leq \alpha$ then $p(i) = 0$

if $\alpha \leq ([Ipv*Ms+L]/ Mv) \leq \beta$ then $p(i) = a*([Ipv*Ms+L]/ Mv) + b$

if $\beta \leq ([Ipv*Ms+L]/ Mv)$ then $p(i) = 1$

where p(i) refers to the probability that a certain product (i) will be counterfeited, Mv is the economic value of the material utilized to create good (i), Ipv refers to the economic value inherent within good (i), Ms is the market share of good (i) and of any goods which can replace the latter, L refers to the number of licenses granted by the producer, α and β represent value limits, a and b are constants, with $a = 1/ [\beta - \alpha]$ and $b = -\alpha / [\beta - \alpha]$. Benghozi, P., Santagata W., (2001), *Market Piracy in the Design-based Industry: Economics and Policy Regulation*, in Economie Appliquée, no.3.

23 Benghozi P., Santagata W., (2001), *Market Piracy* cit., pages 6 – 7.

24 "The high profitability of counterfeit trafficking encourages criminals to use this activity as a way of laundering money". Union des Fabricants, (2003), cit., page 10.

25 Union des Fabricants, (2003), cit., page 9.

26 Benghozi and Santagata hypothesize, in fact, that the status value of a good (i) can be distinguished from its quality by the formula $Qi = f(Si, Zij)$, where Qi is the quality of the product (i). The formula illustrates that the latter is a function of both the status value S as well as other qualitative characteristics (Z) which vary from 1 to j for the individual good (i). Benghozi P., Santagata W., (2001), cit., page 9.

27 If L = the loss deriving from the purchase of a non-original good, ΔQ = the quality difference between the two products, ΔP = the price difference between the two products and W(Sf) = increased gain in status from owning the good, it is possible to formulate the following hypotheses:

if L(ΔQ/ΔP) < W(Sf) then the conscious consumer will acquire the counterfeited good

if L(ΔQ/ΔP) > W(Sf) then the conscious consumer will not acquire the counterfeited good

if L(ΔQ/ΔP) = W(Sf) then the conscious consumer will be indifferent with respect to buying either product. Benghozi P., Santagata W., (2001), cit., page 9.

28 In the second hypothesis, the consumer will acquire the counterfeited good if L([Cfs + ΔQ]/ ΔP) < W(Sf), where Cfs = costs sustained for obtaining information on the quality of the fake good.

In the third hypothesis, the conscious buyer will, on the other hand, lean towards buying the counterfeit good if

L([Cso + ΔQ]/ ΔP) < W(Sf), where Cso = costs sustained for obtaining information on the quality of the original good.

Finally, the fourth hypothesis predicts that a conscious consumer will acquire the counterfeited good if L([Cfs + Cso + ΔQ]/ ΔP) < W(Sf). As noted above, the three hypotheses assume increasing costs for the consumer and illustrate cases where the counterfeiting market has lower demand. Benghozi P., Santagata W., (2001), cit., pages 10 – 11.

29 Refer to: INDICAM, (2004), *Promemoria sui problemi della contraffazione in Italia* (*Memorandum on counterfeiting problems in Italy*), page 7.

30 In July of 2002, for example, the competent authorities of Roissy intercepted a cargo of more than 2.5 tons of counterfeit watches originating from Hong Kong and bound to Spain. A few days later, another cargo was intercepted: in this case, the counterfeited goods were sports clothes from Vietnam that were bound for the Czech Republic. Union des Fabricants, (2003), cit., page 8.

31 Isaac B., Osmond C., (2006), *The Need* cit., page 8.

32 "It is entirely conceivable that infringers may avail themselves of differences between national laws". Commission of the European Communities, (1998), cit., page 8.

33 It should be noted that supply chains will vary in relation to the distribution of the product given that the latter may be partially produced in one country, assembled in another and then subsequently transported and marketed in several other countries.

34 Union des Fabricants, (2003), previously cited work, page. 8.

35 Union des Fabricants, (2003), previously cited work, page 9.

36 "From the point of view of the economic and social consequences, the counterfeiting and piracy phenomenon leads in the case of firms, many of which invest considerable sums in research, marketing and advertising, to a reduction in turnover and the loss of often hard-won market share, not to mention the non material losses and moral prejudice which they suffer as a result of the damage to their reputation." Commission of the European Communities, (1998), cit., page 10.

37 Union des Fabricants, (2003), cit., page 4.

3. Consequences and risks of counterfeiting

The replica of original products and their introduction to the market entails a series of consequences for various parties. These consequences do not exclusively affect producing companies and the parties owning intellectual property rights but may also produce potentially devastating effects for the social and economic framework of a country.

In addition, some negative effects are common to all types of counterfeiting while others are specific to certain categories of goods and are linked to the functions of these products.

An analysis of the consequences of the phenomenon must therefore include those risks which may jeopardize the health and safety of consumers, in addition to any economic losses sustained by companies, workers and the government.

The economic element will be analyzed first, given that it represents the minimum common denominator of the phenomenon; the dangers associated with counterfeiting, as well as certain characteristics of the latter, will be analyzed in relation to certain sensitive products: toys, spare parts for automobiles and aircraft, medicines. It should again be noted that the concept of "danger" or risk – when used in reference to counterfeiting – incorporates the fundamental role played by the relationship between counterfeiting and organized crime. This relationship illustrates the true nature of the phenomenon, thereby abandoning the image of the latter as a simple economic crime and replacing it with a complex and socially dangerous practice.

3.1 Economic consequences

Economic damage affecting producing companies and the parties owning Intellectual Property Rights is the characteristic that is at first associated with this phenomenon. This concept of economic damage, however, proves to be extremely restrictive. It must, in fact, be extended in order to include various other affected parties, including national governments – due to the loss in fiscal revenues – as well as the economy. The latter is negatively affected due to the decrease in investments, R&D expenditure, innovation as well as the loss of market share and job positions.

The current scale of the phenomenon is enormous. The *Motor and Equipment Manufacturers Association* (MEMA) estimates losses derived from the marketing of counterfeited automobile spare parts to be equal to 12 billion dollars with the consequent loss of 750,000 job positions[1]. As previously noted, the WHO – despite the obvious measurement difficulties – estimates the incidence of counterfeited pharmaceutical products to be *circa* 10% of the global market; this figure is even higher in developing countries where 25% of all pharmaceuticals are on average counterfeited,

reaching peaks of 50% in certain countries[2]. A study commissioned to the *Centre for Economics and Business Research* (CEBR) by the *Global Anti Counterfeiting Group* (GACG) reports the purely economic losses sustained by the European market, illustrating in particular the effect of counterfeiting on the pharmaceutical market: 1,554 million Euro in lost revenues and the consequent loss of 292 million Euro in net income[3].

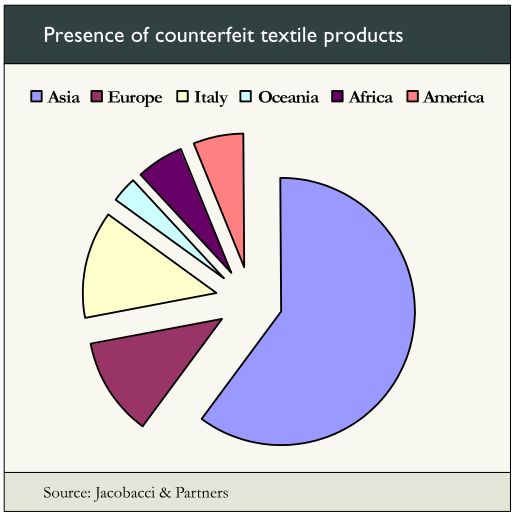
One of the most important toy industries in Canada, headquartered in Toronto, estimated losses of 10 million dollars in 2003 due to the presence of imitations of its products on the market[4]. Additional examples may be illustrated in other sectors. One of the most strongly affected areas is sports clothing; the incidence of counterfeited products is estimated to be equal to 10-12% of the global market. Within the EU alone, 11% of clothing items and footwear is estimated to be replicated, causing losses of more than 7.5 billion Euro[5].

The textile sector is particularly relevant if one considers that the management of counterfeit clothing items is one of the most profitable activities for organized crime, particularly for the Neapolitan "camorra" (a Mafia-type criminal organization). It is therefore not surprising that Italy ranks amongst the countries with the highest percentage of counterfeit textile products, as illustrated in Graphic no. 1.

The large scale of the phenomenon therefore poses risks for a sector which – according to data provided by the *Italian Federation of Textiles Enterprises and Fashion* (smi–ati) – involves 62,000 companies and 525,000 employees within Italy.

Legal firms are forced to compete with illegal entities that do not respect market rules and are not required to comply with production standards. For this purpose, it is useful to note the characteristics of an illegal enterprise[6] and the competitive edge which is gained by avoiding a system of controls, regulations and standards. Not only are these imposed upon the legal company but they may occasionally serve as a competitive advantage for the latter's marketed products, such as in the case of quality controls and compliance with production standards.

Graphic 1



From a purely economic perspective, the illegal enterprise is characterized by certain advantages which provide an initial and immediate competitive edge over the legal producer. Aside from the practice of placing production centers in developing countries – thereby exploiting the lower labor and raw material costs, a practice also utilized by large firms which market legal products – the illegal company also benefits, however, from the economic advantage derived from the use of low quality raw materials. This allows the illegal company to at-

tain significantly lower production costs. In addition, production is essentially proportional to any received requests[7]; the illegal company therefore manages to sell the entire produced amount and receives an immediate payment upon delivery of the product. This prevents any risks deriving from incorrect forecasts of market share and also avoids costs linked to the storage of unsold goods while simultaneously decreasing the risk that authorities may identify the illegal company by locating warehouses for goods. Additional advantages include the fact that the illegal company does not sustain promotional costs for the product – given that it exploits the image of the legal good that it intends to replicate – nor any administrative costs associated with financial statements and accounting.

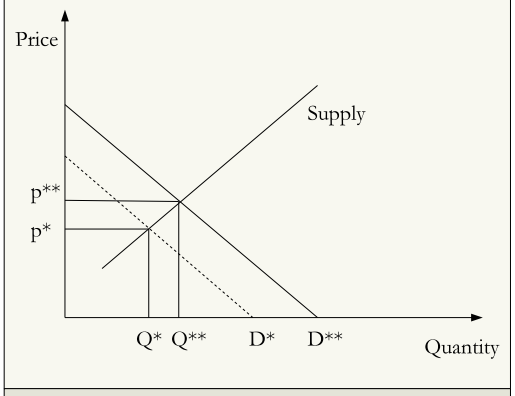
The consequence of this competitive advantage is the marketing of goods which not only imitate the original product and infringe upon intellectual property rights but are also offered at very low prices, causing a significant distortion in the market. Although it is not possible to state that all sold counterfeit goods would have resulted in an equal number of acquired original goods in the absence of counterfeiting – due to the difference in sales prices – the effect on the legal company essentially involves a shift in the demand curve relative to its products which are sold in lower amounts and at lower prices.

An interesting graphical illustration of the above can be found in the CEBR report mentioned above. The variables P** and Q** respectively refer to the equilibrium price and quantity in the absence of counterfeiting, given the supply curve and the demand curve Q'. In the presence of counterfeiting, the demand curve is shifted downwards due to a decrease in the latter. P* and Q* refer to the new equilibrium values which are now lower compared to the previous case[8].

The existence of counterfeit products which penetrate the market entails an additional consequence. In addition to losses sustained by the company on the national market, there are other damages deriving from the possibility that international distributors of their products will – in good or bad faith – decide to acquire supplies from insecure sources that offer the same goods at lower cost.

Graphic 2

Demand curve shift in presence of counterfeiting



Source: Center for Economics and Business Research

Given the above conclusions on the penetration of counterfeit products within the market by means of distributors that are in good or bad faith, the buyers of these products should be analyzed in more detail. Previous references were already made to the high number of unconscious consumers who acquire a replica believing that they are acquiring an original. This ele-

ment involves a significant fallout for producing companies and represents one of the "hidden" costs of counterfeiting. The unconscious buyer, as noted above, will directly associate the low quality of the acquired good with the producer; this results in a loss of goodwill with respect to the latter and thwarts the efforts implemented by the company in order to guarantee product quality and gain market share[9]. A loss of goodwill with respect to the trademark will result in a decrease in future sales of the company and adds to the previously discussed economic damages. In addition, the legislations of certain countries will hold a producer liable for any damages caused by the products to the consumer given that the latter has acquired the product in good faith and was unaware of the illegal origin of the product itself. The consumer may sue the producer for damages, thereby forcing the latter to sustain additional costs for legal defenses[10].

The difference between forecasted and actual revenues has the additional effect of decreasing the propensity to invest in the product. Decreased investments not only imply a lower degree of innovation but also slow-downs in technological progress – within a social/economic context where such progress is deemed essential – as well as decreased investments for integrating sophisticated or costly components within goods and lower promotional expenditure. These will result in a negative fallout on other companies which are linked to the producer, such as suppliers and advertising agencies.

It would be limiting, however, to believe that the economic consequences of counterfeiting exclusively affect producing enterprises and companies linked to the latter. The situation is actually much more complex and the "hidden" costs of counterfeiting must certainly include the elements that affect national governments in the form of decreased fiscal revenues and investments.

The illegal nature of these activities will naturally result in the creation of an underground economy involving production-distribution-sales which not only avoid the normal channels of legal regulation but also those relative to taxation. This element is shared by countries which produce fakes as well as the destination countries of these products. The estimates of losses sustained by member states of the European Union due to the impossibility of taxing these products is cause for concern; they are estimated to be 3,731 million Euro in the toy and sports clothing sector and 1,554 million Euro in the pharmaceutical sector. Losses relative to other sectors are similarly large, totaling 7,581 million Euro in the clothing and footwear sector and 3,017 million Euro in the perfume and cosmetics sector[11]. Significant economic damages are also recorded in countries where counterfeit goods are produced, as reported by data relative to Russia where it is estimated that the commerce of counterfeit products causes losses of one billion dollars for the government[12]. Losses for both producing and importing companies also occur if these products are shipped with forged transportation documents[13]. The negative impact of counterfeiting on revenues of legal companies also indirectly affects the volume of taxes which are collected by governments. In the long term, the lack of incentives for innovation and the decreased production – due to the need for the company to adjust to a new level of demand caused by the existence of counterfeit products – will result in a decrease of the

Gross National Product. This, in turn, may affect the growth rate of the country's economy. The study implemented by the CEBR estimated the impact of these losses on the British economy to be 143 million pounds per year; estimates relative to the total gross domestic product for the European Union are also cause for concern. By affecting the level of wealth that is, in fact, created by the various "economic parties" within EU countries, counterfeiting causes a net reduction in the Gross Domestic Product which – according to estimates supplied by the CEBR – can be quantified as 8,042 million Euro across Europe[14]. It should also be noted that additional reductions for tax revenues are caused by the illegal nature of workers which are exploited to produce the counterfeit goods; it is, in fact, unlikely that the counterfeiters will comply with laws relating to worker rights and compensation.

With respect to governments, counterfeiting may create an additional series of damages derived from an effect that is similar to the loss of goodwill with respect to the producer. Foreign producers could, in fact, be increasingly reluctant to move their production sites to countries where counterfeiting is widespread due to the fear of significant losses. The direct consequences of this loss of goodwill with respect to a government's capacity in ensuring compliance with intellectual property rights include a decrease in foreign investments in the country in question as well as a loss of know-how and technology. The decrease in investments may also involve a decrease in exports due to the negative reputation associated with all products originating from that country, including original goods which may be labeled as being low in quality[15].

3.2 Social consequences

Counterfeiting not only poses economic risks but also involves broader effects that may negatively impact the social fabric of a country due to the risks for consumer health and safety. The loss of numerous job positions – due to damages sustained by companies as a result of counterfeiting – serves as the link between mere economic damages and the risks brought upon consumers. The negative effects on employment are significant and represent yet another "hidden" cost of counterfeiting. It is estimated that counterfeiting causes the loss of 100,000 job positions every year in the European Union[16]; additional estimates have been made at the national level. In France, the *Comitè national anti-contrefaçon* estimated that the effect of counterfeiting on employment resulted in 30,000 lost job positions, while the CEBR estimated 4,000 lost job positions in the UK; other estimates for Germany report 70,000 lost job positions[17].

The economic problem therefore becomes a social problem. Even the loss of a single job position may become a family tragedy for the employee or the worker who no longer has any income[18]. Social costs also affect workers in countries where replicated products are produced given that, in most cases, these workers are employed under conditions of real exploitation without any form of guarantee due to the unlawful nature of their employment.

The low quality of the product may also

result in serious consequences for consumers given the risk for the latter's health and safety. Available case records are extensive. Before considering the specific characteristics and significant risks linked to the counterfeiting of medicines, airplane and automobile spare parts and toys, it is useful to introduce the topic by presenting some examples that illustrate how this risk may also be found in other types of replicated products.

Apparently harmless components, such as cell phone batteries, may result in significant risks if their production does not comply with pre-determined standards. Counterfeit batteries – which are currently very widespread[19] – do not contain adequate internal mechanisms that prevent overloading and may therefore easily explode. In addition, these batteries tend to contain an elevated percentage of mercury. This characteristic cause them to be potentially damaging for the health of consumers and may cause eye, ear, kidney and immune system problems[20].

The creativity and unscrupulousness of counterfeiters seems, however, to have no limits. There are reported cases, in fact, involving the seizure of counterfeit shampoo in North America[21] as well as Zambia[22] that contained bacteria or even acid. In July of 2007, numerous packages of counterfeit toothpaste were discovered in the Spanish market containing glycol diethylene, a substance which is highly toxic for the human body. Spanish authorities seized 100,000 toothpaste tubes; according to the daily newspaper El Pais, 10,000 packages were distributed in the hospitals of Valencia.

The counterfeiting of food and beverages is another highly risky sector for consumers; there are unfortunately numerous examples, as noted in Box 1.

Box 1 lists a few useful examples in order to highlight the fact that counterfeiting can no longer only be viewed from a purely economic perspective. The deaths of numerous individuals who believed that they had acquired a safe product at a convenient price; who are unaware that they are traveling on a means of transportation which utilizes counterfeit spare parts; who are confident that they can heal their diseases with effective and tested medicines: these cases serve as the final warning call for identifying counterfeiting as a real crime. They also illustrate the need to adequately respond to such an unscrupulous and dangerous activity.

Let us now consider certain productive sectors that are particularly susceptible to negative effects with respect to the health and safety of consumers.

Toys

The toy industry possesses all the characteristics that would appeal to counterfeiters. First of all, it is a very extensive sector with a significant economic incidence whose value in Europe was estimated by the CEBR to be more than 35 billion Euro in 2000[23]. In addition to the potential revenues which may be attained, the particular market composition is appealing given that it is dominated by a few large producing companies which also operate as distributors. Market demand is triggered by the effect of the media on the imagination of children by means of current marketing techniques.

It is this latter characteristic, however, which provides the counterfeiters with an

additional advantage. The utilized media allow the counterfeiter to copy the structure of the toy in all its details, thereby making it as similar to the original as possible without necessarily copying the trademark. In this way, the controls phase is more difficult due to the presence – as in certain Asian countries, for example – of regulatory regimes which provide a lower level of protection for industrial designs compared to that granted to trademarks[24].

Even in this case, the company is subject to additional damages which are linked to the lower quality of the counterfeit product – with the aggravating factor that the latter is more difficult to distinguish from the original. In this sector a parent is unlikely to knowingly buy a risky product for purely economic convenience given that they are toys for children. In addition, any liability for ordinary defects of the non-original toy – i.e. relative to problems with the toy itself that do not cause consequences for the child – will often not be reported and, as a result, is completely associated with the producer unless verification procedures are in place.

The toy industry tends to amplify those characteristics which are described as profitability components for counterfeiting given the large scale of the market as well as regulations which, in certain cases, offer less protection compared to other sectors. This therefore explains a 12% incidence of

BOX 1
Examples of risks deriving from counterfeit food and beverages

In 2005, 23 people died in Turkey as the result of very high levels of methyl alcohol within a local beverage that had been counterfeited

In 2004, the use of counterfeit liquor in China caused the death of at least 11 people

In 2004, circa ten children died in China after consuming counterfeit food

In 2003, one person died in Finland from the consumption of counterfeit rum

In 2003, two people died in Thailand following the ingestion of counterfeit wine

In 2002, eleven people in Taiwan died as a result of ingesting counterfeit rice wine which contained concentrations of methanol that were 290 times higher than safety limits

In 2002, the death of a British tourist in Turkey was linked to the consumption of counterfeit liquor

In 2001, at least 60 people lost their lives in Estonia after having consumed counterfeit vodka

In 1998, the consumption of counterfeit wine in China caused the death of 27 individuals, while 200 others were hospitalized

In 1986, the distribution of wine with an elevated quantity of methanol had serious consequences in Italy, causing the death of 19 people and blindness in 15 others

Sources: Altroconsumo, http://www.altroconsumo.it/map/show/12070/src/100601.htm; International Chamber of Commerce (ICC) Counterfeiting Intelligence Bureau, (2007), *The International Anticounterfeiting Directory 2007*; APCO, (2003), *Global Counterfeiting Background Document*, 2003.

counterfeiting for this sector within the European market and which – according to estimates made by Toy Industries of Europe – causes losses for producers totaling one and a half billion Euro per year[25].

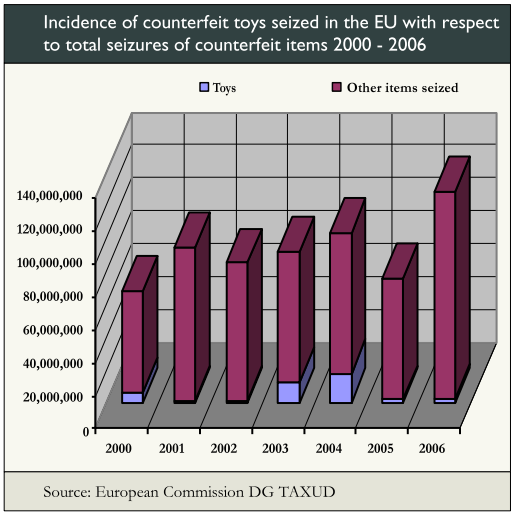
In order to appreciate the short-term evolution of the phenomenon, it is definitely interesting to consider the official statistics of the European Union relative to seizures of counterfeit goods along the borders of the EU; Graphic no. 3 provides a graphic depiction of these statistics. It should be noted that – with the exception of the peak figure recorded in 2000 where toys represented 10% of all seized products, totaling 6,819,113 pieces – the incidence of replicated toys is, on average, 1.5-2% of all seized goods with an average total number equal to one million eight hundred thousand items[26].

The countries of origin of these products are mostly in Asia, particularly China and Thailand, but there are also numerous other products from other countries such as Poland and Turkey where it is believed that the volume of production of counterfeit toys is actually higher than that of original toys[27]. However, the noticeable presence of counterfeit toys in Poland and Turkey should also be linked to their role as transit countries for counterfeit products originating from Asia and intended for the European Union market.

An analysis of the number of seizures provides an estimate relative to the number of counterfeit toys which are introduced to the market. In France, for example, counterfeits for children were seized in the port of Marseille and the airport of Roissy for values equal to Euro 450,000 and Euro 215,000 respectively[28].

These measurements and estimates are very useful in determining the economic incidence of the problem which may reach levels equal to one fourth the production of a company. This is the case, for example, of a French toy producer. Total sales for one of its top products was close to 2.2 million pieces while 850,000 counterfeit pieces had been imported into France and Germany[29].

Graphic 3



These estimates become alarming if one not only considers the quantity of products which penetrate the market but also the parties which receive them. Given that the latter are children, the level of danger grows exponentially. It is important to not forget, in fact, that – due to the characteristics and needs of the final user – toys are subject to very severe regulation and quality controls as well as specific tests that precede their introduction in the market in order to ensure that their utilization does not involve any type of risk for children.

An object which is placed in the hands of a child must be designed and implemen-

ted by taking typical child behavior into account. A toy must not have parts that are easily detachable and can be potentially swallowed. The materials themselves, as well as the colors used during production, must not contain any form of toxicity. Following controls and on the basis of the toy's composition, its size or the size of its parts and its structure, the product will be classified as suitable or not suitable for a certain age group; particular care is given to toys classified for children under the age of 36 months.

These controls are obviously not implemented by counterfeiters whose only interest is to market the products at a good price and with the lowest possible cost of production.

Box 2 provides an example which illustrates the gravity of the problem.

The range of replicated products for children is unfortunately very broad. In addition, any part of such products may be damaging: the dyes that are used – which may contain a high level of lead – as well as materials that are easily flammable.

In 2000, counterfeit figurines with a high level of toxic lead were seized in the UK while the Center for Consumer Protection in Liverpool seized counterfeit toy watches in Liverpool which had easily detachable components and presented a high risk of choking.

The consequences of utilizing such products may be very serious; the primary reason for concern is due to the fact that they are difficult to identify as a result of their close similarity to the originals and may therefore also be found in a supermarket or a specialized store.

BOX 2
What could be found inside a counterfeit toy?

Excellent evidence is presented in the Special Report on Counterfeiting drafted by the International Trademark Association in 2004. During the creation of a TV program against counterfeit products, Lorne Lipkus – a Canadian lawyer operating in this sector – decided to open a counterfeit felt toy in order to analyze its contents. What they found varied from hair to unidentified colored material. During the preparation of the program, Lipkus and his TV crew also visited a waste disposal center for counterfeit products where a significant quantity of felt toys was being incinerated; the estimated value of these toys was circa one million dollars. At this point, Lipkus narrated what had happened a few years ago during a visit to another waste disposal center: several of the employees who entered into contact with the toys and their stuffing developed large rashes on their arms and legs. One of the employees had only noted a similar experience once when he entered into contact with isolating material used for his attic. During the preparation of the program, another coincidental case occurred: the battery space of a counterfeit watch containing the image of a well-known TV personality opened and revealed a counterfeit battery that was already in a state of oxidation and whose liquid was beginning to seep out.

Source: International Trademark Association, (2004) *Special Report on Counterfeiting*.

Spare parts for aircraft and motor vehicles

From an economic perspective, the market for aircraft and motor vehicle spare parts is a thriving sector for the counterfeiter. In the first case, this element is essentially guaranteed by the elevated market price of these products while, in the case of motor vehicles, profitability is guaranteed by the enormous distribution of vehicles and therefore the widespread commerce of spare parts. In both cases, replicated goods are introduced within a legal market with relative ease by means of black or parallel markets. In essence, however, the two product sectors – aircraft and motor vehicle – present different characteristics and sizes which should be analyzed separately.

A) Aircraft

Spare parts for aircraft are generally produced by a variety of small firms and are subject to severe regulation in order to guarantee compliance with certain safety standards. In the United States, for example – and similarly to what occurs in most countries – a specialized government body, the **Federal Aviation Authority** (FAA), regulates the design and production of these components, granting authorization and approving a product after severe controls in relation to planning and design criteria, production facilities and processes and quality controls[30].

This is due to the specific characteristics which these products must have in order to fulfill their specific functions. Any form of structural failure or malfunctioning of the motor can result in catastrophic consequences. Even the production of screws, bolts and supporting components – in addition to more sophisticated spare parts – must comply with specific requirements and produce products of elevated resistance and durability.

In recent years and following the discovery of counterfeit spare parts, controls on the supply of these products have been strengthened; the risk of utilizing a counterfeit spare part, however, remains very high. In order to tackle the problem, the authorities regulating civil aviation in the US and Australia (in the latter case, the **Civil Aviation Safety Authority** – CASA) have created specific programs for the purpose of expanding monitoring activities and controls with respect to products that are suspected to be non-compliant. This category – generally referred to as SUPs (**Suspected Unapproved Parts**) – includes various types of spare parts whose common characteristic is their non-compliance with requirements needed for their approval as safe products that are therefore authorized to be installed on an aircraft[31]. This category also includes counterfeit products[32].

The US **Federal Bureau of Investigation** (FBI) has identified the four most common types of fraud affecting SUPs and their introduction within the distribution chain. The first consists in attaching a valid FAA label to a used spare part that has not been modified or changed; the label will certify the servicing of the product or the latter's refurbishing. Another method consists in manufacturing the spare parts in compliance with the producer's specifications but utilizing low-quality materials. The third method consists in buying and re-selling overproduced parts from legitimate manufacturers. Although these spare parts are not counterfeited, it is possible that these products are production rejects and there-

fore also potentially dangerous. Finally, another type of fraud involves the acquisition of damaged spare parts, or parts which are nearing the end of their useful residual lives, and re-selling them as renewed spare parts[33]. These types of fraud are obviously not only implemented within the USA but are found in all countries.

Data derived from an investigation carried out by the US *Department of Transportation*[34] – although relative to the 1990's – illustrate a growing trend within the market of counterfeit spare parts for aircraft. When the investigation was launched in 1990, the problem of counterfeit spare parts was not yet a priority and only nine reports were recorded. Due to more severe controls, these reports increased to 52 in 1991, 362 in 1992 and 411 in 1994. The figures relative to 1995 and 1996 reported a slight decrease but the numbers continue to be concerning, totaling 317 and 320 reports, respectively[35].

Estimates relative to the size of this market in the United States are cause for more concern, however. Experts in this sector believe, in fact, that the counterfeit market may be equal to 10% of the legal market if all SUPs are included within the estimate. This widespread distribution is understandable given the high level of profitability of these products. A simple component such as a nut may be sold at high prices – *circa* 400 dollars – given its characteristics of resistance and duration[36]. Counterfeiters do not comply with safety specifications for the spare part and may therefore produce the product at very low cost and re-sell it on the market at a very high price, thereby attaining significant profit margins.

Although it is difficult to unequivocally link the cause of an aircraft disaster to the utilization of a counterfeit spare part – due to the problems inherent in verifying the causes of such accidents – it is, in any case, possible to illustrate a few examples where it is suspected that the accident was caused by the installation of a non-compliant spare part. These examples also dramatically illustrate the phenomenon and highlight the number of human lives which are sacrificed for the economic interests of unscrupulous criminals. One example is the case of the Norwegian aircraft Convair 580 which crashed in 1989 when flying from Norway to Germany due to a counterfeit bolt in the tail structure of the airplane, resulting in the death of 55 people[37]. Other examples are linked to an Italian investigation on the trafficking of counterfeit spare parts across several countries. Although Asian countries are often cited as the primary source of these products, it should be noted that North American and European countries also have production sites.

One fact is certain: the market for non-compliant spare parts for aircraft is very large and there are many accidents which could be potentially attributed to these counterfeit parts. A confidential file of US authorities published in *Business Week* estimated that – in the period between 1973 and 1993 – 166 airplane accidents in the USA alone were caused by the use of counterfeited spare parts[38].

The sentence for the case cited in the box above – and which fully falls within the category of criminal activities that could have potentially catastrophic consequences by risking the lives of thousands of people – emphasizes the importance of not considering counterfeiting as a second class crime. The sentences should be proportional to the crime and create a deterring effect in or-

der to prevent unscrupulous criminals from considering the counterfeiting of spare parts as a highly profitable and low-risk activity.

B) Motor vehicles

Similarly to the case of spare parts for aircraft, the market of spare parts for motor vehicles is very appealing for counterfeiters due to its size and the relative ease with which replicated products can be marketed and sold on legal markets.

Even for this market, counterfeit products fall within a broader category of goods: unauthorized spare parts. This category includes: warehouse surpluses of authorized distributors which are sold directly at a sales point without the authorization of the manufacturer; imports from a parallel market, including original spare parts that are transferred from one market to another without the authorization of the manufacturer; and copies of spare parts produced by independent suppliers. The latter are legal if: they possess the same quality level of the original spare part; they are not labeled with counterfeit trademarks; and they are identified as non-original spare parts when sold to the final user[39].

This market – particularly in recent years – has grown significantly in conjunction with the recent increase in motor vehicles across the world[40].

This growth has been particularly no-

BOX 3
Counterfeit aircraft spare parts: the Italian experience

The largest European investigation on the subject was implemented in Italy following the theft of spare parts in the hangar of Meridiana airlines within the Olbia airport in 1995. The investigations reached a decisive turning point when the Italian Guardia di Finanza discovered 80 thousand spare parts within hangar 126 of Ciampino airport as well as a workshop where the parts were assembled for subsequent selling. Hangar 126 was owned by an Italian company, Panaviation, with a registered office in Rome and operating in the sector for the distribution of spare parts for aircraft. Its customers included many Italian and foreign airline companies, including Meridiana, Lufthansa, Air One, the ex-Swissair, SAS, Air France. This company could also rely upon the support of an American distributor, Dunbee; several containers were seized by the Italian Guardia di Finanza which were en route towards this company and contained 30 thousand kilograms of non-compliant spare parts. The investigation yielded alarming results. Panaviation would, in fact, acquire discontinued aircraft destined for scrapping and disassemble the components in order to market them following a simple cleaning and the forging of false documents which certified their refurbishing. Some spare parts originated from low-quality discontinued aircraft of ex-Yugoslavia while others were even taken from a Canadair plane which sank in Sicily. The investigations also confirmed the liability of two other companies which were linked to Panaviation – New Tech Italia and New Tech Aerospace – and extended beyond the Italian territory to US soil through the collaboration of the FBI.

The spare parts supplied by Panaviation were, in fact, suspected of being the cause of two serious airplane accidents: an incident in New York in November of 2001 when an Airbus A300 crashed due to a structural failure during take-off, causing the death of 265 people; another

ticeable in countries with elevated growth rates but with relatively low pro-capita income levels. China is an obvious example: the number of circulating vehicles between 1990 and 2002 has quadruplicated; a similar increase in circulating vehicles was reported in Thailand between 1987 and 1997[41]. These markets are traditionally affected more by the counterfeiting phenomenon, the latter being stimulated, amongst other things, by the elevated price of the original good in relation to the purchasing power of the average salary. Counterfeit spare parts can, on the other hand, be acquired at 50% of the price of an original, thereby promoting the demand for such products and creating the conditions for attracting producers and distributors of counterfeit spare parts in the market[42].

The elevated price of original spare parts should not be underestimated when analyzing the factors causing the widespread distribution of the phenomenon. Large automobile companies are aware of the fact that they can create monopolies with regards to original spare parts and, as a result, they often implement price increases for these products, thereby indirectly providing incentives for the customer to search for spare parts at lower prices.

Similarly to other markets affected by this phenomenon, it is again difficult to provide accurate and reliable data on the scale of the problem. It is, in any case, possible to supply estimates which highlight a

incident concerned the Bari-Djerba flight where an ATR 42 owned by a Tunisian airline company crashed and sank into the sea off the coast of Palermo, causing the death of 16 people. The cause of the disaster was discovered to be the cockpit instruments which did not report a lack of fuel, thereby resulting in engine shutdown.

The investigations conducted by the Guardia di Finanza had the immediate effect of alerting the national government bodies which are entrusted with monitoring flight safety; these bodies implemented severe testing procedures on all airline companies in relation to spare parts acquired from Panaviation and companies linked to the latter. This involved significant costs. Consider the case of Lufthansa which had installed five connectors acquired from Panaviation on General Electric motors. The identification of these parts was, however, impossible due to the lack of serial numbers on the connectors, thereby forcing the German company to replace all connectors on 180 turbines.

The trial relative to Panaviation ended – following plea bargaining – with a sentence of one year and four months of prison for the owner and his daughter as well as the owner of New Tech Italia and a maintenance technician of Meridiana; they were accused of endangering the safety of transportation systems as well as the forgery of public deeds. Other parties involved in the crime were sentenced to several months of prison.

Sources: Abata G., (2002), *La Sicurezza dei voli (Flight safety)* in Il Mattino, article of January 27th; Cocco G., (2005), *Risequestrate i ricambi de lla Panaviation (Seize the spare parts of Panaviation)*, in La nuova Sardegna, September 15th; Di Feo G., Gatti F., (2005), *Fermate quell'aereo (Stop that airplane)*, L'Espresso.

very extended market for counterfeit spare parts that should be cause for concern. Of the 12 billion dollars that are globally lost by the automotive industry as a result of sales of unauthorized spare parts, the MEMA estimates that 3 billion are attributable to the incidence of counterfeiting in the US market while the remaining 9 billion are mostly attributable to losses sustained within the European Union[43]. *General Motors* estimates that 1.2 billion dollars were lost by its company and its distributors[44]. A greater degree of uncertainty relative to the incidence of counterfeiting within the legal market is reported in Europe: the European Commission estimates an incidence of 5-10% of the European market in contrast to the estimate of the *International Federation of Automotive Aftermarket Distributors* which is less than 1%[45].

Aside from this significant quantification discrepancy – potentially due to sector interests – there is, in any case, no doubt that the sector for motor vehicle spare parts is a thriving market for counterfeiters, as illustrated by the results of certain seizures and implemented investigations. According to these investigations, there are 57 companies manufacturing counterfeit spare parts in France alone which are in turn supported by a network of 44 distributors. In the UK, the market for such spare parts is estimated to be equal to 10% of the national market[46].

The fact that counterfeit spare parts can be easily sold within the legal market serves as a significant incentive promoting the growth of the phenomenon, as illustrated by an investigation conducted in France by the *Direction générale de la concurrénce, de la consommation et de la répression des fraudes*; the investigation was conducted in the period between the fourth quarter of 2002 and the third quarter of 2003. A total of 154 French facilities were inspected, including mechanical repair centers, body shops, distributors and specialized importers: 1,200 counterfeit spare parts were found. These spare parts originated from Belgium and Netherlands although the examining judges believed that these countries only served as transit points for the products[47], which are generally manufactured in China, Singapore, Turkey but also Italy, Spain and Portugal[48].

The spare parts which are most frequently counterfeited are those which are broadly utilized. Counterfeiters concentrate on a handful of easily replicable products with low cost and which are also easily marketable[49]. The most replicated products include, in fact, fenders and bumpers, brake pads, shock absorbers, hoods, steering wheels, windshields, fuel pipes[50].

Even in this case, counterfeiters benefit from certain competitive advantages which allow them to market products at extremely low prices. These advantages are essentially derived from an absence of quality controls on the final good which is, on the other hand, tested multiple times by manufacturing companies in order to guarantee the required duration and safety levels[51].

Even in this sector, the lack of quality in spare parts and the nature of the latter may result in significant risks for users. When a counterfeit or low quality product is installed on a vehicle, the risk is that its overall functionality becomes compromised. Even spare parts that are not of fundamental importance will serve specific functions and any defects in their operation can result in very serious consequences. Consider, for example, a steering wheel or

its components built from low quality materials that could easily break; an engine hood which doesn't crumple on impact but penetrates the vehicle; fuel pipes which break and present a fire hazard; brake pads that are ineffective due to the materials of which they are built (compressed mud or wood) and increase the pull-up distance and are set on fire during intense usage; or a windshield that is not sufficiently resistant and disintegrates.

These examples are unfortunately not hypothetical cases but are based on documented incidents in which counterfeit spare parts caused serious accidents.

The elevated social costs caused by the trafficking of counterfeit spare parts are therefore undeniable and are even higher if one considers the fact that there are no official statistics on accidents caused by such products. In addition – and unlike the aircraft sector – there is no legal requirement for authorities to investigate the causes of an accident unless the latter had lethal consequences. A high number of accidents which fortunately did not result in deaths could have been caused by counterfeit products given their widespread distribution; these accidents are not, however, investigated and their causes are not ascertained, thereby creating an obscure area that prevents the phenomenon from being clearly defined.

Notes

1 Majid Yar, (2005), *A Deadly Faith in Fakes* cit., page 8.

2 "Although it is difficult to obtain precise figures, estimates put counterfeits at more than 10% of the global medicines market. They are present in all regions but developing countries bear the brunt of the problem. An estimated 25% of the medicines consumed in developing countries are believed to be counterfeit. In some countries the figure is thought as high as 50%". WHO, (2006b), *Counterfeit Medicines*, http://www.who.int/mediacentre/factsheets/fs275/en/.

3 Center for Economics and Business Research (CEBR), (2000), *Economic Impact of Counterfeiting in Europe*, pages 2-3.

4 Isaac B., Osmond C., (2006), cit., page 10.

5 APCO, (2003), *Global Counterfeiting Background Document*, page 18.

6 The term illegal enterprise/company here refers to a company which produces counterfeit goods.

7 WIPO, (2004c), *WIPO National Seminar on Intellectual Property for Faculty Members and Students of Ajman University*, page 3.

8 CEBR, (2000), *Economic* cit., page 9.

9 "...consumers who are deceived into believing that they bought a genuine article when it was in fact a fake, blame the manufacturer of the genuine product when it fails, creating a *loss of goodwill*. Even cheaper and obvious copies that are bought in good faith represent a serious threat to the company that wants its brands associated with quality and exclusivity." OECD, 1998, cit., page 22.

10 Currently effective legislation in some countries may go even further: "Recent changes in the product liability laws in a number of countries include provisions for manufacturers in relation to counterfeit of their products. The manufacturer of the genuine product may now find her/himself embroiled in expensive litigation to prove that he has taken the necessary measures to protect his product from being counterfeited." Lowe P., (1999), *The Scope of the Counterfeiting Problem*, in International Criminal Police Review, page 93.

11 WIPO, (2004c), *WIPO National Seminar* cit., page 4.

12 APCO, (2003), *Global Counterfeiting* cit., page 2.

13 "False documentation will accompany the false products, understating their sale price, for the purpose of reducing tax imposts in both the producing and importing countries." WIPO, (2004c), cit., page 4.

14 Centre d'Etudes Internationales de la Propriété Industrielle (CEIPI), (2004), *Impacts de la contrefaçon et de la piraterie en Europe*, Rapport final, page 18.

15 CEIPI, (2004), *Impacts* cit., page 18.

16 Council of Europe, (2004), *Counterfeiting: Problems and Solutions, Report of the Committee on Economic Affairs and Development*.

17 CEIPI, (2004), cit., pages 19 – 20.

18 "But it wasn't only lives that were lost or harmed by counterfeiting during the year. Livelihoods were also destroyed. Fifty employees at Danoon Ceramics lost their jobs and the factory, a major employer in a small town in Scotland, faces closure because the products they make are being counterfeited extensively in China. This is far from unusual and many firms in different parts of the world are facing similar problems." International Chamber of Commerce (ICC), Counterfeiting Intelligence Bureau, (2006), *The International Anti-*

Counterfeiting Directory, page 4.

19 "Ainsi, il existe des affaires des contrefaçon de batteries des tèlèphones portables de mouvaise qualitè vendue sus la marque Nokia dont 30 à 40 ont explosè blessant grièvement certaines personnes dont une famme en Finlande et une en Hollande." CEIPI, (2004), cit., page 38. "Several shipments of counterfeit batteries from China have been seized by RCMP and Canada Border Service Agency officers (CBSA). The batteries contained mercury (despite packaging representing that they did not) raising environmental issues, and they exploded under sustained load." Isaac B., Osmond C., (2006), cit., page 14.

20 APCO, (2003), cit., page 13.

21 "In early 2003 U.S. Customs officials seized 17,000 bottles of counterfeit shampoo contaminated with potentially harmful bacteria that were being imported into the United States from Canada. Health Canada Product Safety officers subsequently found and removed the same counterfeit products from drug stores in British Columbia and Saskatchewan and from hair salons in the Greater Toronto Area." Isaac B., Osmond C., (2006), cit., page 15.

22 "Law enforcement in Zambia seized counterfeit shampoo containing acid." WIPO, (2004c), cit., page 9.

23 CEBR, (2000), cit., page 5.

24 "Counterfeiting of toys is slightly different from 'normal' trademark infringement. It often happens that the design of the product is copied and sold under a similar but not identical trademark. This is harder to combat for the trademark owners, especially in Asia where design protection is not as strong as trademark protection." OECD, (1998), cit., page 14.

25 The organization *Toy Industries of Europe* – which represents the interests of toy producers with respect to European institutions – states that one out of every ten toys is counterfeited. CEIPI, (2004), cit., page 66.

26 TAXUD cit.

27 CEIPI, (2004), cit., page 68.

28 "En France, dans le cadre des saisie opéréé à Marseille, les services douanieres ont noté la menace pour la sécurité des enfants constituye par des articles interceptés des jouets et de bouées. La saisie opérée par le service des ports portait sur 8.640 jouet représentant des téléphone portables à l'effigie de la marque *Teletubbies*, 4.104 bouées en plastique pour enfants imitant la marque *Pikachu*…Une autre saisie opérée par les services douaniers de surveillance de fret de l'aéroport de Roissy le 1er Juin 2003 avait permis d'intercepter 483.840 cartes de jeu *YU GI OH* ." CEIPI, (2004), cit., page 69 – 70.

29 CEIPI, (2004), cit., page 66.

30 US Department of Transportation – Federal Aviation Administration, (1995), *Suspected "Unapproved Parts" Program Plan*, pages 1-1.

31 "...Examples of parts that are not eligible for use…are parts rejected during the production process because of defects, parts for which required documentation has been lost, parts that have been improperly maintained, and parts from military aircraft that have not been shown to comply with FAA requirements… 'Unapproved Parts' also occur when a supplier that produces parts for an approved manufacturer directly ships to end users without the approved manufacturer's authorization or a separate, applicable Parts Manufacturer Approval (PMA). An example of this is 'production overrun' parts. Because these parts are not authorized by the Production Approval Holder, one cannot assume that they have met all the requirements of the approval holder's required quality control process." U.S. Department of Transportation – Federal Aviation Administration, (1995), *Suspected* cit., pages 1-4.

32 "Counterfeit parts, a type of 'unapproved part', may be new parts that are deliberately misrepresented as designed and produced under an approved system or other acceptable methods even though they were not so designed and produced. Counterfeit parts may also be used parts that, even though they were produced under an approved system, have reached a design life limit or have been damaged beyond possible repair for aviation standards, but are altered and deliberately misrepresented as acceptable, with the intent to mislead or defraud." U.S. Department of Transportation – Federal Aviation Administration, (1995), cit., pages 1-3.

33 OECD, (1998), cit., page 15.

34 Agents participating in the investigation were authorized to investigate airline companies, suppliers, producers, distributors and authorized repair centers. OECD, (1998), cit., page 15.

35 OECD, (1998), cit., page 15.

36 OECD, (1998), cit., page 15.

37 Lowe P., (1999), *The Scope* cit., page 95.

38 Di Feo G., Gatti F., (2005), *Fermate quell'aereo (Stop that airplane)*, L'Espresso.

39 OECD, (1998), cit., page 14.

40 It is, in fact, estimated that the current figure of 500 million automobiles across the globe will double by 2015. Majid Yar, (2005), cit., page 14.

41 Majid Yar, (2005), cit., page 14.

42 Majid Yar, (2005), cit., page 14.

43 OECD, (1998), cit., page 14.

44 OECD, (1998), cit., page 14.

45 CEIPI, (2004), cit., page 75.

46 WIPO, (2004c), cit., page 11.

47 CEIPI, (2004), cit., page 75.

48 OECD, (1998), cit., page 14.

49 "The two following examples taken from a sales catalog from the parallel market are a good illustration of this:

Only five Citroen BX parts on offer: front bumper, windscreen, windscreen seal kit, bonnet and headlights.

Only ten Peugeot 205 parts on offer: front wing (right and left), bonnet, headlights, indicator, windscreen, front cross-member, radiator and cooling fan."

Brut J.P., (1999), *Car Parts Counterfeiting*, in International Criminal Police Review, page 10.

50 WIPO, (2004c), cit., page 11.

51 "Every vehicle component is the subject of stringent specifications, drawn up of a result of long and costly research. The Peugeot-Citroen Group spends 7.5 billions francs on research, 10% of which is exclusively on safety, partly in the form of 400 crash tests in the most extreme conditions. Before they can be put on the market, all vehicles and their parts undergo component-type approval tests and, in France, these are carried out in conjunction with the technical automotive union, the UTAC." Refer to: Brut J.P., (1999), *Car Parts* cit., page 10.

4. The counterfeiting of medicines

Counterfeit medicines are classified as products which may cause serious damage to the health and safety of consumers. This classification is due to various factors which are essentially linked to the growing distribution of counterfeit medicines, the dangers presented by the latter, the relative simplicity with which it is possible to create a product that is very similar to the original and the interest that organized crime has developed for these products.

In accordance with WHO guidelines on counterfeit medicines, certain definitions should be clarified: the terms drug, medicine and pharmaceutical product will be used interchangeably[1].

Compared with the previously considered sectors of toys and spare parts for motor vehicles and aircraft, counterfeit medicines are perhaps the products with the greatest potential for harming the health of consumers given that their utilization is most of the times linked to a physical or psychological need on the part of the user. The term "most of the times" is used here because, even in the case of pharmaceutical products, the driving motives related to a status value cannot be ignored. Medicines such as Viagra or products utilized with the intent of improving the aesthetic appearance – become thinner or reduce the effects of age – are associated with a status value of the products themselves.

The common characteristic of pharmaceutical agents – aside from their inherent danger – is the fact that they belong to a category of replicated products whose panel of potential buyers is almost exclusively composed of unconscious buyers or users.

The great majority of consumers would not voluntarily acquire a counterfeit medical prescription since the buyers of these products are driven by a diametrically opposed rationale, i.e. the improvement of their health and not the exposure to risks or health problems. The buyer of a counterfeit drug is not only deceived into acquiring a product which she/he didn't intend to buy but also exposes her/himself to serious risks. The production of pharmaceutical agents – similarly to toys and spare parts for motor vehicles and aircraft – is heavily regulated in order to ensure product compliance with the highest quality and safety standards. In addition, all drugs must undergo clinical trials before being marketed in order to verify the potential existence of side effects in patients as a result of the drug in question.

From the perspective of unscrupulous groups, the possibility of exploiting a gigantic market characterized by an almost inexhaustible demand is an opportunity that can not be missed. These groups also exploit recent developments in electronic communications as well as the possibilities offered by parallel markets in order to create a breach in the medicine market. The counterfeit products are then marketed with consequences ranging from ineffective therapeutic results – in the best case scen-

ario – to severe health problems or death.

Before considering additional elements of the problem, the term "counterfeit drug" should be defined. According to the WHO definition, a counterfeit drug is a pharmaceutical product whose origin and/or identity specifications have been deliberately and fraudulently modified. This commonly accepted meaning falls within the broader concept of *substandard medicine* and may also be applied – again, in accordance with WHO guidelines – with regards to medicines that are not protected by a patent such as generic drugs.

This definition is only useful for the purposes of identifying the object of the problem but is one of the few existing definitions for counterfeit drugs, given that such a definition is, in fact, only found within the legal systems of two countries which are both located outside of Europe: the Philippines and the USA. The definition adopted in the USA[2] is based on the concept of trademark and the violation of the latter defines a pharmaceutical product as counterfeit. The definition used in the Philippines[3] focuses more upon the methods through which the product can be faked or the consumer deceived. This definition lists several potential cases and seems more consistent with the "spirit" of the WHO definition.

The lack of specific standards with regards to this phenomenon in the majority of nations illustrates the preference of numerous legal systems to classify various types of fake products under a general meaning, namely "counterfeit products". This formulation of the problem appears limiting, particularly if one considers recent developments and the appearance of replicated products in the market which are capable of constituting a significant risk for the health and safety of consumers. It would therefore seem desirable to create specific standards which label the act of replicating and marketing any products which cause illness, injury or death as a crime and providing for specific penalties that are more severe and may serve as a deterrent.

The distribution of fake medicines has also resulted in a very peculiar implication that is linked to the debate on information disclosure and notices concerning counterfeit medicines.

On the one hand, it is argued that pharmaceutical companies – despite knowing that a counterfeit version of one of their medicines was being marketed – did not issue communication notices to the public or the authorities in certain cases, or issued them with a delay, in order to protect consumer goodwill with respect to these drugs and to avoid alarmism and additional damages to consumers. Another interpretation of this approach is that such actions simply serve as means to protect economic interests and pharmaceutical markets.

The fact that informational disclosure or secrecy is a current issue that should not be underestimated is supported by declarations issued at different times by representatives who hold or held important positions within trading or trade associations. Examples include the cases of the *Association of the British Pharmaceutical Industry* (a British trading association which represents 75 pharmaceutical manufacturers) and the *Royal Pharmaceutical Society of Great Britain* (a British company with the task of uniting pharmacists and regulating their profession)[4]. Fortunately, the Royal Pharmaceutical Society of Great Britain has recently modified its position and re-evaluated the need to inform the public as

soon as there is a risk that counterfeit medicines could be prescribed to a patient[5].

This situation has led the WHO to call attention upon these factors while also highlighting the serious constraints placed upon law enforcement in the case that information is withheld by pharmaceutical companies[6].

4.1 Types of counterfeit drugs

The meaning associated with "counterfeit medicines" incorporates various cases that – for various reasons – are ascribable to the adulteration/replication of a product and/or tampering with the packaging of the latter[7]:

- Products containing the same active ingredients and the same excipients of the original pharmaceutical agent and are correctly packaged and labelled but which have been illegally imported into a country.
- Products containing the same ingredients of the genuine medicine and with genuine packaging but which contain incorrect amounts of ingredients.
- Products which – despite being identical from an external point of view and have genuine packaging – do not contain any active ingredients.
- Products which are externally similar to original products and with genuine packaging but which do not contain the same active ingredients but instead contain harmful substances.
- Products with counterfeit packaging and correct amounts of active ingredients.
- Products with counterfeit packaging but with different amounts of active ingredients.
- Products with counterfeit packaging that contain a different active ingredient.
- Products with counterfeit packaging that do not contain active ingredients.

Given this subdivision, it is possible to classify counterfeit drugs into: perfect fakes, imperfect fakes, total fakes and criminal fakes, in accordance with the categories presented in an interesting report created by Care and published on the latter's website[8].

"Perfect fakes" are original products which have penetrated the pharmaceutical supply chain of a country by means of illegal or unauthorized means. Given that they are, in any case, original drugs, they do not pose a risk for the health and safety of consumers and their presence in the market results in economic damages for manufacturers and the government. They are produced by the same authorized companies but their distribution is implemented through unauthorized importers, retailers or distributors, i.e. parties which were not granted exclusive distribution licenses.

The parallel market – which, it should be noted, is a legitimate economic practice within the EU – is one means by which it is possible to implement operations of this type. This method is based on the possibility of exploiting sales price differentials between countries, thereby allowing parallel importers and distributors to acquire goods in nations with lower sales prices and re-sell them in countries with higher prices. In this manner, these companies impose themselves, however, over exclusive sales agreements which characterize the importing and distribution of certain categories of goods.

"Imperfect fakes" are medicines that are very similar to originals – both in terms of composition as well as appearance – and which have genuine packaging but do not provide the required therapeutic efficacy. They differ, however, from "total fakes" given that they – although sold with genuine packaging – are manufactured without active ingredients and are composed of ingredients whose sole function is to appear as similar to the originals as possible.

The category which poses the highest risk, however, is that of "criminal fakes": counterfeit medicines with genuine packaging that do not contain any healing effect and replicate a drug which is designed to treat certain diseases. The function of the original product guarantees an elevated sales price; as a result, the replication of these medicines is very profitable. At the same time, however, the absence of active ingredients in these products – given their function – often has tragic consequences for the patient. The "criminal fake" category also includes another very dangerous practice: including harmful substances in the composition of the counterfeit medicine, thereby creating an additional health risk for patients.

The counterfeiting of medicines may also involve products which were initially genuine but whose packaging was modified in order to declare that the products have a higher level of active ingredients that the actual amount, thereby allowing for an increase in sales price. Expired drugs may also be placed within packages that report a later expiration date. Finally, another practice should be mentioned: the marketing of stolen, and therefore original, medicines which were not suitably preserved before being marketed[9].

Given the practices related to the modification of packages and the role of the parallel market, more complex classifications have been developed; the latter further subdivide the definitions described above and primarily take into account the criminal practices linked to the counterfeiting of drugs[10].

There is, unfortunately, yet another type of trafficking in addition to counterfeit drugs which often overlaps with the latter. This is the commerce of false active pharmaceutical ingredients, the raw materials which constitute a pharmaceutical agent. This commerce poses a very high risk for the health and safety of consumers and is also due to norms regulating the distribution of active ingredients which – at least in European legislations – are not characterized by the same severity as those regulating the production and distribution of finished drugs. It is possible that certain authorized producers of drugs may unknowingly market counterfeit medicines due to the utilization of fake active ingredients during manufacturing. This is a high risk factor due to the fact that the fake active ingredients may be used by legitimate manufacturers in good faith[11].

Finally, reference should be made to the trade in counterfeit steroids. Their huge demand has opened a door for counterfeiters to infiltrate in this market and the use of fake steroids could be extremely harmful.

4.2 The scale of the problem

Having outlined the type of products that are included within the meaning of counterfeit drug, it is now possible to describe the scale of the problem in conjunction with certain examples which illustrate

the risks resulting from the marketing of these products within the legal supply chain.

Although it was believed – up until a few years ago – that the problem of counterfeit drugs only affected developing nations, it is today widely believed that they are also present in regions that are economically more developed such as Europe, the USA and Canada. A significant difference, however, remains in terms of the type of counterfeit medicines which reach these two markets. In Europe, the United States and Canada, in fact, the trafficking of fake medicines primarily involves pharmaceutical products that are lifestyle-related. These so-called lifestyle drugs include pharmaceutical agents against male sexual dysfunction (Viagra, Cialis), substances which aid in weight loss (Reductil), fake steroids, or other products which slow down the aging process. It should, however, be noted that – although these drugs are the ones that are most counterfeited in these markets – they are often accompanied by fake medicines designed for more traditional pathologies, such as antibiotics, antiviral or anti-anemic drugs.

The counterfeiting of medicines in developing countries is, on the other hand, even worse. The replicated drugs are typically those which are used to treat the most serious diseases such as medicines against malaria, vaccines of all types, antibiotics and anti-retro-virals for HIV. The differences in counterfeit products between these two market "types" reflect the specific marketing strategy adopted by counterfeiters: drugs with the highest market share and/or profitability are marketed. The search for physical/aesthetic perfection is a fundamental element driving demand for drugs or derivatives of the latter in markets with greater wealth. On the other hand, counterfeiters can count on an almost rigid demand curve in developing countries due to the need to combat epidemics or serious diseases, the elevated cost of drugs designed for these functions and the low supply of such products combined with the constant need for medical demand and low levels of wealth. Counterfeiting activities are often facilitated by relatively ineffective legislative protection, the difficulties with which authorities are able to effectively act against organized crime, the high levels of corruption and the existence of illegal parallel supply chains[12].

The traffic routes that are used for these products connect the markets of developing countries with those in Europe and North America in a variety of ways. The raw materials and counterfeit drugs often originate in Asia, America and Eastern Europe and reach the most profitable markets through various trade routes depending on the type of product. China, for example, is often noted as one of the primary sources along with India, Cambodia and Thailand in southeastern Asia as well as Mexico in Latin America[13]. The European continent is also a site hosting production centers for counterfeit medicines. The presence of such centers in Europe, as well as the complexity of the utilized trade routes, is clearly illustrated by the previously cited case involving the marketing of counterfeit Zantac – a drug used to treat gastritis – in which the raw materials were derived from Turkey while the manufacturing process was implemented in Greece. The final product was then marketed through a Dutch importer by means of a Swiss "broker".

Providing accurate data relative to the

counterfeiting of drugs on the global market is quite difficult. The WHO itself has recently revised its estimates. It was, in fact, initially considered sufficient to state that counterfeit medicines totaled about 7-10% of all drugs worldwide, but in recent years there has been a trend in distinguishing the specific situations of individual countries, thereby providing a more accurate depiction of the problem and more accurately describing the composition of the 7-10% total[14]. In the most highly developed countries, the percentage of fake drugs is equal to *circa* 1% of the market; in Africa, Asia and parts of Latin America, this percentage ranges from 10% to 30%. The WHO also

BOX 1
When counterfeit medicines kill

- It is estimated that counterfeit drugs in countries such as Nigeria or Pakistan are equal to 40% or 50% of the total;
- 36.5% of antibiotics and antimalarials drugs included within the list of essential medicines drafted by the WHO are not in compliance with legal regulations in Thailand and Nigeria;
- Estimates provided by the U.S. Federal Drug Administration confirm these figures; the percentage of counterfeit drugs could be equal to 10% of the global market;
- The European Federation of Pharmaceutical Industries and Associations estimates that counterfeit drugs total 10% of the market for medicines in countries in southeast Asia and 50% in Pakistan; in Indonesia, this value is lower, 8%, while in China the situation is more complex, reaching the level of 50% for some products with peaks of 85%. In Nigeria, circa 50% of drugs are composed of products that are generally ineffective;
- Specific studies conducted by the WHO in Brazil and Nigeria suggest that the incidence of counterfeit medicines with respect to the legal market is equal to a percentage ranging from 10 to 30% in Brazil and 40-60% in Nigeria;
- Chinese authorities estimate that - for certain drugs - the percentage of counterfeits is actually predominant with respect to originals, totaling a figure between 50-85% of the total;
- According to estimates provided by the Anti Counterfeiting Group, 5% of the population of the UK is unknowingly purchasing counterfeit drugs.

Sources: Morris J., Stevens P., (2006), *Counterfeit medicines in less developed countries, Problems and solutions*, International Policy Network; Cockburn R., Newton P.N., Kyerematen Agyarko E., Akunyii D., White N.J., (2005), *The Global Threat of Counterfeit Drugs*; WIPO, (2004c), *WIPO National Seminar on Intellectual Property for Faculty Members and Students of Ajman University*; CEIPI, (2004), *Impacts de la contrefaçon et de la piraterie en Europe*; Anderson J., (1999), *The Campaign against Dangerous Counterfeit Goods*, in International Criminal Police Review 476-477, Interpol.

estimates that the percentage of counterfeit medicines in ex-Soviet republics is higher than 20% of the total pharmaceutical market. With regards to drugs that are acquired online, it is also believed that 50% of these products are fakes[15].

It is very difficult to work with statistical figures given the difficulties in formulating estimates and assessing the latter. Box 1 reports some of the data which have been collected from a variety of sources.

The consequences deriving from the penetration of false medicines within the pharmaceutical supply chain are alarming. As previously noted, significant economic damages – in the form of profit losses for manufacturing companies – are caused by the marketing of these products. In the specific case of medicines, it is however necessary to consider, first of all, those elements related to the dangers of this phenomenon.

Before illustrating certain examples of the tragic consequences deriving from the utilization of counterfeit medicines, it is opportune to reflect on an additional element of danger which characterizes this type of illegal trafficking. The presence of lower concentrations of active ingredients compared to the amounts required by the manufacturer of the drug has a potentially even more alarming effect since this may promote the development of new strains of viruses, parasites and bacteria that are characterized by greater resistance to the pharmaceutical agent. The lower quantity of active ingredient may not be sufficient to completely eradicate these pathogens agents within the human body, thereby favoring the development of new and more resistant strains. This is particularly true, for example, in the case of malaria or HIV. Southeast Asia and Africa, for example, are literally overrun by counterfeit Artesiminin, an effective remedy for malaria based on Artesunate. Malarial parasites which enter into contact with doses of Artesunate that are not sufficient to eradicate the parasites will, in fact, develop resistance to the active ingredient, according to statements of the *Pharmaceutical Control Authority* of Nigeria[16]. A similar situation is also occurring with respect to the fight against HIV.

Unfortunately, such cases are numerous. The majority occurs in developing countries; this is primarily due to the type of counterfeit drugs that are present in these locations. It should be noted that the medicines which are replicated in these areas are those which are used to treat particularly serious diseases such as antiasthmatics, antimalarials, antituberculosis drugs and vaccines[17].

In certain cases, counterfeit drugs are used on a large scale in order to combat epidemics with catastrophic consequences. One of these cases occurred in 1995 when an epidemic of meningitis in Niger was exploited by counterfeiters in order to market counterfeit vaccines. It is estimated that *circa* 60,000 patients received the anti-meningitis treatment with the false vaccine and *circa* 2,500 of these patients died[18].

Counterfeit medicines often contain elements that are highly toxic for the human body. This practice is unfortunately documented in various cases. In Haiti, a counterfeit antifebrile agent containing an industrial solvent – the latter also used in anti-freeze liquids for motor vehicles – caused the death of 30 children while the utilization of the same counterfeit medicine in Nigeria caused the death of 109 children[19].

The use of anti-freeze for engines during the manufacturing of fake drugs has unfortunately also caused numerous deaths in Bangladesh; in the period between 1990 and 1993, 339 children took counterfeit paracetamol containing this substance and 70% of them died[20].

Highly toxic substances are often utilized in order to ensure that the final product is very similar to the original. In 2001, 20,000 tables of certain drugs – including a flu medication, a generic aspirin product and an analgesic – were seized in Columbia because they contained boric acid, wax and dyes with a high concentration of lead; these components were added to create a color that was very similar to the original product[21].

Other cases are illustrated in Box 2.

Although developing countries are the largest market for counterfeit drugs, there is a growing penetration of the latter within more developed and regulated markets, such as those in North America and Europe.

In May of 2003, for example, more than 18 million counterfeit pills of Lipitor – a drug produced by Pfizer that is used to lower blood cholesterol levels – were withdrawn from the USA market by the authorized distribution companies themselves. Following this event, a public warning was also issued in Canada[22].

In the Canadian province of Ontario, the pharmaceutical supply chain providing drugs to the public was penetrated by several pills of counterfeit Norvasac, a medicine used to reduce high blood pressure; these pills were sold by a regular pharmacist and could be the cause of the death of five people[23].

The seizures implemented by customs officers at EU borders suggest a significant presence of counterfeit Viagra despite interpretational difficulties. The quantification difficulties mentioned above derive from the fact that, until the year 2005, these drugs fell within the category, "other products" of the classification scheme that is used to catalog seized goods. In any case, it is possible to confirm that, in the year 2000, 25% of this category – which constitutes 61% of all seizures – was composed of products protected by intellectual property rights owned by the company Pfizer, including the trademark "Viagra". This percentage fell to 14% in 2002 and 11% in 2003[24]. It should, in any case, be noted that a decrease in seizures does not always correspond to a decrease in trafficking given the impossibility of customs to control all inflowing cargoes; this is due to the significant current volumes of global trade. A numerical confirmation of these volumes is found in the data provided by Belgian customs: in 2003 alone, customs officers had seized 350 kg of counterfeit Viagra[25]. Moreover, data deriving from customs seizures necessarily do not take into account those products that are produced and consumed domestically, thus creating even more difficulties in the quantification of the phenomenon.

Other examples of counterfeit drugs marketed in North America are illustrated in Box 3.

Documented cases of trafficking involving the active ingredients of drugs rather than the drug itself are also documented. This occurred, for example, in the USA in 1995. Flavine International, an intermediary of raw materials for drugs with headquarters in New Jersey, had acquired

BOX 2
The entire world is affected by counterfeit medicines

- A 2002 report of the International Federation of Pharmaceutical Manufacturers Associations stated that 40% of antimalarial drugs in Southeastern Asia do not contain an active ingredient;
- In 2001, 192,000 deaths were recorded in China as being caused from counterfeit medicines. In the same year, Chinese authorities closed down 1,300 factories producing fake drugs following an investigation of 480,000 cases relative to the usage of counterfeit medicines whose value was estimated to be equal to 57 million dollars;
- In 1998, the Brazilian Ministry of Health declared that at least 60 types of counterfeit drugs were being sold in Brazilian pharmacies and distributed within hospitals. These products also included very widespread analgesics and antibiotics;
- It is estimated that 200,000-300,000 people die each year in China as the result of counterfeit medicines;
- The Xinhua News Agency stated that 90% of the Viagra sold in Shanghai was counterfeited;
- In Pakistan, India, Bangladesh and the Philippines, a certain number of deaths were directly linked to the usage of counterfeit injection vials; the latter exhibited clear signs of counterfeiting in order to provide different expiration dates;
- More than 500 patients - primarily children - died in Haiti, Nigeria, Bangladesh, Argentina and India as the result of utilizing diethylene-glycol during the manufacturing of counterfeit drugs;
- The presence of counterfeit injection vials was reported in certain countries of the Asia-Pacific area. These are often derived from rejected hospital products which are then emptied and filled with different types of materials such as non-sterile starch powder or talc; these compounds can have lethal consequences if injected within the human body;
- A WHO report in Nigeria illustrates a series of "exemplary" cases: numerous deaths of children within a university hospital due to the ingestion of modified paracetamol; the seizure of high-blood pressure medications containing chalk; insulin vials filled with sugared water; analgesic medications marketed as anti-malarial drugs; and medicines that had expired and were re-marketed after modifying the expiration date on their packages;
- According to an investigation implemented in 2002 by the Association of International Pharmaceutical Manufacturers and the Coalition for Intellectual Property Rights, one out of every ten pharmaceutical products in the Russian market is counterfeited and potentially dangerous for the health of patients. These products include OTC and prescribed drugs as well as vitamins.

Sources: Cockburn R., Newton P.N., Kyerematen Agyarko E., Akunyii D., White N.J., (2005), *The Global Threat of Counterfeit Drugs*; WIPO, (2004c), *WIPO National Seminar on Intellectual Property for Faculty Members and Students of Ajman University*; APCO, (2003), *Global Counterfeiting Background Document*; Morris J., Stevens P., (2006), *Counterfeit medicines in less developed countries, Problems and solutions*, International Policy Network.

counterfeit gentamicin sulphate at low cost from unrecognized suppliers located in China. The material was then re-sold to two pharmaceutical companies, Fujisawa U.S.A. and ESI Lederle. Two years later, the Morbidity and Mortality Weekly Report listed 57 toxic reactions following the administration by injection of gentamicin that had been marketed by Fujisawa U.S.A.[26]

BOX 3
Counterfeit medicines: the US experience.

- Packages of Zyprexa, a drug used to treat schizophrenia, in which the original pills were replaced by other white pills bearing the label, "aspirin";
- Counterfeit Serostim, a drug used to treat HIV;
- The vial of a medicine used to reinforce weakened immune systems, Gamimune N, whose content had been diluted;
- Counterfeit packages of Epogen and Procrit injection vials; these two drugs are used to increase the production of red blood cells. The content of the vials was modified in order to contain an active ingredient that was 20 times lower than the amount reported on the package;
- During the course of testimony before the US Food and Drug Administration's Drug Importation Task Force, the Vice President of Global Security within the pharmaceutical company Pfizer declared that an investigation implemented in 2003 – in collaboration with Canadian police forces and the U. S. Drug Enforcement Agency - had led to the discovery of counterfeiting operations within the Province of Quebec. The counterfeiters manufactured Viagra pills which were believed to be intended for the US market;
- In 2002, US customs officers seized 27,000 counterfeit analgesics which did not contain any active ingredients;
- In Florida, 11,000 counterfeit packages of Procrit – a drug used to treat anemia – were discovered; the active ingredient had been diluted to 5% of the amount reported in the package.

Sources: CEIPI, (2004), *Impacts de la contrefaçon et de la piraterie en Europe*; Spies A. R., Van Dusen V., (2003), *Counterfeit Drugs, A Menace Keeps Growing*, in U.S. Pharmacist; Isaac B., Osmond C., (2006), *The Need for Legal Reform to Address Intellectual Property Crime*, Canadian Anti-Counterfeiting Network, Position Paper.

Notes

1 WHO, (1999), Guidelines for the development of measures to combat counterfeit drugs, page 12.

2 Chapter II - Definitions of the Us Federal Food, Drug and Cosmetic Act states the following: "The term 'counterfeit drugs' means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, other identifying mark, imprint, or device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such a drug and which thereby falsely purports, or is falsely represented, to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor." Harper J., Gellie B, (2006), Counterfeit Medicines Survey Report, Council of Europe, page 140.

3 The Philippines Republic Act No. 8203, 2003 states the following: "Counterfeit medicine refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. It shall also refer to:

i the medicinal product itself, or the container or labeling thereof or any part of such medicinal product, container or labeling bearing without authorization the trademark, trade name or other identification mark or imprint or any likeness to that which is owned or registered in a state of the Council of Europe in the name of another natural or juridical person;

ii a medicinal product refilled in containers by unauthorized persons if the legitimate labels or marks are used;

iii an unregistered imported drug product, except drugs brought in the country for personal use as confirmed and justified by accompanying medical records; and

iv a drug which contains no amount of, or a different active ingredient, or less than eighty percent (80%) of the active ingredient it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration."

Harper J., Gellie B, (2006), Counterfeit Medicines cit., page 140.

4 A representative of the Association of the British Pharmaceutical Industry had already stated the following in the 1980's: "It is difficult to declare a fake drug problem without damaging legitimate business", while the Royal Pharmaceutical Society of Great Britain stated that "This Society is not issuing press releases [about counterfeit drugs] because it believes that as much as possible should be done behind the scenes…and that no great publicity should be sought because it could damage public confidence in medicines". Cockburn R., Newton P.N., Kyerematen Agyarko E., Akunyii D., White N.J., (2005), The Global Threat of Counterfeit Drugs, page 101.

5 David Pruce, Director of Practice and Quality Improvement, stated the following in 2005: "If there is a risk that a patient has been dispensed a counterfeit medicine, then it is vital that they are informed. There have been two recent cases in Great Britain where counterfeit medicines appeared in the legitimate pharmacy supply chain. The public announcement of the problem was therefore entirely proper and necessary. It is important that news stories of this type are handled responsibly so that the public confidence in their medicines is not undermined. This could deter patients from taking genuine medicines."

Cockburn R., Newton P.N., Kyerematen Agyarko E., Akunyii D., White N.J., (2005), The Global Threat cit., page 101.

6 The 1999 WHO guidelines relative to the development of measures for contrasting the distribution of

counterfeit medicines state the following: "the reluctance of the pharmaceutical industry, wholesalers and retailers to report drug counterfeiting to the national drug regulatory authorities could impede the national authorities from successfully taking measures against counterfeiting". WHO, (1999), Guidelines cit., page 16.

7 Cfr: Harper J., Gellie B, (2006), cit., page 140.

8 Care Online, (2004), n. 4, page 19, http://www.careonline.it/2004/4_04/pdf/dossier_2.pdf.

9 Care Online, (2004), cit., pages 20-21.

10 A classification of this type was presented, for example, by Jonathan Harper in a contribution to the volume, Coincidence or Crisis. Nine different types of criminal activities linked to the counterfeiting of medicines are described: 1. "Identical copy" – identical formulation with packaging and labelling that are hard to differentiate from original. 2. "Pure counterfeit" – altered/replaced ingredients with familiar packaging (but either no/different/wrong dose, Active Pharmaceutical Ingredient (API) or excipient). 3. "Hybrid counterfeits": 'Reuse of components/refilling' – e.g. genuine containers (ampoules, bottles, vials, syringes)/packaging with substitute or no API; 'Illegal relabelling/repackaging' – genuine formulated product falsely repackaged/relabeled as being from the original manufacturer and intended for the same or diverted to a different market from that originally intended by manufacturer (also includes use of fake pricing labels), includes products wrongly claiming to be an original product (e.g. use of well known name or trademark). 4. "Diversion and illegal trade of genuine medicinal products with genuine packaging and labeling" (whether or not through the internet). 5. "Unpackaged medicinal products" – e.g. wholesale/retail of medicinal products without the primary packaging. 6. "Placing a non-authorized medicinal product on the market". 7. "False documentation" – e.g. granting a certificate or suitability (CoS or CEP) by regulatory authorities without the given company being audited, false CEP, incorrect status on import documentation. 8. "False MMA (Marketing Authorization Application)" – entire marketing applications sold and used; their contents do not have any relationship with the actual operations involved in the manufacture of the API or dosage form. 9. "Waste/expired product" – includes repackaging and relabelling of expired products.

Harper J., (2006), Counterfeit Medicines and pharmaceutical crime in Europe: 'invisibility, biohazard and system failure', in Coincidence or Crisis, Prescription medicines counterfeiting, The Stockholm Network, pages 11-12.

11 A classification of criminal practices was also implemented with regards to the counterfeiting of active pharmaceutical ingredients (API). These practices are classified as follows: 1. "API procurement from uncontrolled/non Good Manufacturing Practice (GMP) origin" – done by some authorized finished medicinal product (FP) manufacturers because uncontrolled API source is cheaper. 2. "Illegal API relabelling/repackaging" – unauthorized API material may also be shipped in containers labelled with the name of a different API. 3. "Ghost API manufacturing plant" – API (possibly not produced via the registered manufacturing process) not manufactured by the 'registered producer' is sold to a FP marketing authorization holder (MAH) (who may be unaware of this fact, as API label mentions only the authorized manufacturer; a broker/trader may play a crucial role in this practice). 4. "Ghost API supplier" – MAH purchases API willingly and knowingly from a different manufacturer from that specified in the marketing authorization (in this case the manufacturing process will normally differ from that described and authorized in the marketing authorization). 5. "Paper curtain" – API manufacture performed through different process from that specified in the marketing authorization (a double documentation system may be used at the manufacturing site: one hidden set containing the true data and another set containing faked data that comply with authority requirements and regulations; such documentation system may even be in place at a site where the API is not manufactured at all). 6. "Authorized facades" – manufacturer/trader with approved certificate of suitability and drug master file supplies API material from a large number of unauthorized manufacturers (all labelling mentions only the authorized manufacturer. This set-up is believed to be widespread in terms of API material imported from China and possibly also India. In addition forged certificate of analysis and other forged documents will also be used in such situations). 7. "Illicit intermediate production" – unauthorized API materials from obscure sources are blended with the registered API material

Harper J., (2006), Counterfeit Medicines and pharmaceutical cit., pages 12 – 13.

12 OECD, (1998),cit., page 17.

13 Morris J., Stevens P., (2006), Counterfeit medicines in less developed countries, Problems and solutions, International Policy Network, pages 3-4.

14 WHO, (2006a), Counterfeit Medicines: an update cit.

15 WHO, (2006a), cit.

16 "A field survey conducted in 2004 showed that 53% of artemisinin-based antimalarials in a range of South East Asian countries contained incorrect levels of active ingredient, which implies that swathes of patients are receiving the incorrect dose. The direct consequences are death and injury resulting from improper treatment. In addition malaria parasites exposed to inadequate (subtherapeutic) concentrations of artesunate may result in the multiplication of parasites resistant to the drug. Even though Artesiminin has been widely available since the late 1990s, scientists are already reporting cases of resistance. According to Dora Akunyili, the Head of the Nigeria's national drug regulator, the racket in fake medicine is directly responsible for this resistance, and is a contributing factor to the doubling of malaria deaths over the last 20 years." Morris J., Stevens P., (2006), *Counterfeit* cit., page 5.

17 "In spite of a lack of hard data, it is clear that counterfeit medicines are not confined to a handful of therapeutic classes. This is especially true in Less Developed Countries (LDCs), where the range of fakes on the markets encompasses treatments for a diverse range of conditions and ailments. The top five counterfeit medicines in the Philippines provide some illustration on this point: 1. Antihypertensive drugs; 2. Anti-asthma drugs; 3. Analgesic medicines; 4. Anti-diarrhoea; 5. Vitamins. This is certainly not exhaustive. Other favorites for counterfeiting include drugs fro treating anemia, HIV, schizophrenia, as well as growth promotion hormone (used in the treatment of HIV). Morris J., Stevens P., (2006), cit., page 5.

18 "The use of counterfeit medications on a broader scale occurred during the meningitis epidemic in Niger in 1995. According to estimates, approximately 60,000 persons were inoculated with false vaccines. In this situation, production of these counterfeit vaccines would have necessitated an industrial-scale manufacturing facility, and it is probable that the 88,000 vaccines identified as false did not account for the entire fraudulent production." Morris J., Stevens P., (2006), cit., page 3.

19 Spies A., Van Dusen V., (2003), *Counterfeit Drugs, A Menace Keeps Growing*, in U.S. Pharmacist.

20 CEIPI, (2004), cit., page 40.

21 CEIPI, (2004), cit., page 40.

22 Isaac B., Osmond C., (2006), cit., page 12.

23 Isaac B., Osmond C., (2006), cit., page 11.

24 CEIPI, (2004), cit., page 43.

25 CEIPI, (2004), cit., page 43.

26 Spies A., Van Dusen V., (2003), *Counterfeit Drugs* cit.

5. Illegal entry into the distribution chain

The modalities through which counterfeit products reach the consumer are an element of the problem which deserves greater scrutiny. A previously described distinction should again be noted with regards to the consumer of counterfeit goods. As previously mentioned, the market for counterfeit goods may, in fact, be subdivided into two sub-sectors: a panel of conscious buyers and a panel of unconscious buyers.

In the first case, the consumer is perfectly aware of the non-original nature of the good which she/he intends to acquire even if not capable of accurately assessing the quality of the replicated product. The consumer is, however, in search for a "good deal" and given that she/he does not intend to pay the requested price in order to acquire the original good it is deemed more advantageous to obtain a copy. This therefore involves parties who make conscious choices and the only element of uncertainty is relative to the actual quality of the counterfeit good; the latter is, in fact, not easily assessable by the conscious buyer. In this case, the non-original products may be directly offered to the buyer without penetrating the legal distribution chain.

In the second case, however, the counterfeit product is marketed as an original and is offered to an unconscious buyer who believes that she/he is buying a genuine good. In this case the consumer is deceived. This situation typically occurs when counterfeiters decide to replicate and market products which are required to comply with certain qualitative standards in order to not pose a risk for the health and safety of consumers. This case is particularly applicable to medicines, toys, food, beverages, electrical appliances and spare parts for automobiles and aircraft. This obviously does not imply that an illegal entry into the supply chain does not occur for other categories of "non-risky" products: there are, in fact, several cases of pirated musical CD's or counterfeit luxury accessories that were sold within stores as originals but for "risky products" it is less probable that a buyer will knowingly choose lower-quality products from these categories. Unlike the first case, it would not be profitable to directly offer a copy of the original product to the potential buyer. In order to sell their products, counterfeiters must market them as genuine and must attempt to penetrate the legal distribution chain in order to reach and deceive the unconscious consumer.

More focus will be given to this second sub-sector; the modalities utilized by counterfeiters to illegally penetrate the distribution chain will be highlighted.

In particular, the system relative to the distribution of medicines will be analyzed; although the latter has certain peculiar features, it may be used as a model in order to illustrate practices that are often common to distributional processes of other product categories. Within this model, specific emphasis will be given to the role played by parallel trade and the Internet as factors which facilitate and spread the distribution of counterfeit products.

5.1 The legal distribution chain

A few rapid comments on the functioning and ramifications of the legal distribution chain may be very useful for understanding certain elements related to its vulnerability. The model for pharmaceutical production/distribution refers to a product whose manufacturing and distribution is subject to a series of very precise regulations. The identification and presentation of areas of vulnerability within a highly regulated distribution system illustrates how the vulnerability of a corresponding production/distribution system that is not subject to rules, or is subject to less stringent regulations, is destined to grow significantly.

The rapid and significant changes which have affected global trade have resulted in a constant search for competitive edge, leading to the need – amongst other factors – to reduce production and distribution costs. Outsourcing[1] has become a widespread phenomenon for producers who can reduce economic costs by allocating part of their productive activity to parties external to the company itself, thereby exploiting differences in labor costs between countries. The drawback of this approach is the increased complexity of the production/distribution chain caused by outsourcing given that various ramifications are created between the parties involved in the production and distribution of the good. This complexity – which does not, in itself, have a negative connotation – does however reduce the capacity for monitoring all parties participating in the production/distribution of the product as well as the transfers between these parties, thereby facilitating the penetration of counterfeit goods within the market.

The pharmaceutical production/distribution chain is not exempt from this phenomenon. Pharmaceutical companies also seek greater flexibility and reduced costs by delocalizing part of their production – and/or the services linked to the latter – to other companies. Delocalized activities include the manufacturing of packages for final products and the production of prescription drug instructions for patients.

An illustration of a hypothetical and simplified structure of the pharmaceutical production/distribution chain will be provided below. Due to the nature of the product, the production/manufacturing process is relatively complex. This process may, however, be subdivided into two primary phases: a primary and secondary production phase[2]. The first essentially refers to the production of active ingredients which constitute the drug and which allow the desired therapeutic effects to be attained. Secondary production activity refers to the manufacturing of the final product by combining the active ingredients with various excipients that allow the human body to properly absorb these ingredients. In this phase, the "medium" of the drug – liquid or solid – is also chosen. Once the drug is completed, it is packaged in conjunction with the prescription instructions.

These phases compose the manufacturing process. With regards to delocalization, the production of active ingredients – due to the special characteristics of the product – is generally concentrated within a few specialized centers which then supply the pharmaceutical manufacturers. The latter then implement the secondary production phase. This last phase – in conjunction with the production of packages and pre-

scription instructions – is more commonly delocalized[3].

Once the finished product is attained, the distribution phase is initiated. Two phases may also be identified here: primary and secondary distribution. The first is entrusted to large wholesale area distributors which receive the product directly from manufacturers and distribute it to retail distributors[4] or directly to pharmacies. The producers themselves may also sell directly to retailers. In this case, the product is intended for exclusive sale to the patient and must not be re-introduced into the distribution chain. The producers may also choose to allocate a part of the product for charitable purposes.

Secondary distribution utilizes intermediary parties operating between the major distributors and retailers. These distributors vary in size and do not distribute the entire range of products of a pharmaceutical company but operate by acquiring certain products from the major distributors or from sources other than the producer; the products are then re-sold to other large distributors or retailers. These operations are made possible by various circumstances which could potentially benefit the final consumer since they lead to lower retail prices. Intermediary producers acquire drugs at reduced prices that are, in fact, derived from surpluses in production or storage on the part of producers or large distributors and pharmacies, respectively; they are therefore capable of re-selling the products at lower prices. Their smaller size allows them to exploit changes in the market and to concentrate on specific drugs that exhibit high demand at specific times and in specific areas; examples include medicines that are used occasionally for certain populations such as targeted vaccination campaigns. Their size grants them a certain flexibility and capacity to respond to changes in demand, thereby allowing them to compensate for warehouse shortages affecting pharmacies or the major distributors themselves in the case of a rapid and unexpected increases in demand for a specific drug[5].

Finally, the existence of significant differences in the sale prices of drugs across different geographical areas creates opportunities for parallel importers; the latter exploit these differences and generate profits by acquiring the product in countries where the price is lower and re-selling it in countries where the sale price is higher. During these commercial exchanges involving countries with differing official languages, the process is rendered more complex by an additional phase: the repackaging of medicines and the replacement of prescription instructions in order to ensure that the package and instructions relative to a drug are comprehensible to the final patients.

Aside from the latter case, repackaging may also occur as a phase within the distribution chain – even in the absence of international trading of the product. The transfer from a large distributor to a retailer – even if this occurs by means of intermediary distributors – provides for a phase in which the large quantities of received medicines are inserted within packages through which the pharmaceutical product will be retailed within the country in question, in compliance with currently effective local laws.

Graphic no. 1 illustrates a simplified pharmaceutical distribution chain. The finished product is delivered from the producer to the large distributor which then

delivers the requested amounts to the retailers. Stock surpluses on the part of the latter or the pharmacies themselves are re-absorbed by the wholesale distributor or by intermediary distributors. These distributors may also distribute the product amongst the various major distributors, thereby linking the various players of the chain with the exception of the producer.

This initial description refers to the rectangle area of the distribution chain illustrated in Graphic no. 1.

The parallel importer/distributor links the markets of the various countries; the position of this player in Graphic no. 1 is, in fact, parallel to the distribution chain existing within a specific market.

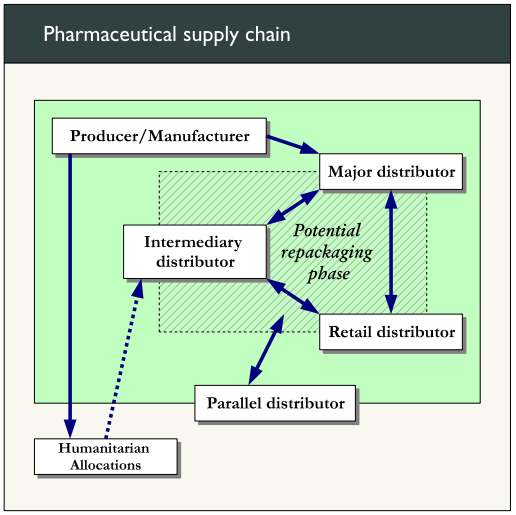
The legal framework within which the various players of the distribution chain operate is also interesting to analyze. These players, in fact, typically operate in accordance with contractual agreements stipulated with the producer as well as licenses granted by the legal system.

The major distributors operate in compliance with a contract stipulated with the producer – which generally provides for the geographical area of their operations – as well as a license granted by the national legal system which outlines the legal framework and the services that the operator is authorized to perform. The license may also grant authorization for the distributor to repackage the product, if required. Specific repackaging licenses may also be granted to specialized operators which exclusively offer this type of service.

Intermediary and parallel distributors are special entities which operate at the secondary distribution level; the description illustrated above may not always be applicable. Parallel distributors require a license in order to operate legitimately but do not, on the other hand, have any form of agreement with the producer. The intermediary distributor is instead not directly subject to national legislation given the international scope of its operations and has not stipulated an agreement with the producer[6].

Elements of uncertainty which should be noted at this point include the various transfers between the players constituting the distribution chain; the need to repackage the product; the implications linked to parallel trading; the "diversion" of drugs intended for humanitarian purposes, a case illustrated outside the border of Graphic no. 1; and additional complications deriving from the utilization of the Internet as a distribution channel.

Graphic 1



5.2 The vulnerability of the distribution chain

Counterfeit products may be inserted into the distribution chain in multiple ways and at almost all levels. The complexity of the distribution process, potential illegal behaviors, the scarce and rarely implemented controls in the distribution and repackaging phases, and the existence of transportation documents that are easily modified are a few of the factors which weaken the system designed to bring the drug from the producer to the consumer[7]. In addition to these elements, the effect of parallel trade and the utilization of the Internet as a distribution channel also create uncertainties.

The excessive complexity of the distribution chain may create vulnerabilities that facilitate the entry of unauthorized or counterfeit products. Certain phases of the distribution and product repackaging processes may be identified as the weak links of the system; it should be noted that the term, "weak link", is not meant to refer to a commercial element or operator that is directly responsible for the penetration of counterfeit products in the market but rather those distribution links which pose a risk for the integrity of the entire chain. The real weak link is, however, a regulatory framework which, despite existing, is neither sufficient nor proportional to the nature of the product and the ramifications of the current distribution process.

Complexity of the distribution process

The complexity of the distribution process has a significant consequence: monitoring the movements of the drug during its path from the producer to the patient is very difficult. The larger the number of brokers within the distribution chain, the greater the difficulty in monitoring the origin of the product as well as identifying the latter's commercial route.

The producers themselves – once the goods are delivered to the major distributor – do not have direct control over these goods and rely on the fact that: 1) the major distributor will comply with the contractual terms as well as the license granted in relation to the distribution operations; and 2) the delocalized producer operates in an honest manner. These two cases will now be analyzed, starting with the second.

As previously noted, the outsourcing of production and services certainly allows the major manufacturers to significantly reduce production costs but this creates an element of uncertainty in the system. This element is proportional to the degree of protection and compliance with intellectual property rights in the country in which the delocalized producer is located. Outsourcing implies, in fact, that the producing company shares manufacturing and industrial secrets relative to the composition and production of the drug, thereby implementing a real transfer of know-how. It is therefore possible that the delocalized producer may exploit the situation by manufacturing greater amounts of the product to be marketed[8] – in breach of the stipulated agreements – or may disclose the know-how to other parties.

On the other hand, distributors as well as all other members of the distribution chain are commercial operators which pursue profit maximization. In accordance with the contract stipulated with the producer, the distributor may only export

products to those areas specified by the owner of the intellectual property rights. The possibility of selling the same product at more elevated prices may, however, create a desire to shift operations towards more favorable opportunities by re-directing sales to more profitable geographical areas.

Intermediary distributors which exploit rapid changes in the demand for a drug as well as incorrect storage levels of goods contribute to the intensification of exchanges between the various parties; as a result, the drug may be transferred multiple times before reaching the patient. In reference to Graphic no. 1, it is possible to imagine multiple exchange lines added to those already present and which overlap with the latter, linking the various large distributors to a large number of retailers and intermediary distributors.

The latter – which were noted as potential clearing houses for market changes – are entities which operate without commercial agreements with the producer and their business is conducted within the secondary distribution chain[9]. They acquire drugs at reduced prices in order to re-sell them where demand is higher, thereby attaining a profit.

During the course of all these transfers, it is possible that the package or instructions are replaced if the drug will be sold in a different country.

The existence of commercial operators that are not subject to specific commercial agreements with the manufacturer adds an element of uncertainty to the system. This element is worsened by various factors. One factor is the fact that intermediary distributors – operating at the level of the secondary market – do not receive the goods directly from the producer but simply re-distribute the goods amongst various market players. In reality, it is not possible to know the supply sources of these intermediary distributors and this poses a significant element of risk. Given that these parties are directly involved in the distribution of significant amounts of product, an imprudent purchase on their part from suppliers that are "low cost" but not "secure" could lead to the penetration of counterfeit drugs within the distribution chain. The ramification of the latter and the various transfers which were previously mentioned would then render it basically impossible to identify the real origin of the medicines in question.

Repackaging

The second weak link in the pharmaceutical production/distribution chain is the repackaging phase, particularly when the latter involves products which are ready for retailing and are then diverted to markets of countries differing from the one for which the original package was prepared. This occurs more frequently as a result of parallel imports or the diversion phenomenon.

In these cases, the original package and the prescription instructions are replaced with new ones in order to comply with provisions of the legal system of the country where the drugs will be sold in addition to allowing patients to understand the therapeutic instructions and the usage modalities of the product. This process may be implemented by the importers themselves – if granted a special license – or by specialized parties which are authorized to perform such services.

This phase is not, however, free from risk and represents a weak link which could

facilitate the penetration of counterfeit products into the market.

Due to the increase in the counterfeiting phenomenon, the original package that is designed by the producer, or by a party delegated by the latter, no longer only fulfills a descriptive function but also guarantees the originality of the drug.

An example of anti-counterfeiting techniques that are used in conjunction with the purely descriptive function of the drug package is the case of Zantac, one of the most successful drugs produced by Glaxo.

The utilized package was initially very simple in design: two white circles (the pills themselves) with a few golden stripes, all enclosed within a two-colored cardboard package. This type of packaging did not serve as an obstacle to counterfeiters and could be easily reproduced.

During the middle period of the 1980's, a large number of counterfeit Zantac packages originating from Greece were introduced into the British market under the form of legitimate parallel imports. In response to this, Glaxo completely re-designed the graphical design of the package and added a seal with a hologram[10].

Producers therefore include anti-counterfeiting features within the packages or labeling. Once the product is opened and repackaged, however, these features become useless. In addition, it is unlikely that those implementing the repackaging will utilize packages containing these devices given their elevated cost[11]. In addition, the serial numbers of medicines – which are very useful in the case of recall of a batch of the latter – are reprinted.

There are additional complications linked to the repackaging phase. Despite the fact that the original packages should be destroyed once they are replaced, they may be re-used by counterfeiters in order to insert non-original products within them, thereby allowing them to be easily marketed[12]. Repackaging also creates several opportunities linked to the adulteration of packages. For example, it is possible that the new package: 1) reports a greater quantity of active ingredients, thereby allowing for the sale price of the drug to be raised, or 2) has a modified expiration date in order to be able to sell expired products.

The last two cases pose tangible risks for the distribution chain. An example of the first case occurred in South America when the buyer of a migraine drug became suspicious after finding pills which did not contain references to the manufacturer. Subsequent analyses revealed that the package did not contain the original drug but a low-cost antistaminic[13].

In order to fully analyze the re-utilization of original packages, the potential utilization of rejected hospital material should be noted; this process is further facilitated in the case that the drug package does not include anti-counterfeiting features. Cases have, in fact, been reported in which counterfeiters obtained rejected packages from clinics or hospitals in order to re-utilize them[14], modifying their expiration dates if necessary[15]. If the packages still contain the drug, the latter may be marketed again, otherwise the package may serve as a container for a counterfeit product. The re-utilization of rejected material is another facet of the phenomenon that is considerable cause for concern, particularly if the utilized substances are not sterilized[16]. In certain parts of Asia, an actual trade of rejected hospital materials[17] has developed and numerous victims in India, Pakistan,

Bangladesh and the Philippines have been linked to the utilization of injection vials that were clearly recycled and contained non-sterile substances[18].

5.3 Entry into the distribution chain

Having defined the so-called weak links of the pharmaceutical production/distribution chain, certain commercial aspects of the phenomenon should be considered: diversion, parallel trading and the use of the Internet as a means of selling and buying.

Diversion

The term diversion refers to those cases in which a product that is designed for a specific market or function is re-marketed, in violation of the producer's instructions; consider, for example, deliveries of drugs to humanitarian organizations or even the supply of free samples to hospitals[19].

This phenomenon occurs in two forms: it may be limited to the national territory of a nation or it may become international in scope. In the first case – and with regards to pharmaceutical products – the phenomenon will primarily involve promotional samples or discounted drugs that are allocated for humanitarian purposes and are re-marketed at full price[20]. The motive underlying these operations is the difference in purchase price between a product that is marketed at full price and one which is allocated for specific purposes. This difference allows for the attainment of significant profits.

A diversion that is implemented on an international scale is driven by the same economic motive of a diversion carried out on a national scale.

Two primary categories of illegal behavior – on the part of entities acquiring drugs directly from the producer – can be identified within an international diversion. 1) The entity acquires goods which are intended for a market where purchasing power is relatively low in order to sell them in markets where purchasing power is higher; as a result, the higher the sales price of the good itself and the greater the amount of attainable profit. 2) The entity fraudulently acquires the products from the producer, declaring an intention to deliver the drugs for humanitarian purposes but in reality re-marketing the drugs after acquiring them at low cost. In this case, the producer is deceived and there are also humanitarian consequences[21].

These international exchanges are implemented through multiple transfers and involve frequent repackaging of the product, thereby providing opportunities for counterfeit products to penetrate the legal distribution chain. According to statements of the US Food and Drug Administration (FDA), the practice of diversion is strongly linked to the counterfeiting phenomenon given that it facilitates the latter. The numerous intermediaries which acquire diverted products are not, in fact, capable of identifying the actual source of the product[22]. The lower cost of goods often provides a sufficient motive for these entities to justify the purchase and distribution of the goods themselves. It is therefore possible that a very low price may actually imply a counterfeit drug rather than a diverted original. The multiple transfers and repackagings also make the authentication phase very difficult for retailers. This task is even complic-

ated by the practice of "layering", the mixing in one consignment of original, diverted and counterfeit products.

In order to limit the growth of the diversion phenomenon, the US Congress approved a law – the Prescription Drug Marketing Act (PDMA) – which prevents any party, with the exception of the manufacturer, from re-importing drugs which are produced within the USA. This act is typically only applicable for those drugs which are produced within the country and therefore has a limited range of application. It does, however, serve as a concrete step forward in limiting a practice which facilitates the entry of counterfeit medicines within the USA. Before theadoption of the PDMA, drugs produced within the USA were often exported and then re-imported in order to exploit the commercial advantages noted above. The re-entry of these products was often accompanied by the presence of counterfeit drugs; the latter were often placed within the same packages of the re-imported originals.

Parallel trading

Parallel trading is a legal commercial practice; there is an ongoing debate on its actual effect on the penetration of counterfeit goods within the market. There are, however, a few potential links between this practice and the abovementioned weak links of the distribution chain: the number of commercial operators through which the product is distributed increases; the number of "transfers" within the distribution chain increases; the number of repackaging opportunities increases. In the absence of a specific regulatory framework, these phases may facilitate the entry of counterfeit products within the distribution system. With regards to the European regulatory framework, a legislative outline has been drafted but a complete and harmonious regulation of the subject within EU member states has not yet been attained.

Parallel trading: the EU approach

The term parallel trading refers to a specific commercial practice that involves importing goods – without the authorization of the producer – that are protected by intellectual property rights and which are already sold in a different market[23]. These goods are therefore marketed and sold within one country and subsequently re-imported into another country[24].

Regardless of whether re-importing involves a modification of the product's package, a distinction can be made between pure parallel imports – products re-imported without any modification from the time in which the owner of the intellectual property rights introduced the products within the market of reference – and other parallel imports – products which have been modified in form or packaging.

The evolution of European regulations and law relative to this subject has been influenced by the need to guarantee the appropriate functioning of a single market and competition without damaging the owners of intellectual property rights or the health and safety of consumers. This objective was certainly arduous to attain; the result is a regulatory and legal framework which – despite providing a foundation for regulation in this area – provides dangerous loopholes which could be exploited by criminal activities.

Two Articles of the Treaty establishing the European Community (EC Treaty) –

no. 28 and 29, concerning restrictions on imports – serve as the foundation for protection of free commerce within the single market. Article 28 sanctions the prohibition of member states to impose quantitative restrictions, or similar measures, with respect to imports within the single market[25]. Article 30 provides for cases in derogation of the preceding article, stating that its provisions are not applicable if, amongst other things, the restrictions are imposed in order to protect industrial and commercial rights[26].

The task of interpreting the breadth of application of these articles falls under the competence of the Court of Justice of the European Communities which has declared – in the case of intellectual property rights – that these restrictions would only be justified if they serve to protect the *specific subject matter*[27] or the *essential function* of a trademark[28].

Having established the impossibility that a party holding trademark rights could limit the circulation of the products protected by these rights – once the latter were marketed within any of the member states of the EU, and given the provided exceptions – it was necessary to clarify whether this effect was also applicable to products marketed for the first time in a non-EU country (so-called *International exhaustion*) or if it should only apply to goods marketed for the first time within the EC's borders (so-called *Community-wide exhaustion*)[29]. This last principle is sanctioned by Article 7[30] of Directive 89/104/EEC relative to the harmonization of standards concerning trademarks; its application was not extended to include products marketed outside of the European Community for the first time, thereby embracing the principle of *Community-wide exhaustion*[31]. This principle was sanctioned further by the Court of Justice of the European Communities in the case, *Silhouette v. Hartlauer*[32].

Once the principle of *Community-wide exhaustion* was established, it is interesting to consider other aspects of the regulations, including the position taken by the European Court of Justice with respect to the repackaging of products subject to parallel trading within the EU, particularly pharmaceutical products.

The position of the Court was clearly outlined during the course of several cases in which the intention to reconcile repackaging with Articles 28 and 30 of the EC Treaty was expressed. In the case of *Hoffmann-La Roche v. Centrafarm*, the Court stated, in fact, that the protection of the specific *subject matter* and of the *essential function* could allow the owner to put forth actions aimed at preventing the repackaging of the owner's products on the part of parallel importers without this resulting in an artificial partition of the market[33]. The latter would occur, for example, if the producer decides to make use of its trademark rights in order to prevent repackaging by differentiating the packages in which the product is sold in different member states – even if the goods in question are not modified. This would, in fact, conceal a compartmentalization of the single market[34].

A legal milestone in the Court's position on this topic is the sentence *Bristol-Myers Squibb and Others v. Paranova* during which the European Court of Justice established certain essential conditions that the parallel importer must comply with in order to not infringe upon trademark rights during the repackaging phase. According to the Court, this phase is allowed at the following condi-

tions: (1) repackaging is required to market the goods in the importing country and to prevent a partition of the market on the part of the party owning the rights; (2) the original conditions of the product are not altered; (3) the name of the producer and importer are reported on the package; (4) repackaging must not result in a loss of reputation for the producer, e.g. in the case of low-quality packages; (5) the importer must notify the producer – with appropriate advance notice – of the former's intention to proceed with the parallel importing of the producer's product, providing a sample of the re-packaged good if requested[35]. The Court also decreed that parallel importers may remove the barcodes found on packages if the latter only serve the purpose of allowing the party owning the rights to trace the product in order to partition the market[36].

Parallel trading and the weak links in the distribution chain

The price difference between markets is the basic cause underlying parallel trading[37]; the phenomenon has recently expanded considerably. It is possible to provide very interesting data from even just the medicines sector in order to understand the development of the phenomenon.

Within the European Union alone, parallel imports involved circa 140 million pharmaceutical products each year; the market share of these imports grew by more than 50% from 1999 to 2003, increasing from 11% to 17%; within the EU, medicines which reach the market by means of parallel importing total circa 20% of the drugs which reach the patient[38].

Given that the United Kingdom is one of the European nations with the highest drug prices, it is not surprising that it is also one of the markets with the highest levels of parallel imports. Of the 140 million pharmaceutical products that were parallel imported each year in Europe, 70% were allocated for the UK as a final destination – totaling therefore circa 100 million drugs. The number of licenses issued in the UK for the exercise of this activity also grew significantly, increasing from 239 licenses in 1993 to 2,916 in 2004[39].

This data illustrates the significant size of parallel trading, involving numerous operators which exercise the activity in an honest manner. Commentary relative to potential links between parallel trading and counterfeiting should therefore not be understood to imply a condemnation of parallel trading; the analysis is meant to highlight its weaknesses in order to improve the functioning and integrity of the overall pharmaceutical distribution chain.

The interpretation that was initially presented – regarding the insufficient level of regulation of various aspects of the production/distribution chain – allows specific emphasis to be given to the case of the European Union and the single market. The latter is based on the principle of free circulation of goods between EU member states. This principle is not coupled, however, with a corresponding EC strategy for the monitoring of product transfers, imports and exports nor for the granting of authorizations and licenses. Each state therefore retains its own rules and continues to apply them[40]. The EC situation therefore involves a significant regulatory inconsistency due to the lack of harmonization, thereby creating opportunities for counterfeiters who may exploit potential legislative weaknesses. Once the product has

entered a member state, it may freely circulate within the EU with minimum controls. A weak control system in any of the member states of the EU would therefore create a weak point for the potential entry of counterfeit products which could thereby reach any other country within the single market[41]. With regards to the pharmaceutical sector in particular, no legislative harmonization exists in relation to the packaging and repackaging of medicines while the existence of unauthorized repackaging centers is considered probable in addition to being a cause for concern[42].

From a practical point of view, the process involves a drug that is sold in a given country and which – after having already moved through the various stages of the ordinary distribution chain – is acquired again by the major distributors and is entered into the parallel distribution chain; the product is then transferred to a new and more lucrative market by means of parallel intermediaries/distributors. The latter – through which the pharmaceutical product is transferred – may be numerous; it is estimated that, on average, a drug which is entered into the parallel market may be subject to 20-30 intermediary transactions[43].

This extension of the distribution chain creates, first of all, a problem of verifiability with respect to the source from which each intermediary receives the product. There is no centralized mechanism within the European Union for verifying the licenses of parallel importers; similarly, there is no obligation for the parties involved in the parallel distribution process to record product batch identification numbers[44]. It is difficult for a parallel distributor to verify the honesty of a supplier of medicines when entering in contact with the latter. Generally, proof of authorization to trade the products is requested; this proof may consist in a license that is issued at a national level and which is sent by fax from the potential seller to the parallel distributor. The latter will not be able, however, to verify the authenticity of the document by appealing to its own national authorities[45]. If this element of uncertainty is multiplied by the number of transfer points within the parallel distribution chain, it becomes obviously impossible to monitor the integrity of the chain and numerous operators may be almost anonymous.

This factor is also linked to the previously mentioned lack of legislation requiring the recording of drug batch identification numbers; as a result, it is basically impossible to trace the trade route and origin of a marketed drug by the time the latter has reached the final consumer[46]. This may jeopardize the health of patients even in cases that do not involve counterfeit products. It would, in fact, be impossible for a pharmaceutical company to recall a batch of medicines which, for whatever reason, should not reach the consumer. This impossibility is occasionally linked to the fact that – during the repackaging phase – the batch identification number may have been removed or modified.

A change in the country of sale of the drug necessarily implies that the package and prescription instructions will be modified or replaced; this is necessary to comply with local packaging standards that are effective in the country where the drug has been imported and to ensure comprehensibility for local consumers[47]. The consequence of this requirement is that the parallel importers themselves are often authorized to directly implement the repack-

aging phase or the latter may be undertaken by another party at any time before the entry into the new market. The repackaging phase may therefore also occur in the exporting country or within one of the countries of transit; the qualitative standards in these countries may be very different from those in the country of final destination.

As previously noted, this situation creates a series of problems which may negatively affect the safety of consumers, as highlighted by the WHO[48]. The instructions for the patient could also, in fact, be translated inaccurately; there could be errors in the translations; the packages with anti-counterfeiting features could be replaced with others that do not contain similar elements; batch identification numbers could be modified or not recorded and even the expiration date could potentially not correspond to the date reported on the original package[49].

Due to these weak points, a dishonest operator could insert a counterfeit drug into the distribution chain with relative ease and be virtually impossible to trace. This could also occur if a dishonest repackager decided to insert counterfeit drugs within the original packages of a repackaged drug. These activities are strongly favored by the significant aesthetic similarity of current counterfeit drugs with respect to the original medicines, thereby making identification difficult even for specialists[50]. What has previously been noted regarding "layering" practices in the case of diversion is also valid for the consignments of parallel traded products. In various occasions parallel traded and original products were mixed with counterfeits, creating even more difficulties for the authentication of originals and the identification of counterfeits.

A weak control system in just one of the 27 member states could allow free circulation of a counterfeit product within the entire single market. The penetration of these products could also occur within the official distribution chain but the excessive ramification of the parallel distribution system increases the latter's vulnerability.

The search for profit may also represent a temptation that is difficult to escape. This normal strategic behavior – profit maximization – may be highly risky in the case of pharmaceutical products if not coupled with a series of guarantees relative to the genuineness of the product. As illustrated in an investigation conducted by the Dutch Inspectorate of Health, this does not always occur. Drugs are often derived from sources that have not been requested to demonstrate their sales authorizations and are sold to parties that are not authorized to market them. In addition, a significant lack of efficiency has been reported in the monitoring systems entrusted with guaranteeing that rejected drugs have been actually destroyed and not re-marketed and there are no systems dedicated to tracking counterfeit products[51].

Certain experts have expressed their concern with respect to this trading practice on the basis of these factors[52].

Internet

The use of the Internet as a vehicle for the distribution of counterfeit products is related to the elements described above concerning parallel trading. Both are, in fact, forms of trading which – due to certain intrinsic weak points and the lack of regulation – have become potential instruments for criminal activities. Parallel trading

primarily serves as a potential vehicle for the penetration of products within the legal distribution chain while the use of the Internet has created an independent distribution process which directly targets final users, thereby both adding to ordinary distribution and overlapping it. Ordinary distribution occurs in conjunction with the supply of drugs through the Internet and – as noted in the case of parallel trading – may result in the entry of illegal products into the legal distribution chain. Within the EU, a distributor which acquires goods from an unauthorized online source could become an entry portal for counterfeit medicines which, due to the single market, could then reach any destination within the Union.

The Internet is an important supply channel for counterfeiters given that it allows them to simultaneously supply products at the retail and wholesale level.

In the first case, the consumer is effectively cheated. Attracted by convenient prices and driven by the constant stream of spam in her/his inbox[53], the potential buyer will start browsing an Internet site which is generally structured to appear as a legal activity. In the specific case of medicines, the site will not only state that the online pharmacy is authorized and registered in accordance with the law but will also request a regular medical prescription if required for the drug in question[54]. This only serves the purpose of reassuring the potential buyer who may then proceed with the purchase even without a medical prescription[55]. There are, in fact, various online pharmacies which, in the end, do not actually require this document in order to complete the transaction. Once the purchase is complete, the products will be sent directly to the patient's home.

In the second case, counterfeiters intend to penetrate the distribution chain, exploiting the fact that various distributors are constantly searching for low-cost products in order to maximize profits – regardless of the possibility of verifying the honesty of the supply source. Once the products are acquired by the distributors, they are marketed as any other drug deriving from an authorized source and it will be almost impossible to trace their origin[56].

The use of the Internet as a distribution channel is rapidly growing, as demonstrated by data provided by the FDA which state that 10 million parcels enter the USA every year[57]. The Internet has the advantage, in fact, of guaranteeing an aura of anonymity due to the impersonal nature of online commercial exchanges.

The impersonal nature of these transactions should be analyzed in greater detail.

The section relative to Intellectual Property Rights described how trademarks serve an identifying function relative to the producer. The trademark is not only a commercial symbol for the entity marketing a good but also serves as a guarantee for the consumer who will choose to buy from the must trusted producers or will acquire goods with the best quality/price ratio.

Online purchases seriously jeopardize this function given that it is practically impossible for the consumer to know who or what lies behind an Internet site. The consumer may also not physically enter into contact with the good she/he intends to acquire but must trust the images that are presented in the online store. The combination of these factors – which could be defined as conditions of non-verifiability – creates a fertile ground for the development of illegal activities which aim to sell

replicated products[58]. Due to this level of anonymity, the investigations implemented by law enforcement officials have been considerably more difficult. As a result, the risk of being subject to sanctions, seizures of goods or criminal proceedings becomes even lower[59].

Counterfeiters have obviously grasped the opportunity and there are, in fact, a growing number of counterfeit goods which are today sold through the Internet. In addition to drugs, a study implemented by the *Office for Fair Trading of the Anti Counterfeiting Group* (ACG) has analyzed what occurs in online auction sites. According to the results attained by means of interviews with producers that are members of the ACG – which only took into account one online auction site in the UK – a fashion producer had discovered the presence of 16,300 counterfeit versions of its products in 2004; this number increased to 16,400 in 2005 and 20,827 in 2006. In the same site, a manufacturer of spare parts for motor vehicles had removed 1,058 counterfeit items in 2005 and 2,461 items in 2006[60]. According to a study commissioned to *Ledbury Research by Davenport Lyons*, 49% of a total of 1,000 interviewed people had bought counterfeit goods believing they were originals and 27% of these purchases were implemented online[61].

The ease with which counterfeit products can be marketed through the Internet has, unfortunately, led to a significant increase in the phenomenon, even with regards to goods such as drugs that are potentially damaging to the health and safety of consumers.

In 2004, an investigation of various Internet sites and the pharmaceutical distribution chain was implemented by the US *Immigration and Customs Enforcement* (ICE). The investigation showed that primary Internet sites could rely upon an additional 650 affiliated sites and that the total value of distributed counterfeit drugs was equal to 25 million dollars. An unauthorized distribution network for medicines was discovered; this network originated in India and extended throughout North America[62]. The ICE believes that the Internet is the preferred tool for criminals involved in the trafficking of counterfeit pharmaceutical products[63]; the cases that were investigated by the *Immigration and Customs Enforcement* speak for themselves, as illustrated in Box 1.

A similar case occurred within the EU a few years ago. As of 2001, in fact, a criminal group had created a network of online pharmacies. The online structure allowed potential buyer to choose from a large number of links to other sites which offered counterfeit drugs from various pharmaceutical companies. This generated significant business volumes by importing large amounts of counterfeit medicines from Asia in order to retail them in Europe by means of the regular postal service[64].

A recent article on the Internet site, www.medicalnewstoday.com, reported the first death in Canada whose cause was confirmed to be the use of a counterfeit drug acquired through an online pharmacy[65].

However even if the cases presented so far represent good examples of the gravity of the situation, it should be noted that a considerable number of other cases could be unreported due to the fact that the injuries or death deriving from the unconscious use of a counterfeit medicine are not attributed to the real cause. In other cases, shame or embarrassment on the part of

BOX 1
Examples of cases investigated by the ICE

Operation Ocean Crossing – February 2005

The ICE discovered a trade network of counterfeit medicines deriving from China and directed towards the United States, the United Kingdom and other European nations. This trade was managed by a Chinese criminal organization that was linked to an American citizen. Three Chinese citizens operating in the province of Tianjin were arrested and the following was seized: more than 55,000 packages of counterfeit Viagra and Cialis, 75,000 loose pills, a device used to seal pharmaceutical packages and a significant amount of counterfeit trademarks bearing the Viagra inscription. In September 2005, a police operation was implemented in three facilities within the region of Henan that were involved in the production of counterfeit drugs. This operation led to the arrest of eight Chinese citizens and the seizure of more than 222,000 pills of counterfeit Viagra, 70,000 loose pills, 260 kilograms of raw materials and 580,000 counterfeit Viagra trademarks. At the same time, U.S. authorities arrested a US citizen who subsequently pleaded guilty to the charge of importing counterfeit drugs.

Operation Rock of Gibraltar

A joint investigation conducted by the ICE, the FDA and the Postal Police led to the identification of various foreign sites involved in the sale of counterfeit drugs within the United States. The investigation revealed that part of the buyers were not in good faith and were completely aware of the illegal nature of the purchases and the offered products; these consumers were induced by the possibility of acquiring medicines without the need for medical prescriptions.

The Internet sites – which were aware of this fact – had organized themselves accordingly by offering a reimbursement service for deliveries that were potentially seized by US authorities in addition to describing various techniques to prevent such seizures. Thousands of US citizens were involved in these purchases, thereby generating business volumes of circa 20 million dollars across a period of 24-30 months. A total of 500,000 packages of regulated substances – as well as medicines whose sale is subject to medical prescription – were seized.

Onelinepillbox.com

Investigations conducted by the ICE, the FDA and the Drug Enforcement Administration (DEA) led to the discovery of an Internet site, onlinepillbox.com, which offers regulated drugs and substances without requiring a valid medical prescription. These substances were sent to US consumers through regular mail. It was later discovered that the delivered substances were unauthorized drugs from Thailand, the Philippines and Mexico.

Source: US Immigration and Customs Enforcement (ICE), www.ice.gov

the consumer could prevent her/him from reporting the case to the competent authorities.

The International Narcotics Control Board - the UN body entrusted with regulating the circulation of drugs subject to controlled distribution – recently expressed its concern with regards to the growth of the Internet as a non-regulated market for the distribution of drugs and pharmaceutical products[66].

The use of the Internet as a means to supply counterfeit medicines recalls the comments noted above with regards to the capacity demonstrated by counterfeiters in diversifying their offer of products in accordance with the territorial context of reference. Due to the usage of specifically designed programs – typically spyware – it is today quite simple to monitor the preferences and commercial choices of users which regularly access the Internet. The collection of information relative to online purchases, email messages which are sent and received or visited sites allows key information to be traced; this information may then be used to identify products to offer to a specific user, thereby aiding the counterfeiter in making marketing choices.

The Internet is not only a preferred supply channel for pharmaceutical products but also for other goods which pose a high level of risk for the health and safety of consumers, such as spare parts for aircraft.

An article printed in the Italian weekly magazine L'Espresso[67] reports the recent spreading of Internet sites dedicated to the sale of counterfeit spare parts for aircraft whose origin is quite obscure. Acquiring these spare parts is as easy as carrying out a normal session of online shopping. There are no specific procedures, in fact, designed to verify the identity of the buyer or seller and the only thing that matters is implementing the transaction. The parts on offer include components used in devices for tire pressurization, vanes for turbines, propeller brakes and entire engines – all easily acquired online. A potential buyer only needs to have sufficient liquid funds and all ordered parts, along with documentation, will be conveniently delivered to the domicile of the purchaser, thereby attaining significant savings.

5.4 The weakness of the system

Graham Satchwell – an expert in the sector and the chief executive of a consulting agency for the protection of Intellectual Property Rights, ProcoSolutions – believes that the true Achilles heel of the system is the lack of regulations at the national and European level. An example is reported in his 2004 book, "A Sick Business", which clearly illustrates how: 1) the lack of a common European authority entrusted with monitoring the functioning of the parallel market[68] and 2) the insufficient level of effectiveness of current regulations can result in the penetration of drugs from obscure sources into the distribution system.

Although the cited example is not directly linked to counterfeit drugs but refers to diverted medicines, it highlights certain potential problems within the system.

The case presented by Satchwell involved a dispute between a manufacturing company and a large parallel importer.

The manufacturing firm had supplied a

large number of drugs for HIV treatment at a highly reduced price for the populations of French-speaking Africa. The products in question were actually sent from Europe to Africa but they never reached the populations in need. On the contrary they were again sent to Europe – where they were acquired by a Swiss company – after having been stored in unhygienic and inappropriate conditions[69]. Subsequently, this company sold the drugs to a parallel importer and, by means of parallel importing, reached the UK market.

During the course of the trial, certain elements of the incident were not noted, including the fact that there were criminal proceedings linked to the African incident as well as the inadequate storage conditions of the goods. The parallel importer had complied with applicable norms by verifying that the products were packaged in the manner required for the British market and had notified the competent authorities of the importing of these products.

There is no evidence that the parallel importer was aware of the illegal origin of the goods[70], but it is this element which deserves greater thought. The previously noted difficulties regarding the possibility that a purchasing distributor could know the actual origin of the offered goods are again confirmed in this case. A significant part of the distribution chain remains anonymous and hidden; parallel commerce certainly does not contribute to creating greater transparency. The situation would certainly not differ if the importer had received a stock of counterfeit drugs rather than diverted medicines, although in this case the origin of the products would have been impossible to determine; the significant similarity between the packaging and the replicated product itself with respect to the original would have made it difficult to identify a counterfeit product.

The sentence was not in favor of the manufacturing company's claims which had sought a conviction of the parallel importer for violation of trademark rights. Given that the drugs were entered into the market of the manufacturer in France before reaching Africa, the Court concluded that its rights had been exhausted and its claims could not be admitted. The reason underlying the denial of the injunction is of particular interest. The Court, in fact, stated this claim could not be admitted given the impossibility of knowing the origin and trade routes of these goods; a favorable sentence would have served as a deterrent for legitimate trade[71].

Another example involves North America, where certain journalists of Dateline – MSNBC pretended to be suppliers of counterfeit drugs and attempted to buy these products from China. The idea of the undercover operation was born following the case of an American woman who had died after using counterfeit Procrit.

This drug helps patients with tumors by providing additional energy for resisting against disease. Given the elevated cost of the medicine – 500 dollars for a weekly dose – Procrit is one of the most commonly targeted drugs by counterfeiters. The case of the American woman illustrates a true penetration of the legal distribution chain given that the drug had been acquired in a local pharmacy. Subsequent investigations on the part of law enforcement showed that someone had introduced the counterfeit versions of Procrit within an undefined point of the distribution chain[72]. These investigations discovered

the existence of a network of replicated drugs that was managed by a criminal in Miami; the latter had operated undisturbed for almost a year, selling 11,000 packages of counterfeit Procrit to national distributors while generating net profits of circa 28 million dollars.

The Dateline journalists decided to take action by creating a report that documented how counterfeit drugs could be smuggled onto US soil. An Internet site was created for this purpose; the site advertised the existence of the Hansen Group – a firm interested in importing pharmaceuticals, particularly Viagra. Shortly after their "business launch", they received an email from a Chinese manufacturer which stated that the latter sold counterfeit goods to US suppliers on a monthly basis, admitting the illegal nature of these operations but justifying the behavior by the high level of attainable profits[73]. Negotiations proceeded smoothly and the journalists managed to have the company send them a sample; the latter was delivered without any problems. The external quality of the sample, including the package, was very high; Pfizer itself, the manufacturer of Viagra, had to implement chemical analyses in order to reveal the counterfeit nature of the product.

The journalists decided to take the matter even further and continued to negotiate, eventually placing an order of 1,000 pills. The latter reached its shipping destination without any problems.

The next step involved organizing a meeting with the supplier who agreed to meet them in China. The conversations recorded by the journalists yielded worrisome details. The supplier stated, in fact, that she delivered her products to various regions around the world[74]. The most alarming statements concerned the quantities of goods which the distributor claimed to be able to supply: 6,000 pills per delivery with a maximum of six deliveries per week, thereby adding up to 30,000 pills per week or 120,000 pills per month.

Notes

1 Outsourcing is defined as the decentralization of the productive process or of a part of the latter.

2 Vander Beken T., (2007), *The European pharmaceutical sector and crime vulnerabilities*, Institute for International Research on Criminal Policy, pages 36-37.

3 Vander Beken T., (2007), *The European* cit., page. 37.

4 There are three major area distributors in the United States, for example; 90% of primary distribution passes through these distributors. US Food and Drug Administration (FDA) Counterfeit Drug Task Force, (2003), *Interim Report*, page 7.

5 US FDA, (2003), *Interim* cit., page 7-8.

6 "Brokers are not directly subject to national legislation, they operate at an international level without being mentioned on bills and they are not a responsible party in the strict legislative sense." Harper J., (2006), cit., page 18.

7 Harper J., (2006), cit., page 19.

8 During the creation of this production surplus, dishonest delocalized producers may not comply with the correct composition of the drug if they intend to reduce raw material costs. It is therefore possible these product surpluses are composed of less effective drugs or, in the worst case scenario, by products which are harmful to the patient.

9 Harper J, (2006), cit., page 18.

10 Power G., (1999), *Pharmaceutical Counterfeiting*, in International Criminal Police Review n.476-477, Interpol, page 15.

11 "I know of no distributor, importer or trader who removes the packaging provided by the Intellectual Property Right Holder and substitutes something that has equal or better anti-counterfeiting features." Satchwell G., (2004), *A Sick Business – Counterfeit medicines and organized crime*, The Stockholm Network, page 11.

12 Satchwell G., (2004), *A Sick* cit., page 12.

13 Power G., (1999), *Pharmaceutical Counterfeiting* cit., page 16.

14 "Currently many prescription drug products do not utilize tamper-evident features. Without tamper-evident features, the original packaging may be reused for counterfeit or diverted product and thereby more easily passed off as legitimate product. The reuse of old prescription drug containers found in trash facilities or taken from hospitals and clinics is also a significant problem because no tamper-evident feature has to be replicated, thereby enabling easy reuse of the packaging to distribute counterfeit, adulterated or unapproved drugs." US FDA, (2003), cit., page 13.

15 "Even more serious is the fraudulent alteration of the expiry date on out-of-life products. One incident involved antibiotic injections found in South America in counterfeit Mexican packaging. The batch numbering of the antibiotic vials showed that the product was originally imported via Panama and then parallel traded into Venezuela before being consigned for destruction when it passed its expiry date. The trail then disap-reappeared with its new identity and an extra 2 years in its shelf life." Power G., (1999), cit., page 15.

16 "The consequences of injecting a patient with insoluble talc, or other non-sterile substitutes can be serious and sometimes fatal. The number of resulting fatalities is impossible to guess, as these products tend to be administered in life threatening conditions." Power G., (1999), cit., page 16.

17 "Throughout the Asian Pacific markets there is a thriving trade in antibiotics vials which have been retrieved from hospital waste and refilled with anything from low cost streptomycin, to non-sterile starch powder or even talc." Power G., (1999), cit., page 16.

18 "Several deaths in India, Pakistan, Bangladesh and Philippines have been directly linked to talc-filled vials which show clear signs of illicit recycling – there are several puncture marks already in the rubber plugs, the plastic and aluminium overseals have been carefully reassembled, and the labels often replaced with poor quality counterfeits to renew an expiry date." Power G., (1999), cit., page 16.

19 US FDA, (2003), cit., page 9.

20 US FDA, (2003), cit., page 9.

21 Satchwell G., (2004), cit., page 10.

22 "Diversion facilitates the entry of counterfeit drugs into the U.S. distribution system because those individuals or entities that sell or purchase diverted drugs are less able to verify the integrity of these drugs, because they are purchased outside the normal distribution chain and without the usual regulatory safeguards." US FDA, (2003), cit., page 9.

23 The fact that these goods have already been marketed differentiates parallel trading from international diversion; in the latter case, the goods have not yet been introduced to the market for which they were delivered.

24 "Re-importation (or parallel trade as it is known in Europe) is the process whereby goods protected by an intellectual property right (such as patent, trademark or copyright) are placed into circulation on one market, and then (re-) imported into a second market without the authorization of the local owner of the intellectual property right." Arfwedson J., (2004), *Re-importation (Parallel Trade) in Pharmaceuticals*, Institute for Policy Innovation – Policy Report 182, page 1.

25 *Quantitative restrictions on imports and measures having equivalent effect are to be prohibited between Member States.* Consolidated Version of the Treaty Establishing the European Community, Art. 28.

26 *The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on ground of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.* Consolidated Version cit., Art. 30.

27 Within industrial property law, the term "specific subject matter" is defined by the Court as the right to utilize a trademark in order to market products for the first time, thereby protecting the owner of the rights from other parties who may intend to exploit the reputation of the owner by utilizing the trademark on the latter's products. "The specific subject matter of a trademark was said to be the right to use the mark for the purpose of putting products into circulation for the first time and to protect the proprietor from competitors wishing to take advantage of the status and reputation of the trademark by selling products illegally bearing the mark." International Trademark Association, (2005), *Parallel Imports: Summary of EC Law and its Application in the EU Member States*, page 3.

28 The term "essential function" is defined by the Court as the guarantee provided to the consumer that a product marketed with a specific trademark has been subject to quality controls on the part of a competent authority in order to prevent the product from subsequent modification or tampering. "The essential function of a trademark, on the other hand, was to guarantee to the consumer that a product bearing the mark had been manufactured by or under the control of one undertaking responsible for its quality and that there had been no subsequent tampering; it was also to create goodwill and retention of custom for the manufacturer." International Trademark Association, (2005), *Parallel Imports* cit., page 3.

29 The debate was of significant nature and no uniform procedure was applied by member states: "...there was an open question as to whether Articles 28 and 30 of the EC Treaty had any application to cases involving the parallel importation of goods first placed on the market outside the EC/EU. In practice, the approach taken by the Member States varied, with some applying a rule of international exhaustion and other applying

a rule of Community exhaustion." International Trademark Association, (2005), cit., page 4.

30 *1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.*

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods especially where the condition of the goods is changed or impaired after they have been put on the market. International Trademark Association, (2005), cit., page 3.

31 The debate which led to this choice was actually quite complex. An initial version of the directive proposed by the Commission, in fact, provided for Article 7 to also be applicable to products that are marketed for the first time outside of the EU, thereby embracing the principle of international exhaustion. The Memo attached to the proposal, in fact, states that: "*The rule under which the right to a trademark is exhausted with the first use of the mark effected or authorized by the proprietor is a direct consequence of its function as an indicator of origin. The place where the marked product is put on the market is not important in this respect. The principle laid down in Article 11* (the subsequent Article 7) *thus applies regardless of whether the product bearing the Community trade-mark was put on the market inside or outside the Community*". This version was subsequently modified due to fears – particularly on the part of the Economic and Social Committee – that an absence of reciprocity in non-EU countries could damage companies with registered offices in the EU. International Trademark Association, (2005), cit., page 4-5.

32 In this case, the Court stated that "*...national rules providing for exhaustion of trade mark rights in respect of products put on the market outside the EEA under that mark by the proprietor or with his consent are contrary to Article 7(1) of the Directive, as amended by the EEA Agreement.*" International Trademark Association, (2005), cit., page 5-6.

33 "…in order to protect the 'specific subject matter' and 'essential function' of a trademark, the proprietor of a trademark prima facie has the right to prevent a product to which a trademark has been lawfully applied in one Member State from being marketed in another Member State after being repackaged and the mark reaffixed, where this occurred without his authority. However, in each case, it has to be determined whether the exercise of this right might be a disguised restriction on trade between Member States, depriving the trademark owner of the benefit of Article 36 (now 30) of the EC Treaty." International Trademark Association, (2005), cit., page 20.

34 International Trademark Association, (2005), cit., pages 20-21.

35 The exact content of these conditions was clarified by the Court on several occasions. With regards to the first condition, for example, the Court noted that repackaging is not justified if a simple overwriting of data can fulfill the same function; the time limit within which the producer must be notified by the parallel importer – regarding the latter's intention to market products of the producer that have been imported in a parallel manner - is fifteen days before the introduction of the goods to the market. The Court, however, entrusted the courts of the individual member states with the task of making case-by-case decisions relative to the potential alteration of the product's conditions as a result of repackaging. International Trademark Association, (2005), cit., pages 22-23.

36 International Trademark Association, (2005), cit., page 25.

37 The differences in sale prices within the pharmaceutical market is also due to agreements stipulated between various European governments and the pharmaceutical manufacturer in order to reflect differences in purchasing power in these countries. Satchwell G., (2004), cit., page 11.

38 Satchwell G., (2004), cit., page 16.

39 Satchwell G., (2004), cit., page 16-17.

40 "Legal provisions governing parallel importation in the EU tend to rely on existing provisions governing import licensing and marketing authorization. As the regulation of pharmaceutical products parallel importation is not determined at EU level, there is broad scope for member states to interpret their own procedures for governing parallel importation." Harper J., (2006), cit., page 17.

41 "As a result of the single EU market, weaknesses in the trade control system of one member state can lead to a critical weak point in the entire EU pharmaceutical regulatory system. Thus, although some member

states, with strong regulatory and control systems, may assume that they have no counterfeit medicine problem on their territory, this assumption may well be false." Harper J., (2006), cit., page 16.

42 "Regulation of medicines (re) packaging, (re) labeling and printing is not performed consistently across European States. Of concern is the probable existence of unregulated or illegal packaging, labeling and printing facilities." Harper J., (2006), cit., pages 16-17.

43 Satchwell G, (2005), *Prescription imports could kill us*, page 6.

44 The batch identification number is assigned by the producer in order to be able to trace the product in case of need, e.g. in the case of recall of an entire batch of products for safety reasons.

45 "If a UK parallel trader wishes to buy from another European dealer then he must first ensure that the foreign dealer is licensed in his own country. He will therefore ask for evidence from the seller. The seller will then fax or post a document that purports to be a license to conduct such trade. There is no one European body with which the UK dealer can verify his seller's credentials, and the UK regulatory authority do not see it as their duty." Satchwell G., (2005), *Prescription* cit., page 6.

46 "In the EU there is no requirement for record the batch numbers of parallel imported medicines, so if a batch of medicines originally intended for sale in Greece is recalled, tracing where the entire batch has gone (for example from Athens to London through Canada to Indianapolis) is impossible." Pitts P. J., (2006), *21st-century international drug terrorism*, in Coincidence or Crisis, page XV.

47 "There is little point in a product being received in Scotland while the packaging is clearly written in Greek." Satchwell G., (2004), cit., page 11.

48 "Because of inadequate regulation and enforcement, the quality, safety and efficacy of both imported and locally manufactured medicines in many developing countries cannot be guaranteed. Smuggling and illegal importation of drugs are rife. Counterfeit drugs are not only sold in countries with ineffective drug regulation but they are also exported or re-exported." WHO, (2006b), cit.

49 Pitts P. J., (2006), *21st- century* cit., page XV.

50 "I have heard from time to time comments such as 'It can be difficult for the layman to identify counterfeit drugs' or 'it would need a trained doctor to examine the package to know whether the drugs where genuine'. Such comments completely miss the point and show a lack of experience in handling counterfeit medicines. The truth is that counterfeit medicines often appear so like the genuine product that no one, not the best specialist can tell the genuine packaging from the counterfeit. And no one, not the best specialist can tell the genuine product from the counterfeit unless the product is subjected to chemical analysis." Satchwell G., (2005), cit., page 4.

51 Harper J., (2006), cit., page 20.

52 "The existence of a significant level of Parallel Import (PI) within the EU, in the absence of adequate controls on repackaging and relabelling, can inadvertently facilitate entry of counterfeit medicines from one member state into another…Although known cases of counterfeit medicines have arisen in the European parallel trading system, the extent to which the practice of PI in itself is a facilitating factor for the dissemination of counterfeit medicines throughout Europe has not been sufficiently studied to draw any firm conclusions. What is clear, though, is that PI is reliant on a significant amount of repackaging, relabelling and printing, and contributes to the increasingly complex pharmaceutical distribution system in Europe." Harper J., (2006), cit., page 17; "It would be incorrect to allege that licensed parallel import medicine traders are directly responsible for facilitating the introduction of counterfeit medicines into the EU…But equally it would be wrong to deny that the growth of complex patterns of trading in medicines in Europe has extended medicine supply chains in ways that increase opportunities for criminals to introduce fake products." Taylor D., (2006), *Facing the reality of medicines counterfeiting*, in Coincidence or Crisis, page 43.

53 "Email Systems, a company that measures spam emails on the internet, reports that in the first three months of 2005 two in five spam emails were offering drugs for sale. As the volume of spam is now almost 90% of all email sent, that means one out of every three emails sent is offering you cut-price drugs over the net." Phillips T., (2005), *Knock off: the Deadly trade in counterfeit goods*, page 202.

54 Satchwell G, (2004), cit., page 8.

55 In this case an additional problem arises: the free circulation of drugs whose sale should be subject to controls.

56 "...internet is not only a threat to the unwary online customer but a ready marketplace from which the unscrupulous European involved in parallel trade can buy and supply others goods obtained from within the EU and outside it." Satchwell G., (2004), cit., page 9.

57 Phillips T., (2005), *Knock off* cit., page 204.

58 "Consumers are potentially at more risk when shopping on the internet than when buying counterfeit goods by traditional (i.e. physical) means. Apart from the fact that it is more difficult to distinguish genuine from counterfeit goods (especially where genuine images are used to advertise counterfeit goods) and that it is not possible for a consumer to perform a physical examination before deciding to purchase, it is often impossible to identify the seller…" The Anti-Counterfeiting Group, Office of Fair Trading, (2007), *Internet Shopping Market Study*, page 4.

59 "...it is often impossible to identify the seller, or to track and seize their stocks of counterfeit goods once their activities have been discovered. The seller literally disappears into cyberspace, effectively taking his counterfeit stock with him." The Anti-Counterfeiting Group, (2007), *Internet Shopping* cit., page 4.

60 The Anti-Counterfeiting Group, (2007), cit., pages 5 -6.

61 Of this 27% of online purchases, 87% were implemented through online auction sites. The Anti-Counterfeiting Group, (2007), cit., page 5.

62 US Immigration and Customs Enforcement (ICE), (2006), Statement of Kevin Delli-Colli before the Sub-Committee on Criminal Justice, Drug Policy and Human Resources, page 2.

63 "ICE smuggling investigations have shown that the internet has become the primary tool used by organizations engaged in the trafficking of counterfeit pharmaceuticals, whether for advertisement, direct sales or communication." US ICE, (2006), Statement cit., page 4.

64 Daniels M., Merchant C., (2006), *Counterfeit Pills and Genuine Treatments*, in IP Risk Management Review, page 16.

65 "Canada's first confirmed death from counterfeit drugs purchased over the internet reinforces long-stated concerns of the Canadian Pharmacists Association. A coroner's report has concluded that pills bought from a fake on-line pharmacy are to blame for the March death of a Vancouver Island Woman. These drugs were later determined to be contaminated with extremely high quantities of metal." Internet Drug Death – A Warning to Canadians, www.medicalnewstoday.com.

66 "The International Narcotics Control Board has identified the role of the internet in the illicit distribution of narcotic drugs, psychotropic substances and counterfeit drugs. The use of the internet to prescribe and sell medicines is fraught with health risks as the source, quality, safety and efficacy of such medicines cannot be guaranteed, and in particular when such internet services are unregulated and unlicensed." International Narcotics Control Board (INCB), (2007), Statement of Dr. P. Emafo, President of the INCB, to the Third Global Congress on Combating Counterfeiting and Piracy.

67 L'Espresso, http://espresso.repubblica.it/dettaglio-archivio/1077207.

68 According to Satchwell, the fact that the system involved in granting authorizations and monitoring the latter is not found at the EC level – but is instead delegated to each individual member state – is an enormous source of weakness in the distribution chain; this is due to the national limitations of jurisdiction of the various government bodies that are entrusted with such controls and audits: "The principle behind the current practice is mirrored in the Medicine and Healthcare Regulatory Agency (MHRA) *Guide to the Implementation of the EC Directive 92/25*. It states: 'Wholesale trading between a dealer in UK and a buyer in Germany…should be no different…than wholesale trading between a dealer in Hertfordshire and a buyer in Essex'. The obvious difference, of course, is that the MHRA can visit and inspect premises in Essex and Hertfordshire but in relation to the manufacture and storage of products from elsewhere in Europe, which might end up in Hertfordshire or Essex, they are blind." Satchwell G., (2004), cit., page 21.

69 "…the goods had been sent to Africa, where they had been stored (at least some of them, and probably all) in sweltering conditions in open-topped barns and rubbish-strew industrial sites populated by vermin." Satchwell G., (2004), cit., page 23.

70 Satchwell G., (2004), cit., pages 23-24.

71 Satchwell G., (2004), cit., page 24.

72 "What surprised us, and what may surprise you about this case, is that Maxine and her family followed the U.S. government warnings you've heard. They didn't import the medicine from Canada. They didn't order it over the internet. They got the medicine the way most of us do – at a trusted local pharmacy….So how did it happen? These records obtained by Dateline show that before Maxine's medicine arrived at her drug store, drugs from the same batch were bought and sold by a series of drug wholesalers and distributors in Texas, Arizona, Florida, and New York. Along the way, someone slipped in the counterfeits." Hansen C., (2006), *Inside the world of counterfeit drugs*, MSNBC – Dateline.

73 "And by e-mail, we began to get offers, including one from a Chinese woman who calls herself '*Cherry Wong*'. *Cherry Wong (on the phone): Every month we sell, we have sent to America.* Over the phone and in e-mails she didn't' mince words. 'This business' she told us, 'is illegal' but 'high profit'." Hansen C., (2006), *Inside the world* cit.

74 "Cherry Wong says her company makes better counterfeits than other Chinese companies – fake medicines good enough to sell to distributors all over the world. Hansen: *You've got Britain, Italy?*; Wong: *Yeah*; *Hansen: Australia?*; Wong: *Australia. Yeah*; *Hansen: Japan?*; Wong: *Japan*;. " Hansen C., (2006), cit.

6. Counterfeiting and organized crime

The links existing between counterfeiting and organized crime are today broadly acknowledged. Although not all acts of counterfeiting are unequivocally ascribable to large criminal organizations, there is no doubt that a significant portion of counterfeit trafficking is managed – at a variety of levels – by organized crime. There is therefore a growing interest in this activity on the part of criminal organizations and an increasing involvement of the latter. For this purpose, it is useful and particularly interesting to not only note the evolution of this interest and involvement but also specifically highlight the reasons underlying the latter, thereby illustrating how the involvement of organized crime has affected the implementation of practices that are ascribable to counterfeiting phenomena.

6.1 Organized crime and counterfeiting

The relationship between counterfeiting and criminal organizations is due to the significant expansion in the areas of interest on the part of organized crime groups. Modern criminal groups do not limit themselves to implementing the activities which are traditionally linked to their organizations such as illegal drug and arms trafficking, the management of tenders or extortions. On the contrary, organized criminal groups have gradually started implementing various types of activities which are often similar to those which were previously considered economic crimes. This area includes the founding and management of companies which operate in financial markets or regular product markets in order to launder proceeds deriving from other crimes committed by the same criminal group or income transferred to the latter in order to implement these money laundering activities. This category also includes counterfeiting, an activity which has currently reached a level of expansion that was previously unimaginable. The involvement of organized crime is one of the factors which has favored the growth of counterfeiting and has forced certain elements of the problem – which were previously scarcely taken into account – to be viewed under a new light. The appearance of unscrupulous individuals has, in fact, favored the birth of a type of replication activity which intends to exploit all market opportunities – even if this implies marketing product categories which pose a high level of risk for the health and safety of consumers.

The development of organized crime

The expanded interest of organized crime with respect to various types of activities and the development of criminal organizations are closely correlated phenomena.

The United Nations Convention against Transnational Organized Crime (2000) – the most important international regulatory tool on this subject - defines an organized

criminal group as a "*structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences... in order to obtain, directly or indirectly, an economic or other material benefit*"[1].

This meaning therefore encompasses criminal activities that are characterized by a certain organizational duration whereby the criminal association is implemented in order to conduct criminal acts which allow the group to generate profits. The duration of this association is not defined *a priori* and should be interpreted as any non-occasional commitment to commit crimes on the part of group members[2]. The numerical element of the definition serves to create a distinction between the individual criminal who may be aided by an accomplice and more complex organizations which involve more people and therefore imply a greater degree of operational capacity, thereby posing a greater threat to public order.

By combining these first two elements to the pursuit of profit, one obtains the standard definition for a criminal organization which thereby encompasses multiple forms of organized crime. This definition is valid for a traditional Mafia organization that is structured in a hierarchical manner and which retains a strong connection to its territory in addition to a division of roles within its organizational structure. At the same time, this definition encompasses modern phenomena such as criminal networks with varying structures and which operate in different sectors and territories; these groups are characterized by their links with other groups which therefore lead to the loss of rigid hierarchies and the strong territorial connection.

The act of committing serious crimes in order to obtain profits is an additional element linking the various types of criminal organizations; this element is common to both criminal groups that are characterized by more traditional organizational structures as well as those with international and transnational scope[3].

Having outlined the elements which are common to all organized crime, the development of the latter should now be illustrated; reference will be made to the expansion of the range of criminal activities as well as the modern operational methods of organized crime.

Organized crime supplies a range of services to potential customers and, from this point of view, does not significantly differ from a normal entrepreneurial venture. Trafficking on the part of these groups is essentially linked to the existence of demand for illegal goods and services; it is the actual evolution of this demand[4]– or rather changes in the object of the latter – which is one of the factors causing the change in criminal structures. The traditional Mafia-type organization – which is linked to its territory and which exercises pressing control over the entities in its territory by means of intimidation and extortion tactics – has gradually expanded to include new opportunities deriving from the globalization of markets and the widespread distribution of technologies. This growth has also involved alliances with other types of criminal groups or with groups operating in other countries.

The development of new profit opportunities that are considerably more lucrative compared to the traditional management of gambling activities or public tenders or extortion activities has revealed a chameleon-like element within these criminal

groups: during the course of the 1970's, these organizations underwent a complete transformation.

Narcotics, weapons and contraband products were goods characterized by elevated demand whose commerce generated significant revenues for criminal organizations. The appearance of these products, however, required a transformation on the part of these groups, an adaptation to a new type of activity and trade. The narcotics trade is one of the milestones in the evolution of structural relationships within the Sicilian Mafia, for example; the latter initiated a series of alliances with criminal organizations from other countries in order to create a division of labor and to subdivide the market, thereby attaining greater operational efficiency and maximizing profits[5].

The underlying reasons for this transformation are linked to the nature of the traded good which is often produced or located in a location that is different and distant from its commercial destination. This is true for both drugs and arms trafficking but is, unfortunately, also an element characteristic of human trafficking. In order to manage trafficking across different areas of the globe, the criminal group establishes alliances with other organizations, subdividing operational tasks and creating an actual illegal production/distribution chain[6]. A hierarchical structure that is linked to a specific territory will most likely not be able to implement these tasks in an optimal manner; criminal groups have therefore not only been internationalized but have also initiated a "transnationalization" of their activities. The existing new synergies not only guarantee optimal logistics but also provide the opportunity to market various goods by utilizing the same methods and, most likely, the same trade routes. These criminal groups are also interested in the facilitation of the distribution process due to the influence which they are capable of exerting on "monitoring" entities by means of corruption and intimidation. These "operations" are obviously easier for a criminal group that is rooted in the specific territory of transit or destination due to the contacts and connections of such a group, thereby making synergies even more advantageous.

The transformation of organized crime groups received an additional boost from the internationalization of markets and the economy. The global markets for goods as well as the financial markets have resulted in a gradual weakening of national borders which were previously a serious obstacle for this globalization process. Even in the case of geo-political areas that were not subject to the level of integration attained in the European continent, regulations involving rigid controls over commercial and financial flows across borders have had to adapt to the dictates of international trade and the significant commercial and financial flows generated by the latter. This was necessary in order to not miss the "globalization train" and risk being cut off from an unprecedented expansion of opportunities and wealth.

Criminal organizations have managed to seize the opportunities inherent in this global transformation – maybe even more than national governments and their populations – and have displayed a surprising level of adaptability to the new status quo, occasionally even preceding national legal systems in this area. This has allowed them to develop a significant competitive edge and governments are today still unable to plan and implement accomplished and effective

common strategies for combating a crime which is increasingly delocalized and globalized. The advent of new technologies and the Internet – in the form of a gigantic "virtual market" – has further highlighted the decreasing importance given to the concepts of border and commercial barriers, thereby allowing for rapid exchanges of information between distant parties and guaranteeing a sort of anonymity for those operating behind a PC screen.

This is the new face of organized crime – increasingly similar to a transnational commercial company combining rigid hierarchies and territorial rooting with flexible structures that are easily adaptable to changing circumstances. Commercial specialization has been repudiated in favor of the simultaneous trade and supply of different categories of illegal goods and services[7].

The interest of organized crime in committing and managing counterfeiting crimes

According to the reasoning underlying the commercial expansion of operations on the part of organized criminal groups, counterfeiting could initially be presented as one of those illegal activities which are historically linked to contraband crimes. A brief analysis relative to this category of crime yields certain fundamental elements which aid in understanding the reasons underlying the interest of organized crime in counterfeiting.

A study conducted by FIA International Research LTD in 2001 – with reference to US national territory – analyzes the problem of counterfeiting from the point of view of the response of organized crime to the demand for contraband products existing within a spatio-temporal environment. This perspective illustrates how counterfeiting is linked to other forms of smuggling as well as other illegal trafficking that is managed by the same criminal group. This trafficking utilizes similar trade routes and is based on the globalization of trade flows. It also re-proposes and confirms the vision of organized crime groups which are dedicated to offering illegal goods and services that are in demand within a territory by producing, collecting and transferring, if necessary, these goods and services to another location.

The existence of demand for illegal products is the foundation from which contraband markets are born. This demand is generated – in a majority of cases – by the request for a good which is not available through legal distribution channels or as a result of the price difference between a good offered by authorized retailers compared to that attainable through illegal channels. This price differential may be due to elevated taxation of the good or the need for manufacturers to recover investments made during the development and production of a specific product.

The combination of these elements – the existence of demand and the possibility of offering the good at a lower price – is one of the primary causes underlying the interest of organized crime in these activities. When considering the opportunities relating to this type of trafficking, organized criminals also take into account the level of profitability as well as the level of risk.

The level of profitability in counterfeiting is significant and is similar to that found in the trade of narcotics – in certain cases even higher[8] – but the level of risk involved in these activities is significantly lower given that law enforcement tends to

focus less upon these crimes and penalties are less severe.

The low level of deterrence which characterizes numerous legal systems with respect to counterfeiting crimes and the generally benevolent attitude of citizens towards this type of trafficking allow one to more easily understand the birth and development of an interest for these activities on the part of organized crime.

The logistical management involved in the trading of counterfeit products is also facilitated by the volume of commercial exchanges between countries as well as the elevated number of containers which arrive in ports and commercial hubs each day[9]. By exploiting the fact that customs authorities of various countries can not physically check all goods inflowing and outflowing from a national territory[10] – at least not without causing an actual block in trade[11] – counterfeiters manage to relatively easily transfer large quantities of counterfeit goods.

The volume of international commercial trading is not the only involuntary ally of organized crime during the latter's trafficking of counterfeit goods. This trafficking is, in fact, also facilitated by modern logistical management of international trade due to the advent of intermodal shipping[12]. The increased complexity of the distribution chain as a result of intermodal shipping allows counterfeiters to more easily conceal the trade route of a cargo of goods[13], thereby transferring the goods in question through various intermediary destinations in order to conceal their origin[14]. These intermediary destinations are often chosen from those hubs which law enforcement authorities do not consider to be "high risk", thereby making the origin of the good appear less questionable. This creates additional practical difficulties when attempting to detect counterfeit goods; attempts to remedy this problem have involved the creation of systems that are designed to calculate customs risk – relative to certain trade routes or products – or by means of the adoption of computerized customs management systems[15]. Box no. 1 describes what has been done in this field by the Italian Customs Agency that owns one of the international best practices on computerized customs risk management.

The problem becomes more complex when the imported object is not a finished counterfeit product. In order to evade border controls, counterfeiters resort to a variety of techniques to disguise the goods – by mixing original and counterfeit products, for example[16] or by using double bottomed transportation means. The latter technique was used, for example, in the year 2000 when a Bulgarian ship transporting goods from Ukraine and ex-Yugoslavia was inspected; a double bottom – created from one of the fuel tanks - was discovered to contain more than 220,000 pirated CDs whose market value was estimated to be 500,000 dollars[17].

The practice of subdividing the components of a product across several shipments is also widespread. Consider the case in which a cargo of shirts and counterfeit trademarks – which will be placed on the shirts – are shipped separately or the case in which a product is delivered first, followed by its package[18]. The manufacturing process of the counterfeit good is, in these cases, completed after delivery in order to subdivide the risks involved in shipping. If, in fact, it is only the container containing the shirts or products without trademarks

that is intercepted, the cargo will not be seized during customs controls and the loss will only involve a part of the good itself; in the case of the abovementioned examples, this loss would include the counterfeit trademarks or the packages subject to subsequent shipping.

In the third edition of its report on links between counterfeiting and organized crime, the *Union des Fabricants* illustrates a few examples relative to the logistical management of counterfeit product trafficking;

BOX 1
A best practice of computerized customs' risk management

The project of fight against counterfeiting – the *Fully Automated Logical System Against Forgery and Fraud* (FALSTAFF) – worked out by the Italian Customs Agency is hinged on a multimedia database of original products, which is included in the information system of the Agency.

Each producer, manufacturer or right holder applying for customs protection generates a form in the database, which contains several data related to the products for which protection is requested – information on routes and quantities traded, technical information for the identification of the product, photos of the trademark and of the product itself as well as packaging information.

Customs officers can query the database obtaining real time information and, in case of an application for action, they can also refer to the support of experts of trade associations and/or quality certification bodies for the products concerned.

The database is also integrated with the customs control circuit, thus allowing for the definition of further risk profiles which result in corresponding actions aimed at protecting trademark rights.

The customs control circuit performs a real time analysis of all import and export declarations submitted to customs and automatically redirects them to the relevant control channels matching those risk profiles. The risk profiles are elaborated also on the basis of parameters indicated in the forms submitted by right holders to the Agency.

The implementation of the system is one concrete and positive step undertaken by the Italian Customs Agency to meet some of the most urgent needs resulting from the First World Congress on the Fight Against Counterfeiting: identifying the highest possible number of counterfeit products and counterfeiting strategies; and taking the fastest possible actions in these respects. These tasks are achievable only through the adoption of electronic means.

FALSTAFF was awarded in 2005 the Honor Mention in the eEurope Awards, European Oscar for the better initiatives related to eGovernment, held in Manchester. The motivation was that FALSTAFF constituted an innovative and ambitious project aimed at combating the counterfeiting phenomenon within the European Union single market. It could as well represent an excellent example to be followed by the other European customs agencies as well as to improve the efficacy of cooperation among the EU member states.

Source: Italian Customs Agency, www.agenziadogane.it

these examples are very useful as practical illustrations of the types of concealment noted above[19]. Other examples have been provided by the Italian Customs Agency.

- In July 2006 the Italian customs and the Guardia di Finanza intercepted various tons of counterfeit Louis Vuitton products, whose commercial value was estimated in circa 15 million Euro. The merchandise originated from China and was directed to Italy, Greece, Croatia and Montenegro.
- In July 2005 the Italian Guardia di Finanza seized a container with 15 tons of counterfeit toys. The container originated from China and passed through Hungary before being intercepted at the border Italian – Slovenian border, transported by a truck.
- In September of 2003, almost 15,000 counterfeit glasses – with an estimated value of 1,262,650 Euro - were seized in the port of Roissy. The cargo originated from the port of Dubai and was en route to Abidjan.
- In December of 2003, customs officials in Roissy carried out another important seizure. In this case, almost 245,000 counterfeit labels of famous brands such as Lacoste, Timberland, Nike and Ecko were discovered. The origin of the shipment was Hong Kong and the goods were en route to Morocco.
- Operations on the part of French customs authorities have ascertained that European countries such as Germany and Finland serve as transit points for counterfeit goods produced in China whose final destination is the Russian market.

In addition to the characteristics outlined above, a counterfeit product also presents other benefits for organized crime. One of these characteristics is the relatively low level of apprehension which this type of illegal activity generated up until recently. Given that this activity was initially perceived as associated only to luxury goods, the trafficking of replicated goods did not generate sufficient concern to warrant incisive action on the part of law enforcement officials. The advent of organized criminal groups managing these activities has, however, multiplied the number of goods subject to unauthorized replication, thereby leading to the previously described "evolution" of counterfeiting and its transformation into a large scale trade[20]. Increasing evidence of the presence of counterfeit goods - which are potentially harmful to the health and safety of consumers – in the market has disowned the idea that counterfeiting is a "victimless crime". In addition, the significant potential for intimidation and corruption on the part of organized crime has facilitated the expansion of trafficking in replicated products as well as the opportunity to offer them within normal sales channels, thereby also reaching unconscious consumers.

Illegal trading which is both highly profitable and presents low levels of risk is certainly appealing to organized crime. This appeal is enhanced by the relative logistical simplicity of the commerce itself, the widespread distribution of technologies which allow for a faithful reproduction of the product and the possibility of exploiting existing trade routes and synergies that were previously created by various groups managing other types of illegal trade[21]. The combination of these characteristics ensures that counterfeiting is an opportunity that modern organized crime will not fail to exploit[22].

6.2 Counterfeiting as an illegal activity of criminal groups

The modern version of counterfeiting is included amongst the category of "interests" of organized crime and is managed by the same groups involved in other types of trafficking[23]. In addition, it serves as an important instrumental tool for the criminal group given that it allows the latter to more easily launder the proceeds from other crimes and is itself a significant source of liquid funds. These funds may subsequently be re-invested into other illegal trades or other "interests" of the organized crime group.

Management of production and distribution

A potential starting point for an analysis of the criminal management of counterfeiting activities may again be traced back to the current scale of the phenomenon – both in terms of production as well as distribution of counterfeit goods. The broad scale of the phenomenon, the economic resources that are utilized, the capacity to evade controls and penetrate the market by means of various systems, as well as the experience derived from specific cases, support and leave little doubt with regards to the strong level of involvement of organized crime during the management of counterfeiting activities.

Before analyzing this topic, however, it is important to note the existence of counterfeiting activities on a smaller scale. This type of counterfeiting is definitely not close to disappearing and suggests the existence of what could be defined "crimes of opportunity", i.e. a crime which resorts to counterfeiting but could equally well have resorted to retail drug selling and is therefore not dedicated to any type of trafficking in a stable manner. It is this element which differentiates this type of crime from those committed by large and more hierarchical organizations that are firmly involved in the management of various types of trafficking. In the first case, the organizations are significantly smaller and indiscriminately resort to various types of criminal activities[24]; they may also be used, however, by larger organizations as the final endpoint for the distribution of illegal goods[25]. Their existence should, however, be taken into account in order to avoid the association, "counterfeiting = large scale organized crime, always and in all cases". There is no doubt, however, that the penetration of replicated goods of all types and in significant quantities suggests an entrepreneurial organization for the production and distribution of these goods. These two phases can only be implemented on large scales with the availability of significant amounts of capital and strong organizational links between parties operating across different locations. Counterfeiting activities more related to luxury goods on a restricted scale and of low quality, typical of the years between 1960 and 1970, was progressively flanked by industrial scale counterfeiting, which later resulted in better quality of the so called "fakes". From low quality fakes they became good and very good fakes and the very low quality level of counterfeiting is now almost disappeared. Even this shift in product quality indicates that the production structure behind the phenomenon should be efficient and organized.

The production phase in modern counterfeiting is clearly different from that im-

BOX 2
Vulnerability of the European Pharmaceutical sector with respect to organized crime

An interesting study conducted by the Institute for International Research on Criminal Policy analyzes the vulnerability of the European pharmaceutical sector with respect to penetration on the part of organized crime.

An elevated level of vulnerability was noted, for example, in certain elements of the market such as the nature of the product, the conditions for entry in the sector and alternative markets.

With regards to the nature of the product, this vulnerability is due to a variety of pre-existing causes: product integrity, defined as the relative ease with which the product could be manipulated; product mobility, defined as the possibility of transporting the good to different locations and marketing it; product elasticity, referring to the frequency with which the demand curve for a product may change; product differentiation, defined as the relative simplicity with which a copy of the original could be made; and the value stability of the product. For this purpose, pharmaceutical products are particularly vulnerable to penetration by organized crime given that they are easily modified and are not difficult to transport due to their reduced size. In addition and from a strictly economic perspective, they can be considered non-superfluous products which are therefore not subject to changes in their essentially rigid demand curve. At the same time, they retain their value over time while the widespread distribution of technology allows for very similar replicas to be made.

The conditions for market entry and trade management are also highly vulnerable to penetration on the part of organized crime. These factors are analyzed in reference to current legislation and market characteristics. Legislation which regulates the market entry of new operators and the implementation of trading are susceptible to criticism with respect to their level of quality. According to the study in question, this criticism is due to the presence of overly technical terms, rendering comprehension difficult for the parties that are entrusted with controls; this situation is further aggravated by the advent of the single market given that legislation in this sector has not been harmonized. In addition, certain economic characteristics of the pharmaceutical market facilitate the penetration of organized crime – in particular, the oligopolistic nature of this market and the strong competition within it.

Finally, the existence of an irregular market – and the possibility that criminal organizations utilize the latter in order to market counterfeit drugs – is an additional element of vulnerability within the pharmaceutical sector. A large variety of pharmaceutical products is, in fact, present in this market, ranging from antibiotics to the so-called lifestyle drugs and anabolic products. The irregular market also guarantees anonymity for purchasers, a characteristic which may be appealing in the case of buyers who are interested in acquiring drugs without medical prescription or anabolic or lifestyle drugs.

Source: Vander Beken T., (2007), *The European pharmaceutical sector and crime vulnerabilities*, Institute for International Research on Criminal Policy.

plemented in the past due to the abandonment of prior methods. The modern version is, on the other hand, characterized by the high volume of produced quantities, the size of some of the discovered production sites, the significant level of technology used during production and the overall entrepreneurial management. Each of these elements illustrates a transcendence of the previous version of counterfeiting and demonstrates the availability of large quantities of capital that are allocated for these activities.

Criminal organizations – aware of the significant profits that are attainable – have invested in developing this activity and have transformed the latter into a real mass production industry that is capable of supplying conscious consumers and deceiving unconscious ones. Box no. 3 illustrates just a few of the examples relative to successful police operations that show the scale of the problem. The illustrated cases refer to different types of products, including pharmaceuticals, and share the common characteristic of involving large quantities of goods.

Such a large scale of production is supported by the growing distribution of highly advanced technologies which allow for more rapid – and, in particular, accurate – replication of originals. With regards to these technologies, the *Union des Fabricants* reported the discovery of production sites in countries such as China, Thailand, Turkey or Russia which were equipped with significantly advanced manufacturing tools that, despite the elevated costs, are available to counterfeiters[26].

It should also be noted that the outsourcing of production provides an additional opportunity for counterfeiters to improve the production phase. Once the complicity of the delocalized producer is ensured, it will be possible to produce quantities of goods that exceed the received job order amounts[27] by utilizing the same production tools that are available to the party owning the intellectual property rights. In this way, an additional advantage is attained: ownership of a good whose quality is basically identical to that of the original good[28].

In addition, the previously noted examples relative to concealment techniques, particularly the use of different shippings for different components of a product, illustrate a significant level of organization and interconnections between groups operating in different and very distant locations. According to the *Union des Fabricants*, the majority of counterfeit products which are marketed within the EU originate from sources outside the EU, specifically China, Thailand, Morocco or Turkey. The EU itself is, however, a very active production center for a range of replicated products. Countries such as Italy or Portugal, for example, are often associated with the counterfeiting of clothing items while Spain and Italy are the countries that are most highly associated with the production of fake spare parts for automobiles[29]. These products are not only intended for domestic markets but are also exported; as a result, the EU community is an important strategic area for the sale, production and transit of counterfeit goods.

The final phase of the distribution process – when the product reaches the consumer – is also structured in a variety of ways and illustrates different types of adopted solutions which often depend upon the nature of the marketed counterfeit good and the type of consumer which the illegal

product targets. In cases involving the offer of types of goods which do not pose risks for public health and safety – such as pirated CDs or most clothing items – and if these are intended to target a conscious consumer, it is in fact possible that the counterfeiters, as previously noted, will resort to street trading; this may also be implemented by means of small criminal groups involved in the retailing of illegal goods.

With regards to this type of product, the choice of a marketing method may change if the targeted consumer changes. If the criminal group plans to target and truly deceive unconscious consumers, the goods in question must be entered into the legal distribution system. This entry may occur through several stages. It is, in fact, pos-

BOX 3
Examples of the law enforcement response to counterfeiting

- In the month of January alone in the year 2007, 6,000 liters of counterfeit oil and almost 148,000 clothing items and 700,000 DVD's were seized in the Italian national territory.
- In November 2006, the Italian Guardia di Finanza discovered a laboratory in the province of Rome which was involved in the production of counterfeit cosmetics and perfumes of various brands. The operation led to the seizure of 600,000 packages.
- In September 2006, the Anti-Fraud service of the Italian customs together with the Guardia di Finanza operating at Fiumicino airport seized 1,500,000 counterfeit clothing items shoes commercial value was estimated in more than 1,5 million Euro.
- In December of 2004, French authorities seized 258 rolls of counterfeit fabric reproducing the Louis Vuitton brand. The total length of the seized fabric was 9,405 meters, sufficient to create more than 28,000 fake wallets and more than 18,000 counterfeit bags.
- Again in December 2004, other important seizures were carried out in France. The first involved more than 94,000 counterfeit felt animals which were not in compliance with currently effective safety standards, while the second involved more than 10,000 clothing items reproducing counterfeit trademarks. The latter originated from Spain and were en route to the Italian and French markets.
- During the summer of 2004, a significant quantity of counterfeit and non-sterile contact lenses which were intended for the legal market were seized.
- In January 2000, German police seized 500,000 pirated CD's that were produced in Ukraine and were en route to Uruguay.
- 16 people were charged and 1,500 tablets of Stamina Rx – a compound which was considered a natural aphrodisiac - were seized in the operation "Do-it-Yourself Pharmacy" initiated by ten Italian national Italian district attorney offices.

Sources: Confesercenti, (2007), *Contraffazione e criminalità informatica (Counterfeiting and IT crimes)*, TEMI – Centro Studi e Ricerche sulla Legalità e Criminalità Economica; WIPO, (2004), *WIPO National Seminar on Intellectual Property for Faculty Members and Students of Ajman University*; Union des Fabricants, (2005), *Rapport contrefaçon & criminalité organisée*, 3eme edition; Italian Customs Agency, undistributed material.

sible that the replicated goods are delivered to a retailer who may be obliging or even a member of the organization[30] that is entrusted with selling the goods. There are, however, cases involving counterfeit products which were discovered in stores managed by owners who were in good faith and who had been deceived by the counterfeiters.

Another particular method which is primarily linked to the territorial presence of Mafia-style criminal organizations involves forcing the retailer to offer counterfeit products. In certain cases, this method has replaced the requirement of a "protection money fee" and is based on intimidation tactics which generate fear on the part of retailers with respect to the criminal organization and prevents them from reacting[31]. In other cases that are not directly linked to the replacement of this "protection money fee", the retailer is simply threatened and intimidated in order to force the sale of replicated goods[32].

If the counterfeit product poses a risk for the health and safety of consumers[33], the criminal group will attempt to penetrate the legal system at a higher level by operating as an actual distributor. This type of market entry provides additional benefits for the counterfeiter given the possibility of marketing significant amounts of non-original goods to retailers that are attracted by the low cost of the products[34].

Finally, the level of commercial access offered by the Internet as a meeting point for supply and demand should be noted, including the creation and distribution of actual catalogs promoting counterfeit goods[35].

A high level of organization is also noticeable not only in the production process but also within the distribution phase for the counterfeit product, providing additional evidence of the involvement of organized crime in the management of these types of illegal trafficking. The involvement of transnational organized crime has endowed counterfeiting with a surprising level of elasticity and response capacity. The latter allows for rapid responses to changes in product demand as well as increases in levels of risk in certain locations.

Responses to such changes often involve rapid changes in utilized distribution routes and interchanges between marketed products. One reported case even involved a full CD production plant – managed by Chinese organized crime in Hong Kong – which was dismantled and rebuilt in Paraguay[36]. Despite the fact that each counterfeit product – due to its origin – has certain "types" of distribution channels, the network of connections used by counterfeiters to conceal the origin of the good and linking the various countries of transit does not have a fixed structure but may change, depending on the presence of more or less strict controls in certain areas versus others[37]. In addition, the existence of trade routes and concealment techniques – that were previously used with success for other types of trafficking, such as narcotics – allows counterfeiters to utilize consolidated distribution channels[38] and to use the same commercial route to transport different types of goods – "Contraband activities also enhance the capabilities of existing smuggling channels and assist in the launching of new ones. That is, they facilitate the ability of organized crime groups to diversify their lines of business. They can use the same networks to steal and distribute a variety of products and thus be more responsive to current contraband demands

(...) The Italian Mafia also uses its infrastructure to handle a variety of illegal goods. First developed to handle untaxed cigarettes, it was subsequently used to smuggle narcotics"[39]– thereby responding to changes in demand and deceiving controls on the part of law enforcement officials.

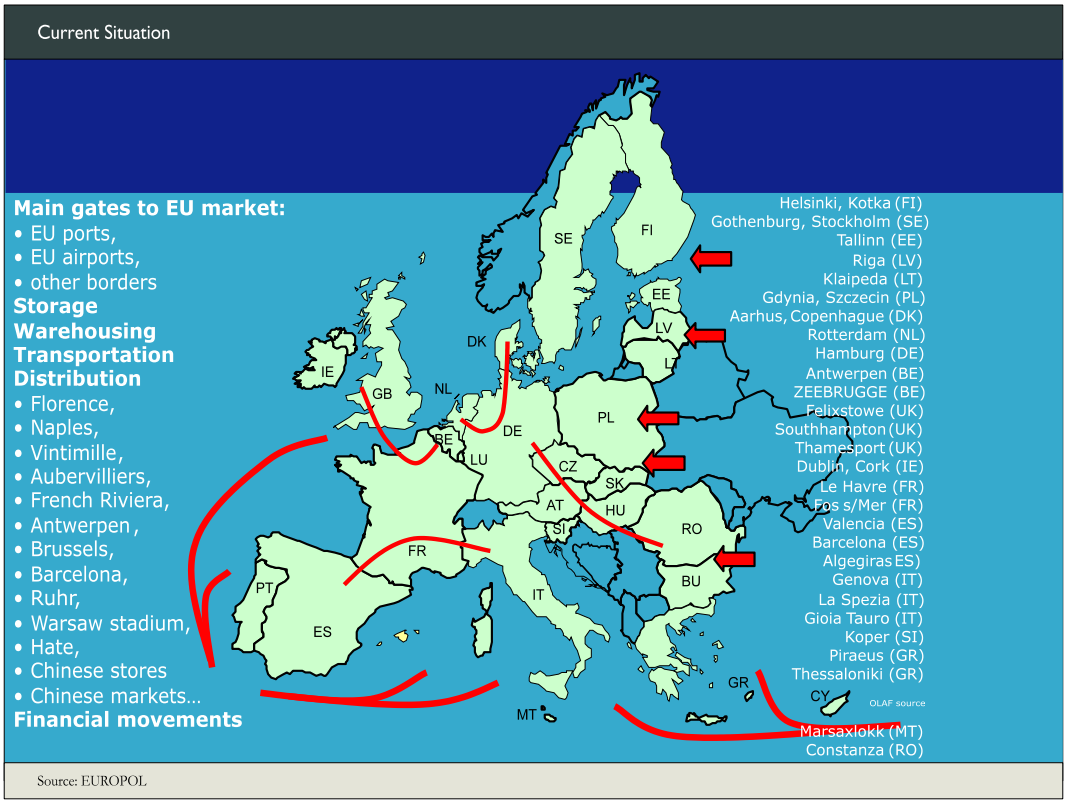
A diagrammatic representation of the potential trade routes used by counterfeiters has been created by Europol. This diagram also illustrates connections between criminal groups operating in various countries.

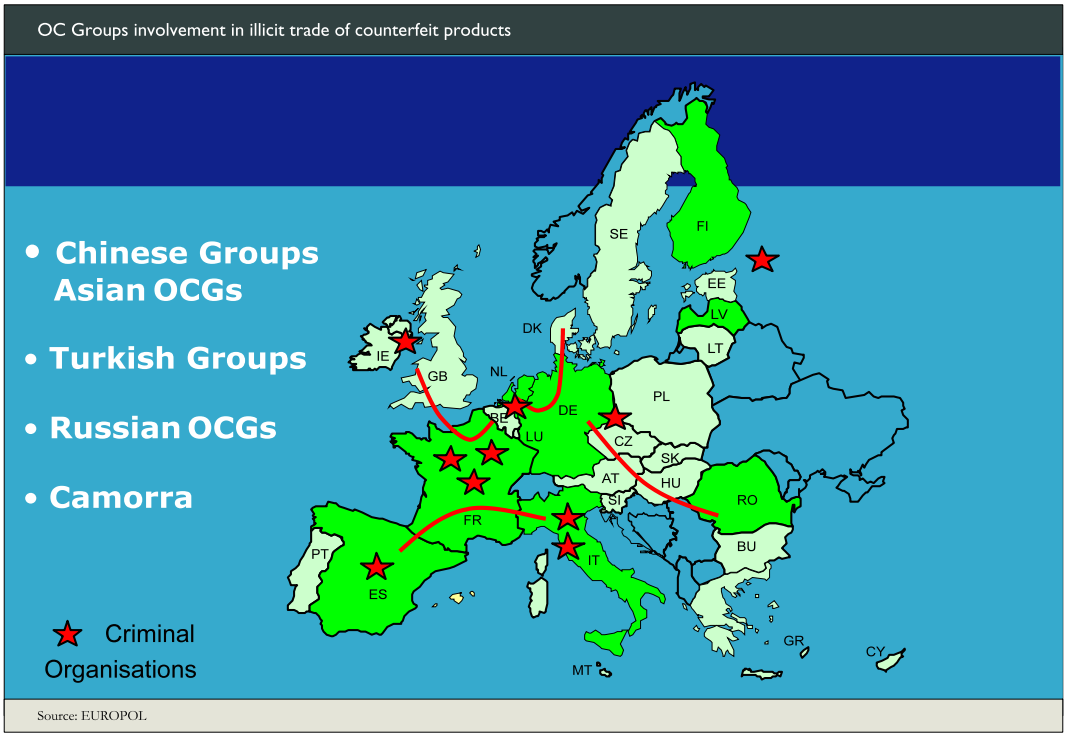
Criminal management of counterfeiting

The link between counterfeiting and other crimes committed by organized crime is not limited to shared trade routes and concealment methods or their potential interchangeability. Box no. 4 illustrates cases where the parties involved in the production or trafficking of replicated goods were also implicated in other types of trafficking or illegal activities, thereby further confirming the involvement of organized crime in the management of such operations as well as the strategic role of the latter.

Given the high level of profitability and the low levels of risk, counterfeiting serves a dual function for the organized criminal group: a source of financing for other illegal activities and a tool to launder proceeds derived from various crimes[40]

Money flows linking counterfeiting to other types of illegal trafficking involve a variety of connections; there are cases in which the proceeds from other crimes are





used to finance counterfeiting and cases where the opposite has occurred. This double connection can also be illustrated, for example, in reference to certain cases involving the trafficking of narcotics. In 2003, local authorities in Thailand discovered and blocked a trade of counterfeit goods and cannabis where the proceeds from the latter were re-invested in the acquisition of replicated goods intended for the French market. A similar case occurred a year earlier in the USA where investigations relative to drug trafficking highlighted the fact that the same criminal group was involved in the sale of counterfeit goods whose production was, in fact, financed with the income generated from drug sales. A case involving the opposite situation occurred in Mexico in 2002: proceeds derived from the sale of counterfeit CDs were most likely re-invested in drug trafficking and in the management of prostitution[41].

The end result is a complex economic system whose goal is often the laundering of capital derived from illegal activities; this system connects the illegal activities of the organization with various "businesses" and criminal groups. Counterfeit goods are produced or acquired with money generated from other illegal activities exhibiting a high risk level and are sold and marketed according to the modalities described above, thereby allowing these proceeds to be laundered by re-investing the amounts in activities which are characterized by lower risks for the organization[42]. The economic and commercial connections are often more complex and tend to link several criminal groups. If, for example, one adds the presence of minor criminal groups to the

previously mentioned example, new money flows must be taken into account given that these minor groups control the territory where certain final retailers of counterfeit goods operate. These money flows connect retailers to the minor criminal group – by means of "protection money" payments - as well as minor groups to large criminal organizations. In the latter case, the minor groups use "protection money" revenues to acquire narcotics, for example, which they can re-sell to retailers in their market of reference. It therefore becomes possible to identify the sources of black money which is re-invested and laundered through counterfeiting[43].

The entry of organized crime within the counterfeiting market has additional consequences. One of these involves the use of massive work forces in support of the significant production volumes that are currently reached by criminal ventures. Regardless of whether production activities

BOX 4
Organized crime and counterfeiting

- In February 2005, French Authorities identified and arrested the members of a criminal organization involved in the trafficking of narcotics between France and Spain. During this operation, law enforcement officials also discovered and seized counterfeit goods, weapons and fake credit cards.
- Investigations conducted by the District Antimafia Bureau of Rome in 2005 led to the discovery of an organization involved in the importation of counterfeit goods by means of forged transportation documents. This organization was involved in money laundering activities and systematically resorted to activities for transferring and concealing capital.
- In September 2004, a criminal organization involved in the illegal trafficking of narcotics – particularly heroine and cocaine – was dismantled in France, more precisely in Pont-Sainte-Maxence. Following the investigations, authorities discovered that the criminal group had implemented an actual marketing effort of illegal goods, selling counterfeit and stolen goods along with drugs.
- In October 2001, a police operation conducted by Czech authorities along the Polish border led to the seizure of significant quantities of pirated CD's and narcotics.
- In November of 2000, 22,000 goods labeled with the trademark Head and Shoulders were seized in London from the same areas that the criminal group used as a center for drug trafficking.
- In December 1998, investigations following a rummaging operation implemented by British customs officials within a plant used to produce a variety of counterfeit goods – clothing items, designer bags, perfumes and champagne of 52 different brands – ascertained that the owner of the plant was involved in a variety of illegal activities and was subsequently arrested for peddling narcotics.

Sources: Union des Fabricants, (2005), *Rapport contrefaçon & criminalité organisée*, 3eme edition; CEIPI, (2004), *Impacts de la contrefaçon et de la piraterie en Europe*, Rapport Final; Italian National Antimafia Bureau, undistributed materials.

occur within or outside the EU, worker exploitation is widespread and often involves minors. In the case that the product is not manufactured in a European country, counterfeiting is linked to illegal immigration and human trafficking. Immigrants or victims of this trade are exploited by counterfeiters during the production and distribution phases and are often forced to endure grueling work shifts under poor hygienic and safety conditions. It is often the criminal organizations themselves which manage the trafficking of human beings that will subsequently be used as workers. As discovered during the course of a 2002 investigation relative to pirated music CDs conducted by the Spanish Civil Guard, part of the organization was involved in collecting the workforce while other members of the criminal group acquired the CD burners and rented apartments and basements to use as production centers. The workers were exploited in a variety of ways, either as sales "personnel" in the streets or production workers[44].

Another consequence of the entry of criminal groups within the management of counterfeiting is the elevated intimidation power of these organizations; the latter often resort to violence in order to ensure the smooth operation of their "business". This intimidation power is also used with respect to public authorities, particularly in countries where criminal groups are stronger. In Malaysia, the president of a municipal council was subject to death threats in 2001 after initiating actions against those selling counterfeit Video Compact Disks. In Russia, the director of the *Russian anti-piracy organization* (RAPO) was subject to a murder attempt which, according to evidence, was directly linked to an operation that was conducted several days before; during this operation, 117,000 counterfeit DVDs and 1,060,000 counterfeit bags were seized. In Northern China, one of the commanders of the economic investigations unit of the Industry and Trade Administration was stabbed and killed in his office by a trader of counterfeit liquors following the seizure of more than 1,200 crates of counterfeit liquor from this trader during the course of an operation conducted by this commander[45].

Serious death threats were also sent to the head of the *National Agency for Food, Drugs Administration and Control* (NAFDAC) in Nigeria who was actively involved in combating the spread of counterfeit drugs in her country.

In 2003, she was assaulted when driving home in her car by an armed gang which riddled her vehicle with bullets. Several months later, her office and laboratory were burned and several armed men broke into her home but she fortunately was not present[46].

Examples of certain criminal organizations involved in counterfeiting

The most well-known criminal organizations which are involved in the counterfeiting market include the Chinese triads, the Japanese Yakuza, the Neapolitan Camorra and the Russian Mafia.

The latter is particularly active in the counterfeiting of musical CDs, software and DVDs[47].

An investigation conducted in Great Britain in 2001 revealed the existence of a criminal network of Russian origin which simultaneously managed various forms of

trafficking. The significant availability on British soil of counterfeit CDs with Russian or Eastern European origins had alarmed local authorities, leading to the initiation of an undercover operation. They discovered that the activities of this criminal group were not limited to the trafficking of counterfeit products but also involved the trading of arms, pornographic materials and counterfeit credit cards. The link with these types of activities convinced the British authorities that organized crime was involved; subsequent investigations led to the arrest of several members of the organization[49].

Various sources and cases confirm the active involvement of organized crime of Asian origin. Several years ago, a considerable criminal network of Asian origin – involved in counterfeiting – was dismantled in the region of Madrid, Spain. The operation in question led to the seizure of 230,000 CDs and 346 CD burners in addition to other counterfeit items as well as a sum of 48,000 Euro[49].

According to the *Union des Fabricants*, the Japanese Yakuza had colonized its respective national market, shifting from the management of large-scale counterfeit trading to control over the retailing of these products. In addition, the counterfeiting market also serves as an area of alliance between the Yakuza and other organized crime groups of Israeli origin[50].

Criminal organizations of Asian origin also appear to be active within the USA. In 1995, an undercover operation conducted by US authorities, in collaboration with the Asian Organized Crime Section of the US Department of State, revealed the fundamental role played by a Korean criminal group in the management of significant volumes of traded counterfeit products[51].

A criminal group of Asian origin also managed an important trade of counterfeit CDs which were distributed in the UK during the Christmas period of 2002. Investigations revealed that the Asian criminal organization exploited Afghan refugees seeking asylum by using the latter as a sales force in the streets or markets[52].

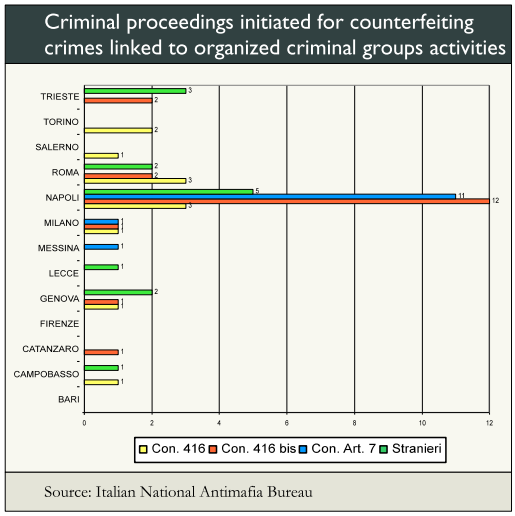
Chinese Triads, on the other hand, managed a significant amount of counterfeit DVDs in the UK in 2002. The retail distribution phase utilized Chinese illegal immigrants whose entry into UK territory was planned by the criminal organization itself; the latter was also involved in the trafficking of human beings from China[53].

The Chinese triads also appear to be particularly active on US soil, as illustrated by an investigation conducted in southern California in 1995. This investigation – which led to the seizure of significant amounts of counterfeit software in addition to counterfeit security holograms produced in China – revealed the existence of a criminal group of Chinese origin that had rooted itself on US soil and had strong ties with Hong Kong triads[54].

Italian criminal organizations are also particularly interested in the trafficking of counterfeit products. With regards to their involvement, the contacts established with the Italian National Antimafia Bureau as well as the S.C.I.C.O. (Central Service for the Investigation of Organized Crime) of the Italian Guardia di Finanza allow a more complete informational outline to be presented.

The Italian National Antimafia Bureau confirms the significant profitability of counterfeiting for criminal organizations;

the latter consider these activities as low risk and profitable investments given the leniency of public opinion with regards to these crimes. Implemented investigations confirm that the counterfeit goods are often sold at a retail level – not only by exploited immigrants but also by regular retailers who acquire the goods due to their low costs.



Source: Italian National Antimafia Bureau

The graphic summarizes the criminal proceedings registered within the General Registry by the District Antimafia Bureaus for counterfeiting crimes linked to the crimes of criminal association (Article 416 of the Penal Code), criminal Mafia association (Article 416 bis of the Penal Code) and facilitation of criminal Mafia association (Article 7 of Law 203/1991). Although the whole Italian territory is affected by counterfeiting activities, the Campania region, particularly the port of Naples, is specifically active[55]. The Neapolitan Camorra is the Italian criminal group that is most interested in this type of trafficking, confirming what reported also in several studies[56]. In particular, the Italian National Antimafia Bureau believes that the Camorra's interest in counterfeiting can be interpreted as an evolution of their previous activities as "magliari" ("merchant swindlers") and fully included within the growing commercial expansion of the criminal group's areas of interest.

This criminal organization often resorts to controlling apparently legal commercial activities through which it can introduce replicated goods, thereby creating a significant economic-financial web involving a variety of countries – particularly Western European countries, the United States, Brazil, Canada and Australia. This embedded financial network – which serves as confirmation of the elevated organizational level and internationalization currently attained by the Camorra – allows for the attainment of capital funds which, after being "cleaned", can be reinvested in a variety of different legal commercial activities, thereby increasing the operational capacities of the organization.

A very particular role is also played by immigrant Chinese citizens who organize themselves into structures with criminal connotations, thereby dedicating themselves not only to the production and marketing of counterfeit goods but also facilitating the illegal immigration of their fellow citizens; once the latter reach Italy, they are then inserted within these production and distribution structures. With regards to the latter, the Italian National Antimafia Bureau highlights the growing links between Chinese criminal organizations and the Neapolitan Camorra.

Investigations conducted across the whole national territory also confirm the international ramifications of counterfeit goods trafficking and the involvement of the same organizations in other forms of il-

legal trading and crime money laundering as well as the use of corrupting techniques and intimidation in order to force retailers to sell counterfeit goods. In particular and with regards to the latter point, the Italian National Antimafia Bureau notes that several years ago certain individuals associated with high-level members of the Camorra had moved to Liguria and were forcing local retailers to exclusively acquire fake designer trademarks.

Other elements relating to the operational modalities of organized crime were discovered during an investigation conducted in 2005 by the District Antimafia Bureau of Rome. In particular, the following were noted: 1) the use of forged transportation documents for the purposes of concealing the real origin of the goods[57] and 2) significant transfers of capital towards China on the part of various interconnected parties following the filing of tax returns on the part of these parties which were inconsistent with the financial figures implied by the transfers. As a result, there was a link with counterfeiting activities in addition to operations involving the concealment and transfer of capital.

Finally, investigations relative to the operations of the Camorra in Naples are enlightening. Certain significant elements were, in fact, discovered due to statements made by parties collaborating with law enforcement officials. The results of these interrogations confirmed that counterfeiting was managed in conjunction with other illegal activities, such as narcotics peddling, and that the proceeds deriving from counterfeiting were reinvested into various activities. In the area surrounding Naples, there were numerous plants producing fake leather jackets which were controlled by the criminal group and which not only supplied their goods within Italy but also abroad. The criminal group managed counterfeiting activities in practically the whole world, including countries such as Brazil, Germany, Russia, France, Belgium, Ireland, Switzerland, the United States, Great Britain and Spain. According to these collaborator statements, the Camorra retained a monopoly with respect to the counterfeiting of fake leather jackets as well as counterfeit Bosch drills – produced in Hong Kong – in all of Germany. These collaborators also confirmed that the proceeds deriving from these illegal activities were significant in amount – and often greater than those attainable from the trafficking of narcotics.

Notes

1 *United Nations Convention against Transnational Organized Crime*, Art. 2 (a).

2 A group of three or more individuals who act in concert for the sole purpose of robbing a bank, for example, would not be considered a criminal group.

3 "The 'transnational' nature of a crime therefore differs from its 'international' nature. The latter expression refers, in fact to a criminal group that not only operates within its country of origin but also implements operations abroad (for example, it is well known that the 'Ndrangheta families also operate in France, Germany, Canada, Australia, etc..). The former expression, on the other hand, refers to cooperative actions implemented by criminal groups of differing national origins in order to more effectively manage certain criminal markets". Zuccarelli F, (2006), *The phenomenon of trademark counterfeiting and organized crime. Domestic and international investigations for contrasting illegal replication activities*, page 2.

4 "Contraband markets are demand driven. Whenever there is enough demand for a contraband product and it is sufficiently lucrative to supply it, organized crime groups will enter the market (and eventually dominate it)." FIA International Research LTD., (2001), *Contraband, Organized Crime and the Threat to the Transportation and Supply Chain Function*, page 12.

5 "In 1975, the Turkish Mafia established an alliance with the Sicilian Mafia whereby the Turks would supply basic morphine for heroine and the Sicilians would refine it. The two organizations had previously subdivided the European market, leaving the central and southern areas to the Italian Mafia and camorra and the northern areas to the Turks. A subsequent development occurred in October 1987 when the 'Caruana' and 'Cuntrera' families and the 'Medellin' Columbian cartel in the Caribbean island of Aruba decided to join the alliance; this new arrangement provided for an exchange of European heroine with cocaine produced in Columbia, thereby monopolizing the Atlantic narcotics market". Zuccarelli F., (2006), *The counterfeiting phenomenon* cit., page 2.

6 "... in particular, narcotics and weapons but also illegal immigrants, toxic wastes pornographic material, the human slave trade, etc.. These goods are normally produced in locations that differ from their areas of utilization; their transfer from one country to another is implemented by escaping controls, bribing parties entrusted with monitoring these transfers and using legal institutions such as banks and financial companies for payments. In this manner, ties between criminal organizations in different national territories are strengthened." Zuccarelli F., (2006), cit., page 2.

7 "The idea that each illegal trafficker specializes in a single type of good is equally obsolete... In reality, the economic and technological opportunities deriving from globalization facilitate illegal traders in switching business interests and moving from one type of good to another…Maureen Baginski, executive vice-director of the FBI, stated the following: '*The area of specialization has become the network itself and its capacity to supply, transport and deliver illegal goods in different countries. The type of good itself has acquired secondary importance*' " Zuccarelli F., (2006), cit., page 7.

8 "Indeed the profitability of infringing products is now beginning to exceed that of drugs and arms, on a profit/weight basis." WIPO, (2004c), cit., page 6.

9 "Consider: American imports and exports total about $1.7 trillion a year; nearly 14 billion tons of goods and raw materials, valued at over $8 trillion, move over the U.S. transportation system every year; On a typical day, 38 million tons of commodities are shipped on the nation's transportation system; more than $400 billion is spent each year on the movement of cargo in the United States. This creates a massive inspection challenge for law enforcement." Refer to: FIA International Research LTD., (2001), *Contraband* cit., page 14.

10 It is estimated, in fact, that 3% of containers which cross borders are subject to controls.

11 "The immense size and complexity of the transportation and supply function provides organized crime groups with an almost infinite number of ways to conceal smuggled, counterfeit or pirated goods." FIA International Research LTD., (2001), cit., page 13.

12 "...standardized cargo containers, computerized cargo tracking and automated cargo transfer equipment…[that] enable shippers to securely and efficiently transfer containers delivered by sea to other ships for onward shipment or to commercial railroads and trucks for overland transportation." FIA International Research LTD., (2001), cit., page 16.

13 "Criminals are able to exploit the complexity of the intermodal system...to conceal the true origin of the cargo within which contraband is hidden." FIA International Research LTD., (2001), cit., page 16.

14 "Les contrefacteurs pratiquent aujourd'hui des techinques telles que la <<rupture de charge>>; cette technique consiste à acheminer un produit contrefait vers sa destination finale en le faisant passer par un ou plusieurs pays tiers qui, autant que possible, ne sont pas réputés être des pays producteur de contrefaçon dans le domaine considéré." CEIPI, (2004), cit., page 26.

15 A similar system was implemented, for example, by UNCTAD through the creation of ASYCUDA, an integrated customs management program, while the Italian Customs Agency created the "Fully Automated Logical System Against Forgery and Fraud" (FALSTAFF). The latter has proven to be a powerful tool in the hands of customs officials for calculating risk and aiding in the identification of counterfeit products along borders.

16 CEIPI, (2004), cit., page 27.

17 CEIPI, (2004), cit., page 27.

18 CEIPI, (2004), cit., page 26.

19 Union des Fabricants, (2005), *Rapport contrefaçon et criminalité organisée*, 3eme edition, pages 13 -14.

20 "La contrefaçon est passée à partir des années 1990 d'une activité artisanale – de petits ateliers clandestins – à une logique industrielle, s'appuyant sur des installations coûteuses et modernes. Les contrefacteurs n'agissent plus de manière isoleée et ponctuelle et sont devenues de véritables <<entrepreneurs internationaux>>, reliés à de grands résaux etrêmement organisés. Jamais la contrefaçon n'a sempblé aussi fortement structurée. Union des Fabricants, (2005), *Rapport contrefaçon* cit., page 9.

21 CEIPI, (2004), cit., page 33.

22 "It could be the buying; it could be the selling; it could be the manufacturing. But with the profits on offer, organized criminals are not going to leave it all to some guy in a garage, are they?" Phillips T., (2005), cit., page 124.

23 "According to the Secretary General of Interpol, counterfeiting is a full-fledged criminal activity. It is not peripheral to other criminal activities but at the very heart of them." APCO, (2003), cit., page 20.

24 CEIPI, (2004), cit., page 31.

25 FIA International Research LTD., (2001), cit., page 8.

26 "... il est inquiétant d'observer que, même s'ils nécessitent un financement important (de 50.000 à 100.000 euros pour certains moules et de 300.000 à 600.000 euros pour une ligne de production de matières plastique), ces équipements sont malgré tout à la portée des contrefacteur. Cela prouve bien l'on n'a plus affaire à de petits délinquants amateurs." Union des Fabricants, (2005), cit:, page 10.

27 This is possible by implementing an unscheduled work shift or by subcontracting the received job order.

28 WIPO, (2004c), cit., page 7.

29 CEIPI, (2004), cit., page 25.

30 "…plusieurs personnes interrogées affirment que d'une manière générale, les détaillants qui vendent de produits de contrefaçon le savent, notamment au regard du prix du produit ou de sa qualité, et nombre de ceux qui vendent de tels produit sont de membres à part entière de cette chaîne criminelle." CEIPI, (2004), cit., page 28.

31 Confesercenti, (2007), *Contraffazione e criminalità informatica (Counterfeiting and IT crimes)*, TEMI – Centro Studi e

Ricerche sulla Legalità e Criminalità Economica, page 9.

32 "In the late 1990s, Humatrope, an Ely Lilly product, was being illegally manufactured in a factory at Pilling near Liverpool. The offender was sentenced to five years, though he maintained that he was forced to manufacture this product having been subject to assault and death threats by a Liverpool crime gang." Satchwell G., (2004), cit., page 49 .

33 Examples include medicines, toys, spare parts or foods and beverages.

34 Union des Fabricants, (2005), cit., page 15.

35 CEIPI, (2004), cit., page 27.

36 WIPO, (2004c), cit., page 8

37 Union des Fabricants, (2005), cit., page 14

38 CEIPI, (2004), cit., pages 24-25

39 FIA International Research LTD., (2001), cit., pages 32-33

40 "The draw of counterfeiting for organized crime syndicates is that it is relatively safe due to public perceptions that counterfeiting is a 'victimless' crime and the corresponding 'soft' penalties under the law. It is also by its very nature a source of tax-free income that generates enormous profits. It is therefore targeted as a way to generate funds for other criminal activities and as a vehicle for laundering funds from other criminal activities." APCO, (2003), cit., page 20.

41 Union des Fabricants, (2005), cit., page 19.

42 FIA International Research LTD., (2001), cit., page 30.

43 FIA International Research LTD., (2001), cit., page 30.

44 Union des Fabricants, (2005), cit., page 17.

45 Union des Fabricants, (2005), cit., page 20.

46 Phillips T., (2005), cit., pages 209-210.

47 APCO, (2003), cit., page 22.

48 Alliance Against Counterfeiting and Piracy, (2003), *Proving the Connection – Inks between intellectual property theft and organized crime*, page 12.

49 Union des Fabricants, (2005), cit., page 27.

50 Union des Fabricants, (2005), cit., page 27.

51 APCO, (2003), cit., page 21.

52 Alliance Against Counterfeiting and Piracy, (2003), *Proving the Connection* cit., page 14.

53 Union des Fabricants, (2005), cit., page 27.

54 APCO, (2003), cit., page 21.

55 The Italian National Antimafia Bureau states that large cargoes of counterfeit goods – contained within containers from China – were seized in the harbor areas of Naples and Gioia Tauro.

56 "En Italie, la fabrication du faux autour de Naples est aux mains de la Camorra. Selon un rapport de l'IFPI et les informations fournies par le procureur general de Naples, 100 gangs de la Camorra sont actifs dans ce domaine et sont impliqués dans les trafics de drogue, d'armes, d'extorsion et de contrefaçon." Union des Fabricants, (2005), cit., page 24.

57 In the case in question, the goods originating from Singapore appeared to be from Dubai.

7. Conclusions and proposals

Our overall analysis has illustrated the complexities of the "counterfeiting phenomenon" and the scale of the latter in addition to highlighting certain particularly sensitive themes. If, on the one hand, some areas of weakness are ascribable to inherent characteristics of the phenomenon, others are linked to an inadequate response to the problem on the part of the various affected parties.

Before recommending potential intervention strategies, the salient features of what has often been called the "modern version" of counterfeiting should be summarized. This term was used to emphasize the evolution of this phenomenon which has undergone a profound transformation with respect to its initial form.

The most relevant differences may be summarized as 1) the current scale of counterfeiting; 2) the involvement of organized crime in its management; and 3) the significant consequences on other sectors of society.

Returning to our previous analysis, the following can be noted with regards to each of the points above:

- In 2005 alone, a conservative estimate of the OECD reports that counterfeiting had an impact of circa 200 billion dollars on world trade (for more considerations regarding this estimate, please refer to chapter 2 of this report).
- Criminal organizations consider counterfeiting to be a particularly appealing activity due to: 1) the significant level of profitability, 2) the low level of attention allocated to this activity on the part of law enforcement officials; 3) the low level of severity of sentences, and 4) its versatility – given its role as a source of financing for committing other crimes as well as a tool to launder proceeds deriving from other illegal activities.
- Counterfeiting involves significant and numerous negative consequences at the: 1) economic level, caused by profit losses for companies, unfair competition, tax revenue losses on the part of governments; 2) social level, due to yearly job losses and the serious threat to the health and safety of consumers caused by the presence in the market of particularly sensitive categories of counterfeit products such as medicines, toys, spare parts for aircraft and automobiles, foods and beverages; 3) level of public order, due to the increased presence of widespread illegality across national territories.

7.1 A complex strategy

It is now clear that counterfeiting is a particularly complex activity – not just in terms of its implementation but also in light of the many sectors it involves. Any response to the phenomenon must necessarily take this characteristic into account by presenting a multidisciplinary and multi-

sectorial approach to the problem. Even an effective response, but one which only involves a part of the phenomenon without taking into account this complexity, would be limited and not fully effective. The key elements of such a broad strategy must involve the criminological aspects of the phenomenon as well as the consumers and producers themselves.

A brief note should be made at this point. Anybody who attempts to study the "counterfeiting phenomenon" will encounter significant difficulties in collecting reliable data relative to its scale, development and the consequences of its activities. This situation is partly due to the nature of the phenomenon itself – which is based on commercial exchanges that occur in an underground market – and partly due to the lack of attention to this problem on the part of various parties during the course of its development.

Counterfeiting has, in fact, been underestimated as a crime. This is not only due to an incorrect conception of the problem – i.e. the view that it is a "victimless crime" – but is also caused by its almost craftsman-like origins and the fact that the phenomenon almost exclusively targeted luxury goods in its initial stages. These characteristics have allowed the problem to not generate much public concern and did not attract the attention of law enforcement authorities and governments; the latter did not allocate priority to this type of activity when preparing anti-crime strategies. This is extremely understandable given that the large-scale development of narcotics and arms trafficking, for example, in the same period had captured public attention. The elevated danger posed by these illegal activities were, in fact, not only noted by authorities entrusted with combating these forms of trafficking but also by civil society; the dangers deriving from the widespread distribution of these practices was therefore easily understandable. As a result, counterfeiting was capable of evolving and transforming itself over a long period of time, broadening its operations and expanding the range of goods which were subject to replication. In a short period of time, the phenomenon acquired a global scale and was managed by the same criminal organizations that were involved in the trafficking of drugs or weapons, the same activities that were previously subject to anti-crime intervention.

The result of these factors – the low level of attention on the part of society and the development of an underground market – when combined with the difficulty in identifying these products along national borders and distinguishing them from originals, leads to the previously noted measurement problems relative to the scale of the phenomenon, thereby creating uncertainty with respect to the latter. Consider, for example, that even two renowned international organizations such as the WHO and the OECD have recently revised their estimates relative to the scale of the problem.

The latter, in particular, had estimated the incidence of the phenomenon with respect to global trade and preferred to utilize a numerical figure – 200 billion dollars – rather than the previously used percentage estimate of 5 to 7%; this was due to the fact that the percentage calculation lacked strong factual support despite the fact that it could be neither confirmed nor denied.

It would therefore be desirable to commit greater efforts in identifying data which is useful for an analysis of the phenomenon in addition to systematic data collection and processing. The presence of more data would be fundamental in order to proceed with incisive actions against counterfeiting while the processing of this data would allow the effectiveness of these operations to be verified. Both the public as well as private sector should actively contribute towards these objectives.

On the one hand, in fact, national institutions could supply interesting information with regards to the criminal component of the problem – the number of seizures along borders; the types of seized goods and their percentage with respect to overall seizures; the origin of counterfeit goods; the methods utilized to conceal the origin of the products; the transfer through specific free transit points or commercial hubs; types of forged transportation documents; the criminal organizations that are most commonly involved and their national or transnational nature; the effect of criminal proceedings; the areas most affected by the problem; and the outcome of law enforcement actions. These are just a few examples. The contribution of the private sector would be equally important, particularly in light of the fact that producers often utilize their own investigational methods in order to quantify the impact of counterfeiting on their products and do not often want this data to become public; this is mostly due to fears that consumers will lose goodwill with respect to their product with a consequent negative effect on sales. Producers – given that they are an alternative source of data and often are the only parties that know the secrets and production characteristics of their goods – can supply a significant amount of data relative to the product. The multisectorial nature of an approach to the problem should be noted here as well as the cooperation that will be necessary between the various affected sectors – a cooperation which has, up until today, been somewhat superficial.

The adoption of procedures and methods for the purposes of systematic data collection as well as the periodical review of this data and the sharing of any attained results amongst the various parties – in compliance with the need to guarantee confidentiality, where required – is today absolutely necessary. For these purposes, the creation of national and international databases would be desirable in order to collect all non-sensitive information that is obtained by law enforcement officials and private entities in relation to the phenomenon.

The public sector

There are different elements that should be highlighted with regards to a) the response of governments to counterfeiting and b) the activities carried out by law enforcement officials.

Having already discussed the importance of adopting more effective methods for data collection and processing on the part of institutions affected by counterfeiting, the significance of the regulatory process with respect to the distribution of the phenomenon should be now analyzed.

The low level of deterrence which characterizes the laws relative to this phenomen-

on within numerous national legal systems has been previously and repeatedly noted. This subject should, in reality, be analyzed with a much broader view that takes into account the general attitude that governments have had with respect to counterfeiting. Only in very recent approaches – which take into account the involvement of organized crime in the management of these illegal activities – have the consequences of this phenomenon been considered and estimated; governments have therefore begun to state that counterfeiting was a significant problem whose solution could no longer be deferred. In many cases, however, and as noted on many sides – including international organizations and members of law enforcement bodies which are actively involved in combating counterfeiting – these declarations of intent have not been accompanied by the adoption of incisive actions and the allocation of human and financial resources to combat the problem. The result of this discrepancy between declarations of intent and concrete intervention is not only noticeable in the marked lack of incisive actions but also in the existence of a legislative framework that is completely inadequate to counter the dangers and widespread distribution of the phenomenon.

From a purely legislative perspective, there are a variety of elements which should be noted, also in light of the situation existing outside of the European Union.

An initial note should be made with regards to the low level of deterrence of the legislative framework; this is due to various factors. The first factor is related to the sanctions and penalties that are provided for criminals that are involved in counterfeiting for various reasons. At both the penal as well as the civil or administrative level, these penalties are completely inadequate for the purposes of deterring the commission of a crime and contribute towards forming an incorrect image of counterfeiting; this image is inconsistent with the significant involvement of organized crime in its management as well as with the serious risks which certain types of counterfeit products pose for consumers.

For this purpose, it should be noted that even in the case of "street" counterfeiting – visible every day in numerous cities and mostly involving CDs or DVDs or luxury goods – it is highly probable that organized criminal groups are involved; the final seller is often a victim her/himself of the phenomenon, exploited and forced to sell counterfeit products by criminal gangs. These sellers will only retain a small part of the revenues which will fall almost entirely into the hands of criminal groups in order to finance other illegal activities. Once the force lying behind the sale of these products is acknowledged, the legislative provisions which aim to combat the phenomenon are revealed to be very weak – even without considering the aggravating factor derived from the serious consequences that the counterfeiting of drugs, toys or spare parts of motor vehicles and aircraft can pose for the health and safety of consumers when entered into a legal market and sold as originals to unconscious buyers.

The low level of severity of administrative sanctions and penalties – in conjunction with the ineffective application of the latter – allows counterfeiting to be an illegal activity that poses minimal risks for criminal organizations; it was, in fact, recently reported that the relapse rate amongst criminals arrested for counterfeiting crimes was high. When comparing potentially attainable profits and consequences, the balance is definitely tipped in favor of the income potential, thereby creating incentives rather than deterrents for committing the crime.

It is therefore necessary that legislative regulations provide a stronger deterrent effect – giving priority to criminal sentences as opposed to administrative remedies – and are effectively applied.

In addition, it should be noted that currently effective legislation in certain national legal systems exclusively punishes the importing of counterfeit goods as well as the sale of the latter on national territory while different penalties are provided for in the case of exporting, transit and acquisition of these goods, crimes that are occasionally not punished.

Legislative provisions should punish all the phases linked to counterfeiting – from production to sales – without distinguishing between activities focusing on the exporting, transit or importing phases of non-original goods and without omitting specific norms that also sanction their purchase.

Activities linked to the commission of the crime, such as the storage of goods or the conscious supply of raw materials, should be given more attention on the part of competent authorities and legislators.

Moreover, norms punishing the conscious buyers of counterfeit products should also be more severe.

With regards to the subject of combating crime on the part of law enforcement, various points should be highlighted. First of all, the previously mentioned "tolerance" with respect to counterfeiting is not only due to the weak regulatory provisions or the lack of incisive intervention on the part of governments. The "war" against counterfeiting is often not, in fact, considered a priority amongst law enforcement officials, thereby decreasing the possibility of implementing an effective strategy. This attitude is certainly not due to negligence but is also linked to the previously mentioned "distorted vision" of counterfeiting which views the dangers of the latter to be limited.

It is therefore important that educational and awareness programs are implemented within law enforcement environments, particularly with regards to involvement of organized crime and its consequences for all of society.

Another aspect of the phenomenon is linked to themes relative to the identification of counterfeit goods on the part of competent authorities and the implementation of investigations, in view of identifying also the illegal production and

distribution chains.

In this case, it is difficult to identify a link between counterfeiting and organized crime; this connection is usually established following more complex and in-depth investigations which also analyze, for example, movements of capitals on the part of the affected parties and their potential connection to other crimes and criminal organizations. Investigations, however, often end at the time of seizure of the counterfeit goods and the opportunity to charge the same parties with criminal association is lost; if the latter were charged and applied, the consequences would be considerably more serious for the involved parties.

In order to improve the quality and depth of investigations on the part of law enforcement officials, codes of conduct or investigational protocols could be established; the latter would be applicable when the counterfeiting crime is discovered and would provide for a series of guidelines to follow in order to pursue the investigations in more depth.

In this regard, more attention should also be given to the possibility of identify and trace back the counterfeit production and distribution chains.

In addition, the organization of educational/training courses activities for law enforcement officials should be supported and extended, in order to illustrate the most effective investigational techniques and to constantly update the national and international regulatory framework of reference.

With regards to the recognition of counterfeit goods – a topic of particular significance for customs officials – the starting point for analysis revolves around the significant difficulty in distinguishing original goods from copies of the latter. This is largely due to the technologies that are available to counterfeiters who manage to increasingly create copies that are almost identical to the originals; these copies are often even difficult to recognize by sight on the part of the owners of the intellectual property rights themselves. This is another area where the importance of collaboration between the public and private sector emerges given that a contribution on the part of producers would be very useful in facilitating the work of Customs Agencies.

In other cases, these difficulties are due to the use of forged documentation or concealment techniques.

There is therefore the obvious necessity to improve the training of customs officials by organizing specific courses on the topic of identification and recognition of counterfeit goods as well as on the most commonly used concealment techniques and document falsification methods.

In order to remedy these difficulties, Customs Agencies in certain countries have recently adopted computerized systems for calculating customs risk; some of the more advanced applications allow customs officials to only focus on certain containers which the data processing system deems to be of particular risk. These systems increase the effectiveness of customs actions by optimizing the utilization of human and

economic resources. This is a particularly important aspect. Given current trade volumes and the impossibility of controlling an elevated number of containers or goods that are inflowing, outflowing or in transit, it is of fundamental importance that customs officials concentrate their efforts on "high risk" shipments. This point is of particular relevance in light of the significant organizational capacities of organized crime groups, particularly in relation to the capacity to adjust distribution routes in response to increases or decreases in customs controls in specific commercial hubs.

The adoption of computerized risk management systems should be promoted in conjunction with technical assistance programs relative to their installment, where required, in addition to training courses for personnel entrusted with utilizing these systems.

The computerized analysis and management of risks linked to the distribution phase, particularly with regards to international flows of goods and their changes/adjustments and to Free Trade Zones, could serve as another weapon in the "war" against counterfeiting, thereby obtaining a more accurate and detailed understanding of the operational methods of criminal groups.

Greater attention should also be given to monitoring postal packages given that regular mail or express couriers are today one of the preferred methods of counterfeiters for the delivery of certain types of counterfeit products – for example, drugs acquired online.

As previously noted, it frequently occurs that the counterfeiting crime is associated with the forgery of transportation documents of the cargo of counterfeit goods when the latter is identified. This forgery is sometimes linked to an under invoicing of products, a technique which also facilitates the laundering of proceeds derived from the crime. The widespread distribution of document forgery is easily understandable if the extreme simplicity of this operation is taken into account. The transportation document is often only an A4 sheet and, given that it does not contain any type of safeguarding to prevent forgeries, it is extremely easy to reproduce an identical copy for the purposes of deceiving customs officials. While the private sector has therefore attempted to make its product packages more secure – by means of bar codes or holograms – a similar effort has not been implemented with regards to transportation documents.

Legislation which provides for certain mandatory characteristics of transportation documents would be desirable in order to render forgery more difficult.

Two very delicate issues are related to the regulatory theme but are not directly linked to crime suppression activities; they concern the methods used by counterfeiters to distribute their products.

The first issue is related to the security of the legal production/distribution chain. This is a particularly sensitive topic given that its regulation clashes with the requirement to guarantee free trade, particularly in light of current trading volumes. It would therefore be desirable for producers themselves to create and share codes of conduct in order to ensure that production and, in

particular, the distribution phases are more secure. If such an effort is not implemented, the distribution chain – significantly more than production – appears to be definitively vulnerable for the reasons described in the relative chapter.

Given the difficulties involved in this issue, it is in any case necessary to begin analyzing the effects on international trade which would be caused by the adoption of norms that are meant to guarantee the security of the production and distribution phases of goods. Subsequently, the adoption of norms which guarantee consumer safety should be considered, thereby preventing counterfeit products from penetrating the legal distribution chain.

A particularly delicate issue concerns the utilization of the Internet on the part of counterfeiters as a vehicle to reach elevated numbers of potential buyers as well as a sales channel. The reasons underlying this choice on the part of counterfeiters have been previously discussed. The Internet today appears to be a gigantic market where it is difficult to set down any rules and where it is even more difficult to have them enforced.

More resources must be allocated to the analysis of the specific dynamics which affect the utilization of the Internet as a supply and sales channel for counterfeit products. The results of these analyses should serve as a foundation for the creation of a regulatory framework as well as the implementation of actions designed to guarantee consumer safety.

The private sector and civil society

Although intervention activities with respect to the private sector and civil society are less in number compared to those mentioned with regards to the public sector, their importance is equally significant, particularly in light of the implementation of a multisector strategy to combat counterfeiting.

With regards to producers, in particular, certain comments that were previously made when discussing the public sector are again applicable. Producers, in fact, hold a large responsibility in ensuring the security of the production and distribution phases of goods.

The adoption of codes of conduct on the part of producers would be desirable in order to ensure the security of the production phase – for e.g., controls over the supply sources of raw materials, greater auditing of delocalized production – as well as of the distribution phase; in the latter case, greater rigor in monitoring the various transfers which bring the finished product into the hands of the consumer should be applied.

More research should also be dedicated to the role of middlemen and shippers and to how their behavior could weaken the distribution chain.

In order to prevent negative consequences for consumers, the producers themselves are also responsible for the immediate disclosure of any information relative to the existence of a counterfeit version of one of their products on the market. This is a particularly delicate issue given the fear that these announcements create amongst producers; the latter believe that the public may lose goodwill with respect to their products and may switch to competing goods.

It should not be forgotten, however, that certain categories of goods pose a particular risk for the health and safety of consumers and the latter have a right to be informed about such information in order to protect themselves.

Strong collaboration with law enforcement officials in order to facilitate their investigational activities, as well as immediate and widespread public disclosure of information regarding the presence of counterfeit versions of their products on the market, are key points for effective action.

With regards to the private sector, one area that deserves greater attention is the lack of information and awareness relating to the "modern version of counterfeiting", particularly its serious consequences and its links with transnational crime. This lack of awareness is common to both producers and consumers and is linked to the repeatedly cited existence of a distorted vision of counterfeiting.

For this reason, it would be appropriate to develop and implement specific educational campaigns targeting producers and consumers in which the serious risks linked to counterfeiting – as well as the consequences created by the involvement of organized crime in its management – are highlighted.

7.2 An interpretation: coordination and cooperation

It has been repeatedly noted that counterfeiting is definitely a complex activity that is based on synergies involving different aspects of the phenomenon which are created amongst different criminal groups. It was also noted that the response to this phenomenon – in order to be truly effective – must tackle the problem from a multisectorial and multidisciplinary perspective. A strategy of this nature is therefore based on cooperation between the various involved entities as well as the coordination of the latter.

With regards to the sector relative to the prevention and suppression of crime, counterfeiting affects various entities and agencies such as customs, police forces, certain special teams and the magistracy. In order to not waste human and economic resources, these entities must cooperate and coordinate themselves in order to implement a more incisive response to the problem.

At the same time, it is necessary to involve the private sector to a greater extent by organizing meeting/training events which allow for an active exchange of opin-

ions between the entities entrusted with combating crime and the producers subject to significant economic damages. Round tables between the public and private sector would provide an excellent opportunity for the exchange of ideas as well as the assessment of certain proposals and intervention strategies from multiple points of view. This would also create a more participatory and joint approach to the problem.

Finally and given that counterfeiting is now a global problem, it is also essential that more emphasis is given to the opportunities created by international cooperation. These opportunities not only refer to cooperation that is strictly linked to the implementation of investigations – police cooperation – but also cooperation between various international organizations that are interested in the phenomenon.

The creation of a common platform for discussion on counterfeiting and any elements linked to the latter should be implemented, thereby allowing for the development of strategies of broader scale while assessing the efficacy of such strategies over time. This platform would contribute towards more rapidly implementing the previously mentioned proposals and could be used to offer targeted technical cooperation services; examples include the case by case identification of the best experts and practices for organizing training courses, the implementation of studies analyzing the impact of specific intervention policies or the creation and implementation of informational campaigns. This platform would therefore become a reference point for countries and entities that are interested in combating the counterfeiting phenomenon.

In particular, an International Permanent Observatory on Counterfeiting could provide services and facilitate a needed acceleration in the execution of the above mentioned proposals. Good practices now applied in some specific areas (i.e. medical products) might represent a good model of coordinated action for other sectors too.

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1977 – The US Federal Aviation Administration discovered counterfeit fire detection and control systems in more than 100 Boeing 737 aircrafts. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1982 – In a factory in Florida, FBI agents seized counterfeit "Qualude" pharmaceuticals worth 5 million of US$. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1987 – Counterfeit spare parts were discovered by US investigators in more than 600 helicopters in service with NATO forces. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1989 – A counterfeit bolt installed on the tail assembly of a Norwegian Convair 580 aircraft caused the death of 55 passengers and crew members as the plane crashed whilst enroute from Norway to Germany. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1990 – In Nigeria, 109 children died after ingesting a counterfeit pharmaceutical product containing paracetamol and an industrial solvent. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1990 – Between 1990 and 1993 counterfeit paracetamol syrup was ingested by 339 children in Bangladesh. 70% of them did not survive. (CEIPI, *Impacts de la contrefaçon et de la piraterie en Europe*)

1993 – Between 1993 and 1996 huge quantities of poultry unfit for human consumption were sold nationwide in Great Britain. The poultry was purchased by unsuspecting butchers and restaurants. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1994 – In the United Kingdom a wholesaler discovered that good quality counterfeit Zantac had been sent to him by a Greek source. (Satchwell G., *A Sick Business*)

1994 – In the United Kingdom counterfeit washing powder was found to contain caustic soda which burned the hands of people who used it. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1995 – Bulk pharmaceutical ingredients shipped to the United States from China were counterfeit. A US broker of bulk drugs bought counterfeit gentamicin sulfate at low price from unapproved sources in China and distribute the ingredients to two medicines producers. (Spies A., Van Dusen V., *Counterfeit Drugs: A Menace Keeps Growing*)

1995 – In Haiti, 89 people died after having taken a counterfeit paracetamol-based syrup contaminated with diethylene glycol – a toxic substance used for example to produce antifreeze liquid for the automotive sector. (WIPO, *WIPO National Seminar on Intellectual Property Rights for Faculty Members and Students of Ajman University*)

1995 – In New Zealand, counterfeit tail rotor blades that disintegrated in flight cause an helicopter to crash. (FIA International Research LTD., *Contraband, Organized Crime and the Threat to the Transportation and Supply Chain Function*)

1995 – A clandestine facility used by the Italian Camorra to produce counterfeit medicines was discovered in Naples. (Satchwell G., *A Sick Business*)

1995 – After police investigations in the United States of America a Chinese crime group with links with the Hong Kong Triads was discovered and dismantled. The Crime group was active in producing counterfeit software and fake holograms manufactured in China. (*Interpol International Crime Police Review N. 476-477*)

1996 – A fake meningitis vaccine distributed in Niger is believed to have caused the death of more than 3000 people. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1996 – Counterfeit baby formula was seized in the United States of America. Several kids that ingested the product experienced convulsions. (FIA International Research LTD., *Contraband, Organized Crime and the Threat to the Transportation and Supply Chain Function*)

1997 – Five counterfeiters in China have been found guilty of producing and selling fake liquor, causing the death of 36 persons in different regions of the Country. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1997 – A helicopter crash in New Zealand led to the initiation of criminal proceedings against a supplier of counterfeit helicopter blades. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1998 – The consumption of counterfeit alcohol containing a high level of methanol caused the death of 27 people in China's Shanxi Province while other 200 consumers were hospitalized. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1998 – After investigations initiated in Switzerland and related to pirate CD ROMs dispatched via registered air mail as samples of "ready to serve microwave meals", 44 consignments containing 2.5 million CDs were intercepted. The consignments were delivered through a free trade zone in Naples to front organizations, most of them linked to the Camorra. (Hetzer W., *Godfathers and Pirates: Counterfeiting and Organized Crime*)

1998 – The Brazilian Health Ministry reported that at least 60 counterfeit drugs, including several painkillers and antibiotics, were distributed in the country by hospitals and pharmacies. (WIPO, *WIPO National Seminar on Intellectual Property Rights for Faculty Members and Students of Ajman University*)

1998 – Investigations conducted in Canada brought to light the existence of a large scale criminal activity linked to Asian crime groups operating internationally. The same group was involved in trafficking of counterfeit goods as well as of heroin. (Union des Fabricants, *Counterfeiting and Organized Crime*)

1999 – In Indonesia millions of counterfeit painkillers and anti-impotence drugs were seized by the law enforcement officers during a raid conducted on a warehouse located in the Sunter sub-district of North Jakarta. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

1999 – A patient in the United Kingdom found that the pharmaceutical products sent to him by a pharmaceutical producer had been damaged during the transit. It was later discovered that these medicines were part of a larger consignment intended for the Red Cross in Russia and that the Russian mafia was believed to be involved in this diversion. (Satchwell G., *A Sick Business*)

1999 – Counterfeit peanut butter, for the value of over 100,000 USD, was sized in China after different raids. The peanut butter factory was a disused school converted into a factory and the hygiene conditions were totally unsuitable for food manufacturing. (APCO, *Global Counterfeiting Background Document*)

1999 – In Ivory Coast, the use of counterfeit Scotch whisky killed several people. (APCO, *Global Counterfeiting Background Document*)

2000 – Counterfeit and ineffective malaria medicines sold in Cambodia as Mefloquine and Artesunate, caused the death of dozens of people. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2000 – In the United Kingdom, a counterfeit injectable painkiller manufacturing centre was discovered in Newcastle. (Satchwell G., *A Sick Business*)

2000 – More than 150 people died in Ecuador due to the consumption of counterfeit and contaminated alcohol. (APCO, *Global Counterfeiting Background Document*)

2000 – In Zambia counterfeit shampoo containing acid was found and seized by the local law enforcement officers. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2000 – In a hospital in Quebec, reconditioned and unsafe industrial circuit breakers connected to an intensive care unit were discovered. The products presented counterfeit certification marks. (Canadian Anti Counterfeiting Network, *The need for legal reform in Canada to address intellectual property crime*)

2001 – According to the Chinese newspaper Shenzhen Evening News, the use of counterfeit drugs caused the death of approximately 192,000 people in China during the year 2001. (WIPO, *WIPO National Seminar on Intellectual Property Rights for Faculty Members and Students of Ajman University*)

2001 – In the United States of America – and precisely in California, Ohio, Kentucky, Michigan, New Jersey, Florida and Missouri – counterfeit Serostim, a medicine used for the AIDS treatment, penetrated the market and was discovered along with counterfeit Nutropin AQ and Neupogen. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2001 – In the Chinese Guangdong Province, 308 tons of counterfeit toxic rice were discovered and seized. The counterfeit rice contained mineral oil and other substances and presented also excessive levels carcinogen aflatoxin B1. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2001 – The use of counterfeit vodka caused the death of at least 60 people in Estonia. The vodka was sold in refilled plastic bottles and contained poisonous methyl alcohol. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2001 – Counterfeit Viagra tablets originating from Thailand were discovered in the United Kingdom. (Graham Satchwell, *A Sick Business*)

2001 – In Colombia 20,000 counterfeit tablets of a generic of aspirin and of painkillers were found. The tablets contained boric acid and lead paint to give the product a color similar to the original. (CEIPI, *Impacts de la contrefaçon et de la piraterie en Europe*)

2002 – The Italian law enforcement authorities discovered a big counterfeit airline parts ring that was selling substandard and unapproved parts to different airline companies. The unapproved parts were sold with falsified documents to state their airworthiness. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2002 – After investigations carried out by the Canadian law enforcement authorities it was reported that probably 20 containers of counterfeit toys were imported in Canada. The toys posed a choking hazard. (Canadian Anti Counterfeiting Network, *The need for legal reform in Canada to address intellectual property crime*)

2002 – Counterfeit diet pills caused several deaths in China. The pills contained banned substances and were produced in China. (WIPO, *WIPO National Seminar on Intellectual Property Rights for Faculty Members and Students of Ajman University*)

2002 – A factory of counterfeit drugs was raided in India. The investigators found, among other counterfeit medicines, 10,000 vials of a fake and expensive antibiotic. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2002 – A traffic of pirate DVDs managed by the Chinese Triads was discovered in the United Kingdom. The criminal organization was also involved in trafficking in human beings from China. (Union des Fabricants, *Rapport contrefaçon et criminalité organiseé 3eme edition*)

2002 – The use of counterfeit alcohol is believed to be the cause under the death of a British tourist in Turkey. Toxic methanol was in fact found in her bloodstream during the autopsy. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2002 – During the Christmas holidays, traffic in pirated CDs was discovered in the United Kingdom. The traffic was managed by Asian mafia criminal organizations that imported the CDs from the Indian Sub-Continent. (Union des Fabricants, *Rapport contrefaçon et criminalité organisée 3eme edition*)

2002 – In London counterfeit versions of Johnnie Walker Black Label were found for sale. The counterfeits contained very high levels of methanol. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2002 – The United States of America Customs Service seized 27,000 of counterfeit analgesics containing no active ingredient. (APCO, *Global Counterfeiting Background Document*)

2003 – The United States competent authorities seized counterfeit batteries and electrical goods, whose value was of approximately 8 million US dollars. The products' approval marks were counterfeit and these parts caused dangerous explosion of toys and electronic equipment. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2006*)

2003 – In Laos and in Cambodia law enforcers intercepted counterfeit versions of Artesunate tablets, a drug used for the treatment of a particularly resistant strain of malaria. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2003 – Counterfeit shampoo was found in different parts of Canada, sold in drug stores or utilized in hair salons. The shampoo contained dangerous and potentially harmful bacteria, that could generate risks for the human health if coming in contact with open wounds or the eyes. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2003 – In the United States of America, law enforcement officers discovered counterfeit version of the anti-anemia drug Procrit. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2003 – A distributor of aircraft parts and two of his officers were found guilty of selling counterfeit civil and military aircraft parts. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2003 – The consumption of counterfeit wine, containing a component used to produce industrial chemicals caused the death of two people in Thailand. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2003 – Counterfeit rum containing ethyl glycol, a solvent used for different purposes, caused the death of one person in Finland. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2003 – In the United States of America more than 18 million of counterfeit "Lipitor" tablets were found and recalled from legitimate pharmaceutical drug supply companies.

(Canadian Anti Counterfeiting Network, *The need for legal reform in Canada to address intellectual property crime*)

2004 – Four internet sites were closed by the US Food and Drug Administration for selling counterfeit contraceptive patches with no active ingredient. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2004 – In China the use of counterfeit baby milk-powder formula containing no nutritional value caused the death of at least 13 babies. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2004 – At least 11 people died in China while dozens were hospitalized due to the use of counterfeit liquor. The liquor contained formaldehyde and were mostly bought at a rural market. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2004 – In France a distribution point for different illicit substances (cocaine and heroine) and stolen and counterfeit goods was discovered and dismantled. (Union des Fabricants, *Rapport contrefaçon et criminalité organisée 3eme edition*)

2004 – During "Operation Fastlink" more than 10 countries cooperated to dismantle well-known criminal organizations involved in on-line piracy. More than 120 searches were performed worldwide and more than 200 computers were seized, including 30 computer servers. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2006*)

2005 – The Italian Customs intercepted 1,136,000 counterfeit toys at the State borders and the Italian Guardia di Finanza seized 7,249,369 toys already on the market. (Confesercenti, *Contraffazione e criminalità informatica: i danni all'economia e alle imprese* - *'counterfeiting and IT crimes: damages to the economic system and to the enterprises'*)

2005 – Different people were arrested the United States, Canada, Israel, France Belgium, Denmark, the Netherlands, the United Kingdom, Germany, Portugal and Australia. These arrests were conducted during the "Operation Site Down", conducted in 10 different countries to hit the criminal organizations involved in the illegal distribution and trade of copyrighted materials. The value of the seized pirated works was approximately of 50 million US dollars. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2006*)

2005 – Counterfeit raki – a typical Turkish alcoholic beverage – containing lethal levels of methyl alcohol caused the death of 23 people while dozens were hospitalized. The raki bottles carried original labels that were previously stolen by the counterfeiters and attached on the fake product. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2005 – In a warehouse located in Umm Al Quwain – one of the seven emirates of the United Arab Emirates – the police seized counterfeit car parts whose valor was of approx. 10 million US dollars. More than 100,000 counterfeit parts were seized,

including fake brake pads, clutches and filters. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2006 – A counterfeit drug containing diethylene glycol caused the death of 11 people in China. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2006 – The Italian customs and the Guardia di Finanza seized more than 1,5 million counterfeit items (clothes and sunglasses) at the Italian airport of Fiumicino. The estimated value exceeded 15,000,000 Euro. The counterfeit sunglasses posed risks to the eyes' safety to their low filtering capacity. (Italian Customs Agency)

2006 – 35,000 counterfeit electrical products were seized by the Italian Guardia di Finanza. The products posed risks of electric or thermal shock and of blaze. (Confesercenti, *Contraffazione e criminalità informatica: i danni all'economia e alle imprese - 'counterfeiting and IT crimes: damages to the economic system and to the enterprises'*)

2006 – The Italian customs and the Guardia di Finanza seized a container with 15 tons of counterfeit toys originating from China. (Italian Customs Agency)

2006 – The use of diethylene glycol in counterfeit cough syrup, anthistamine tablets, calamine lotion and rash ointment killed 38 people in Panama. (ICC Counterfeiting Intelligence Bureau, *The International Anti-Counterfeiting Directory 2007*)

2007 – The Italian customs and Guardia di Finanza in Naples seized different shipments of counterfeit products (from sunglasses to toys) whose value was estimated in 11,000,000 of Euro. (Italian Customs Agency)

2007 – Counterfeit Colgate toothpaste, containing diethylene glycol, was found on sale in different Countries: i.e. Spain, the United States of America, Panama, the Dominican Republic and Australia. (http://webintel.wordpress.com)

International legislative background

1. International Intellectual Property Law

1. Agreement on Trade-Related Aspects of Intellectual Property Rights (Official Gazette RS-MP, No 10/1995)

2. Convention Establishing the World Intellectual Property Organization (Official Gazette SFRJ-MP, No 31/1972 and 4/1986, Official Gazette RS, No 24/1992, Official Gazette RS-MP, No 9/1992, No 3/2001, No 3/2007)

Copyright

1. Berne Convention for the Protection of Literary and Artistic Works (Official Gazette SFRJ-MP, No 14/1975 and 4/86, Official Gazette RS, No 24/1992, Official Gazette RS-MP, No 9/1992, No 3/2007)

2. Universal Copyright Convention (Official Gazette SFRJ-MP, No 54/1973, Official Gazette RS-MP, No 15/1992)

3. Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (Official Gazette SFRJ-MP, No 13/1977, Official Gazette RS-MP, No 15/1992)

4. Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of Their Phonograms (Official Gazette RS-MP, No 8/1996)

5. Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (Official Gazette RS-MP, No 8/1996)

6. World Intellectual Property Organisation Copyright Treaty (Official Gazette RS-MP, No 25/1999)

7. World Intellectual Property Organisation Performances and Phonograms Treaty (Official Gazette RS-MP, No 25/1999)

Industrial Property

1. Paris Convention for the Protection of Industrial Property (Official Gazette SFRJ-MP, No 5/1974, No 7/1986, Official Gazette RS, No 24/1992, Official Gazette RS-MP, No 9/1992, No 3/2007)

Patents

1. Patent Cooperation Treaty (Official Gazette RS-MP, No 19/1993, No 3/2007)

2. Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure (Official Gazette RS-MP, No 21/1997, No 3/2007)

3. Strasbourg Agreement Concerning the International Patent Classification (Official Gazette RS-MP, No 7/2001, No 3/2007)

4. Patent Law Treaty (Official Gazette RS-MP, No 4/2002)

5. Convention on the Grant of European Patents of 5 October 1973, as last amended on 10 December 1998 (Official Gazette RS-MP, No 19/2002)

6. Protocol on the Interpretation of Article 69 of the Convention on the Grant of European Patents of 5 October 1973 (Official Gazette RS-MP, No 19/2002)

7. Protocol on the Centralisation of the European Patent System and on its Introduction (Official Gazette RSMP, No 19/2002)

8. Protocol on Jurisdiction and the Recognition of Decisions in respect of the Right to the Grant of a European Patent (Official Gazette RS-MP, No 19/2002)

9. Protocol on Privileges and Immunities of the European Patent Organisation (Official Gazette RS-MP, No 19/2002)

10. Agreement dated 17 October 2000 on the application of Article 65 of the Convention on the Grant of European Patents (Official Gazette RS-MP, No 19/2002)

11. Act Revising the Convention on the Grant of European Patents of 29 November 2000 (Official Gazette RSMP, No 19/2002)

12. Implementing Regulations to the Convention on the Grant of European Patents (Official Gazette RS-MP, No17/2003)

13. Rules Relating to Fees of 20 October 1977 as last amended by decision of the Administrative Council of the European Patent Organisation of 13 December 2001 (Official Gazette RS-MP, No 17/2003)

14. Agreement between the Government of Slovenia and the European Patent Organisation on co-operation in the field of patents (Official Gazette RS-MP, No 15/93, No 11/2000) (applicable for requests for extension of European patents filed before 1 December 2002)

15. Agreement implementing Article 3(3) of the Agreement between the Government of Slovenia and the European Patent Organisation on co-operation in the field of patents (Official Gazette RS-MP, No 2/1994, No 11/2000) (applicable for requests for extension of European patents filed before 1 December 2002)

Industrial designs

1. Hague Agreement Concerning the International Deposit of Industrial Designs (Official Gazette RS-MP, No 20/1994, No 3/2007)

2. Geneva Act of the Hague Agreement concerning the International Registration of Industrial Designs (Official Gazette RS-MP, No 4/2002)

3. Common Regulations Under the 1999 Act, the 1960 Act and the 1934 Act of the Hague Agreement (Official Gazette RS-MP, No 15/2006)

4. Locarno Agreement Establishing an International Classification for Industrial Designs (Official Gazette SFRJ-MP, No 51/1974, Official Gazette RS, No 24/1992, Official Gazette RS-MP, No 9/1992, No 3/2007)

Trademarks

1. Madrid Agreement Concerning the International Registration of Marks (Official Gazette SFRJ-MP, No 2/74, Official Gazette RS, No 24/1992, Official Gazette RS-MP, No 9/1992, No 3/2007)

2. Protocol to the Madrid Agreement Concerning the International Registration of Marks (Official Gazette RSMP , No 21/1997)

3. Common Regulations under the Madrid Agreement Concerning the International Registration of Marks and the Protocol Relating to that Agreement (Official Gazette RS-MP, No 2/2006)

4. Trademark Law Treaty (Official Gazette RS-MP, No 28/2001)

5. Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks (Official Gazette SFRJ-MP, No 51/1974, Official Gazette RS, No 24/1992, Official Gazette RS-MP, No 9/1992, No 3/2007)

6. Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks (Official Gazette RS-MP, No 7/2001, No 3/2007)

7. Nairobi Treaty on the Protection of the Olympic Symbol (Official Gazette RS-MP, No 5/1998)

Plant varieties

1. International Convention for the Protection of New Varieties of Plants (Official Gazette RS-MP, No 13/1999) (within the competence of the Ministry of Agriculture, Forestry and Food)

2. The most relevant conventions

Paris Convention for the Protection of Industrial Property

The Paris Convention for the Protection of Industrial Property, entered into force in 1883 but subsequently modified in various occasions, is aimed at creating a Union among the ratifying countries in order to guarantee a more efficient protection of industrial property. As well specified in the first article, the term industrial property is utilized with a broader scope covering patents, utility models, industrial designs, trademarks and indications of origin (art. 1.2). The need to protect trademarks or patents is integrated by the necessity to punish unfair competition practices within the territory of the Union.

The system outlined by the Convention is based on a right of priority that is acquired by the subject who filed, in one of the Member States, a request to obtain a patent or to register a trademark or a utility model. The right of priority performs its peculiar function when the before mentioned subject decides to file the same request in a different Member State. The rules governing the system are established by articles from 3 to 4 bis. They provide for a maximum validity period given to the right of priority and for the regulations of those juridical implications that, in this period, could arise between the filing of the first request and other requests subsequently filed in different Member States. The latter necessity is not only consequential to a subsequent filing presented by a subject different from the one enjoying the right but it is also important in the case in which the same subject intends to obtain a patent or trademark in more than one country of the Union. Following the provisions of art. 4 bis, each patent obtained in one of the Member States is independent from an other patent with the same object that has been obtained in any other Member States or in a third country. The right of priority, as intended by the Convention, performs its function also in the case in which the same subject, who already filed a request in one Member State, decides to file a request for a patent or trademark, with the same object, in a different Member State. In this case, and for the entire duration of the right of priority, the need arises to safeguard not only the subject that for first filed the request, but also all the other subjects that intend to present the same request with the same subject and in the same country. This latter safeguard is particularly important in cases in which the request filed by the first subject is not approved or is dropped. In these cases, art. 4.C.4 provides for the right of priority to be attributed to the first request, in timely order, that was filed subsequently to the dropped or not approved one.

The independency of patents and trademarks is better understandable if one thinks over the fact that – in order to be effective and especially in cases in which the request is filed in more than one Member State by the same subject – the safeguard granted to the subject enjoying the right of priority needs the creation of a system in which the filing of a request in one Member State is not prevented or invalidated by the granting of a patent or a trademark with the same object in any other Member State or by the entering into production of the object of the request (art. 4.B). This would prevent the requesting subject

to enjoy the patent or trademark granted and would force her/him to wait for the conclusion of all the granting procedures initiated in all the Member States by other subjects filing an application with the same object. The independency of patents and trademarks has the function of preventing these interferences and is of fundamental importance when the system is not based upon the mutual recognition of patents and trademarks.

Art. 5.A.1 is inspired by the same *ratio*. It states that a subject to whom a patent was granted in one Member State has the possibility to import articles produced in other countries of the Union and that this behavior will not result in a forfeiture of the patent.

In the case of a subsequent request filed to obtain a trademark already registered by the subject in another country of the Union, this request must be accepted by any Member State, the only condition being the presentation by the subject of a certificate proving that the registration was granted in one country of the Union. However, the registration may be refused if the trademark itself could infringe rights already acquired by third parties in the Member State (art. 6 *quinquies*).

The protection accorded by the Paris Convention to the holder of an industrial property right who is a national of one country of the Union, has the effect of granting to the right holder the right to enjoy in any country of the union the same treatment and the same rights that the Member State accords to its nationals, including legal remedies against any infringement of her/his rights (art. 2).

Other provisions, i.e. the remaining paragraphs of art. 5, are related to the framework that forms the basis for exercising industrial property rights that, in the case of patents for instance, provides for compulsory licenses which serve the purpose of avoiding that inactivity on the part of the right holder – the so called *failure to work* – could result in an abusive exercise of her/his rights.

The Paris Convention contains also provisions related to the identification of remedies against the infringement of industrial property rights. In these regards art. 9 provides for an obligation to seize on importation those goods which unlawfully bear a trademark or trade name. This provision must be applied in all those countries of the Union in which the trademark was registered and the seizure is made upon request of the competent authorities or of the interested party. While this obligation is valid also in the Member States where the unlawful trademark was affixed, the competent authorities are not bound to seize goods in transit. In the case in which the legislative framework of the Member State does not provide for the seizure on importation, the latter should be substituted with a prohibition of importation or with seizure inside the country. Following the last paragraph of art. 9, legislation of those countries of the Union which does not provide for seizure on importation, seizure inside the country and prohibition on importation should be modified accordingly. In the meantime these measures should be replaced by the remedies provided by the national laws of the Member State in such cases to its nationals. Art. 10 extends the validity of these provisions also to the cases related to a false indication of origin.

The legislative framework outlined by the Convention is completed by art. 10 *bis* and 10 *ter*, which deal respectively with unfair competition and with the remedies that the holders

of an industrial property right are entitled to use in cases of infringement of such rights. The wording of these articles appears not mandatory. Art. 10 bis call for the necessity for any Member State to grant an effective protection against unfair competition for any national of a country of the Union. Unfair competition is defined as every act of competition contrary to honest practices in industrial or commercial matters. Art. 10 ter provides for a generic commitment undertaken by all Member States to grant, to all nationals of a country of the Union, appropriate and effective legal remedies to repress those acts constituting a violation of an industrial property right under the Convention.

Berne Convention for the Protection of Literary and Artistic Works

The Berne Convention, as the Paris Convention, is also aimed at creating a Union among the ratifying countries but protection, in this case, will be granted to literary and artistic works. Due to the different subject of the protection, the framework outlined by the Berne Convention differs from the one previously taken into consideration and in particular the provisions related to the right of priority are not present, since they are mostly linked with the system of patents or of grants. The object of protection is constituted by a vast typology of works, from literary works in broad sense to paintings, drawings and architecture, from photographic works to musical compositions, choreographic works and entertainment, and cinematographic works (art 2.1). To all these works, protection is granted by the Convention in each country of the Union and their authors are the subjects entitled to enjoy the rights descending from its provisions. In case the author is a national of a Member State, she/he will enjoy the rights provided even without a publication of her/his creation while, in case the author is a national of a third country and intends to enjoy the same rights, the first publication of her/his work in one of the Member State or a simultaneous publication in different countries among which at least one is a Members State of the Union, is a precondition for the attribution of these rights (art. 301). However, art. 4 provides for different criteria in the case of cinematographic and architecture works.

The system outlined by the Convention grants to the subjects entitled the right to enjoy, in each Member Country different from the one of origin, of those rights that their national laws provide for their citizens and of those rights identified by the Convention. Exercise of these rights cannot be limited by Member States and is not consecutive to the circumstance that the work already enjoys protection in the country of origin. The country of origin is the Member State of the Union where the work was published for the first time. In the case of simultaneous publications in more countries of the Union, the Member State in which the relevant legislation grants the shortest duration for the protection will be identified as the country of origin. In case of simultaneous publication in a third country and in a country of the Union, the latter will be considered as country of origin (art. 5).

The Berne Convention affirms that the author enjoys both economic and moral rights. Moral rights refer to the right to claim the authorship of the work and to oppose to any distortion or modification of the work (art. 6 bis). Moreover, the author enjoys the exclusive right to authorize the translation and reproduction of her/his work. The latter provision is

not applicable in some determined circumstances specified by the national legislation in which free utilizations of the work are allowed. The economic rights are enshrined in art. 14 ter and refers to the right to enjoy an interest in any sale of the work subsequent to the first transfer by the author of the work.

The author is entitled to exercise the right of action aimed at obtaining recognition of her/his rights upon identification and, to this end, it is sufficient that her/his initials appear on the work, even in the case in which a pseudonym is utilized.

As already made in the Paris Convention, the Berne Convention indicates a series of requirements which lead to the creation of specific rights upon certain subjects. However, even in this case the implementation phase of the said rights appears to be weak, particularly for what concerns the cooperation among Member States for the granting of the provided protection. Art. 16 is the only relevant provision in these regards. It affirms that non-authorized copies of literary and artistic works that are protected under the Convention should be seized in any Member State which grants protection to the said works. This provision should be applied also when the non-authorized copies originate from a country that do not grants protection to the said work, while the seizure should be made in accordance with the legal provisions applicable in the Member State in which the seizure is made.

Madrid Agreement Concerning the International Registration of Marks

The international legislative framework related to registration and securing of International Marks is outlined by the Madrid Agreement Concerning the International Registration of Marks of 1891 (hereinafter the Madrid Agreement) and by the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks of 1989 (hereinafter the Madrid Protocol). These two legal instruments form the so called "Madrid System"[1].

In order to obtain protection for the International Mark, the interested party has to file a request for registration of the Mark. Following the provision of this onus, the two legislative instruments create an international registration system, under the administration of the World Intellectual Property Organization (WIPO).

Their innovative character lies essentially in the simplification of the registration procedures that they introduce. Prior to the Madrid Agreement, the Mark ought to be registered in each country within which the subject intended to establish trade relations. The Agreement provides for the creation of a Union among the ratifying countries. Nationals of a Member State which already registered the Mark in their country of origin – whose meaning is defined later – may obtain protection for the said Mark in all the countries of the Union through its registration at the International Bureau of Intellectual Property, created within the WIPO[2]. The terms Member State or country of the Union shall be utilized interchangeably.

Following art. 1 of the Agreement the country of origin is identified in: 1) the country of the Union where the applicant has a real and effective industrial or commercial

establishment; or 2) in case she/he has no establishment, the country of the Union where she/he has her/his domicile; or 3) in the case in which the applicant has not a domicile in one of the countries of the Union but is a national of a Member State, the country of which she/he is a national. The three indications are listed in a hierarchical order of importance.

The Madrid Protocol was adopted with the intent of introducing some innovations within the system of international registration of Marks created by the Madrid Agreement. One of the major differences between the two legislative instruments lies in the requirements indicated by the instruments to obtain the international registration of the Mark. While the Agreement states that the registration can be filed to the International Bureau of Intellectual Property only when the Mark is already registered in the country of origin, art. 2 of the Protocol affirms that the same protection can be obtained on the basis of an application for registration filed to the competent national Office. If the national registration - that constitutes the basis for the international registration - becomes invalid, so will the international registration. Following art. 9 quinquies of the Madrid Protocol, international registrations revoked by the International Bureau of Intellectual Property may be converted, upon request, into national or regional applications for registration. In these cases, the date of deposit of the application is identified with the date in which the international registration was granted and the priority given to the eventually revoked international registration is also maintained. Moreover, the hierarchical order of importance for the individuation of the country of origin is no more present in the Madrid Protocol.

Following the new provisions contained in the Madrid Protocol, each member country is free to choose a system of national individual taxation. Fees are freely established by the Member States, the only limit being identified in the impossibility to exceed the fee requested for a national registration of a national Mark (art. 8).

The Madrid Protocol extends the participation to the international system for the registration of Marks also to those international organisations which owns a regional system for the registration of Marks.

Apart from these differences, the Madrid Protocol and Agreement have a similar structure. International registration of a Mark is, in fact, not intended to create an international Mark rather a centralized deposit system, whose efficacy is very similar to a series of national or regional applications for registration. For what concerns the interested party, the international registration cannot be filed directly by her/him, being this a competence of the national or regional bureau for industrial property to which the subject filed the application for registration.

The Madrid Agreement and Protocol are two different legal instruments and they can have a contemporaneous/joint/separate application. On the basis of the interested countries, international applications for registration could find their regulation on the Protocol or the Agreement alone or in both instruments. In the latter case a safeguard clause contained in art. 9 sexies of the Protocol, states the prevalence of the norms contained in the Madrid Agreement for those countries that are Contracting Parties of both the Agreement and the Protocol.

Agreement on Trade Related Aspects of Intellectual Property Rights

The Agreement on Trade Related Aspects of Intellectual Property Rights of 1994 (hereinafter TRIPs Agreement) promoted by the WTO, improves the definition of Intellectual Property Rights (IPRs) as well as their utilization and implementation. The preamble to the treaty confirms this orientation and Member States affirm the need to create a system to grant the application of the Convention, deeming of fundamental importance that the ratifying countries actively cooperate to this end, in particular overcoming possible disputes arising among them. The Berne and the Paris Convention form the basis for the system outlined by the TRIPs Agreement that further develops their potential and collects in one text the subject matter to which protection is granted, thus eliminating the different regimes of protection that were in fact granted to industrial property (Paris Convention) and to literary and artistic works (Berne Convention). The major aim of the Treaty and of the outlined system is to contribute to technological innovation and to its diffusion, in order to create mutual advantages for producers and consumers, thus encouraging the growth of social and economic welfare and a balance of rights and obligations (art. 7). To this end, art. 1 states that Member States commit themselves to ensure that the norms of the Convention find proper application and to accord the treatment they indicate to the citizens of the entitled Member States. The latter are identified thanks to the norms of the Bern and the Paris Convention, which find explicit reference in the TRIPs Agreement. Another reference can be found in art. 2, which affirms that, in relation to the definition and utilization of the rights provided by the Convention and in relation to the indication of those measures intended to ensure their enforcement, Member States have to comply with the norms of the Paris and of the Berne Convention and the obligations descending from these two legislative instruments cannot be derogated by the TRIPs Agreement.

Two are the guiding principles of the Convention that are aimed at creating effective cooperation among Member States for the protection of IPRs. The first guiding principle provides for the application, in any of the ratifying countries and with regards to a national of any another Member State, of a protection and treatment not less favorable than the one that the legislative framework of the Member State accords to its nationals (art. 3). The second guiding principle is the clause of the most favored nation (art. 4), following which the ratifying country that should decide to accord a more favorable treatment to the nationals of another Member State, is bounded to extend this treatment to the nationals of all the other ratifying countries. The exceptions to this general rule are essentially related to the case in which the object of the more favorable treatment does not concern only procedures related exclusively to IPRs or derives from a Treaty entered into force before the TRIPs Agreement.

Copyrights, trademarks, indications of origin, industrial designs, patents, layout designs of integrated circuits, information related to production processes are the specific subject matter of protection. Moreover the Treaty contains norms related to control anti competitive practices and unfair competition. Articles from 9 to 40 better specify each

category. For each one they indicate: definition, term of protection granted by the Convention, specific norms typical of a given category, and some limitations related to the utilization of conferred rights. Copyright, for instance, is extended by article 10 to include computer programs while art. 19 relates to the requisite of use in relation to trademarks. The latter aspect is particularly important when the legislative framework of a Member State requires use of the trademark to maintain its registration. In this case, the registration can be cancelled only after an uninterrupted period of non-usage of at least three years, unless valid reasons exist that justify the non-use by the trademark owner, who owns the burden of proof in this case. The rights generally conferred by the Convention to the various typologies of IPRs are related to the possibility of exclusively benefit from what falls within the subject matter of protection, being it a production process, a patent, a trademark or an indication of origin. However, for each category the Convention provides a different term of protection.

Articles 39 and 40 of the TRIPs Agreement are related specifically to different aspects connected with the practice of unfair competition. Art. 40 specifies that, in certain cases, a restriction of competition and of the transfer of technological know-how could derive from an exclusive use of IPRs. In order to avoid that an improper use of the rights provided for by the Convention and of the system outlined for their enforcement could lead to situations of this kind, paragraph 2 of the same article affirms that no provision on the Convention could impede to a Member State the identification of those practices deemed to be contrary to the rules of competition. The Member State could consequently prohibit or control them, the only limit being that this limitation and control do not result in an unjustified restriction of the protection granted by the Convention. Each Member State has the possibility to require to the nationals of any Member State who reside in its territory and who enjoy the rights conferred by the Convention, to clarify the use they are making of such rights. Information of this kind should be obtained by establishing cooperation with the country of which the said subject is a national. If the subjects enjoying IPRs release confidential information in the course of an action aimed at obtaining protection of such rights against unfair competition, the said information receive protection by art. 39.

Perhaps the most important section of the TRIPs Agreement is the one related to the enforcement of the IPRs conferred by the Convention. This section constitutes a noticeable improvement with respect to the previous Treaties and contains a series of provisions indicating remedies and procedures aimed at fostering an effective implementation of the Convention. In these regards, Member States commit themselves to ensure implementation, among their respective legislative frameworks, of those provisions of the Agreement aimed at providing remedies and procedures to respond to any infringement of IPRs covered by the Convention (art. 41.1). The said remedies and procedures are civil, administrative and criminal. The former are outlined by articles from 42 to 49. Art. 42 affirms that Member States must make available to IPRs holders civil proceedings aimed at ensuring the respect of such rights. The following articles indicate a series of powers owned by the judicial authorities in the course of proceedings. Art. 43 states that the judicial authorities must have the power to order, to the opposing party owning a specific evidence, to produce the said

evidence. This power should be utilized only when the plaintiff previously presented reasonable evidence to support its claims and when the evidence that lies in the hands of the resistant is relevant to substantiate the said claims.

For what concerns the goods constituting an infringement to an IPR, the judicial authorities have the power to order to the subject intending to put these goods into the channels of commerce to desist from such an activity. The said authorities have also the power to order that the said goods are not put into commerce immediately after customs clearance. However, Member States are free to not apply this provision in the case in which the subject who acquired, ordered or imported the goods prior to knowing or have reasonable grounds to know that the goods in question and their trade constituted an infringement to an IPR. If this is the case, the right holder could be entitled to receive compensation (art. 44.1 and 44.2).

Following art. 45, if the judicial authorities, in the course of proceedings, deal with a subject who voluntarily infringes the rights conferred by the Convention, they have the power to order to the infringer the payment of damages suffered by the right holder, comprising judicial expenses. Infringing goods can be destroyed or confiscated upon order of the judicial authorities and without compensation of any kind and the same measure could also be applied to the means of production of such goods. In the latter case the judicial authorities must consider the respect of proportionality between the measure ordered and the seriousness of the infringement (art. 46). The infringer could also be ordered by the judicial authorities to reveal to the right holder the names of third persons involved in the illicit activity (art. 47). Art. 48 of the TRIPs Agreement is dedicated to the case in which the plaintiff abused of the judicial procedures aimed at protecting an IPR. In this case the judicial authorities may order that compensation in favor of the responded for the damages eventually suffered is paid by the plaintiff.

The Convention affirms also that a power of ordering provisional measures is held by the judicial authorities of the Member States. The said measures could be aimed at preventing a violation of an IPR – especially in case in which infringing goods could be put into the channels of commerce in the territory under their jurisdiction – or to preserve relevant evidence regarding the alleged infringement. The provisional measures can be adopted *inaudita altera parte* – without a hearing of the respondent – where appropriate and in particular when a delay could cause irreparable harms to the plaintiff or could result evidence being destroyed. In any case in which the said measures are adopted *inaudita altera parte*, the affected parties must be immediately informed by the competent authorities and the plaintiff must produce reasonable available evidence to demonstrate to the judicial authorities that the plaintiff is the right holder and that inaction on their part could cause an infringement of his rights or a continuation of the said infringement. Provisional measures adopted could be subsequently revoked if legal proceedings aimed at obtaining a judgment on the merits of the case are not initiated within a reasonable period of time. Being this the case, if the revocation depends from an act or omission by the applicant or in the case in which the risk of an infringement of an IPR is found to be non existent, the defendant could ask the judicial authorities to order the applicant to provide adequate compensation

for the suffered damages (art. 50).

Provisions related to criminal remedies and procedures are contained in art. 61. It affirms that Member States should commit themselves to ensure that criminal procedures and penalties are provided for by their legislative framework, at least for the most serious infringements as the willful counterfeiting of trademarks or copyright piracy held on a commercial scale. The footnote to art. 51 explains the difference existing between counterfeit and pirated products. Counterfeit trademark goods are intended to be those products which bear without authorization a trademark which is identical to the trademark validly registered for such goods. Pirated copyright goods are unauthorized copies of original goods which are made directly or indirectly from the original. Following art. 61, criminal remedies should include imprisonment and/or monetary fines. They should in any case provide a deterrent to the perpetration of the crime. Infringing goods as well as their means of production may be seized, forfeited and destroyed.

The TRIPs Agreement encourages the Member States to increase the efficacy of border controls. In these regards, art. 51 affirms that a right holder has the possibility to lodge a written application to the customs authorities of a Member State requesting the suspension of the release into free circulation of suspected infringing goods. To this end, the applicant must provide the competent authorities with clear evidence and an accurate description of such goods. If the legislative framework of the Member State so requires, the applicant could also be ordered to provide for a sum of money as an assurance to protect the defendant and the competent authorities, and to prevent abuses. The Convention tries to avoid inaction on the part of the applicant. If after 10 working days from the date in which the seizure of the alleged infringing goods took place, the customs authorities are not given notice of the initiation of legal proceedings to decide on the merits of the case, the alleged infringing goods are released and can be put into the channels of commerce (art.55). A similar outcome (art. 53) could occur after the payment of a sum of money on the part of the defendant. In this case, however, the term indicated by art. 55 should already be expired without any pronouncement by the judicial authority, the sum paid by the defendant should be adequate to constitute a valid assurance for the right holder, and all the importation procedures must already be completed. In case in which the goods were detained by the customs following a wrong indication by the applicant or in the case in which the seizure of such goods is revoked, the competent authorities may order to the applicant to pay compensation to the defendant for the damages that the goods eventually suffered. If the Member States so decide, the competent authorities may have the power to act *proprio motu*, ordering to take into custody those goods for which sufficient evidence exist on the fact that they could infringe laws related to IPRs. Being this the case, the said authorities have the power to ask information to the right holder and they consequently have the duty to inform the latter and the importer of the said goods on the measures adopted (art. 58). Art. 59 states that the competent authorities have the power to order the destruction of infringing goods and that the said authorities are not in the position to allow a re-exportation of goods bearing a counterfeit trademark.

The TRIPs Agreement encourages the development of political cooperation among Member States. The ratifying countries commit themselves to enhance cooperation aimed at reducing the trade in counterfeit goods and at sharing relevant information on the issue, creating specialized offices for this purpose. Exchange of information should also be improved with regard to the respective legislative frameworks in force in the Member States. The ratifying countries also commit themselves to support the economic development of less industrialized countries, providing for a postponed entry into force of the Convention in these Member States.

WIPO Copyright Treaty

As indicated by art.1, the WIPO Copyright Treaty (hereafter WIPO Treaty) is a special agreement within the meaning of the Bern Convention. The contracting parties explicitly agree to comply with the Paris Act[3] of the Berne Convention, even in case in which they did not ratify the Bern Convention itself.

Articles 4 and 5 of the WIPO Treaty specify two subjects that should fall within the protection accorded by copyright: computer programs and databases. Following articles 6, 7 and 8 the author of a literary and artistic work has the exclusive right to authorize the distribution and rental of the said works. Communication of the works to the public must also be authorized by the author. These are all exclusive rights even if they can be limited or subjected to some exceptions (art. 10).

Similarly to what has been provided for in the TRIPs Agreement, the Member States commit themselves to ensure the availability, in their respective legislative frameworks, of effective legal protection and remedies against the circumvention of technological measures used by the authors, in connection with the rights conferred by the WIPO Treaty (art. 11). Art. 12 extends the provisions of art. 11 also to those cases in which Rights Management Information[4] has been removed from the product by a third party as well as cases relative to the knowing distribution, importation or broadcast of modified works where the Rights Management Information has been removed.

The WIPO Treaty encourages the ratifying countries to adopt, in accordance with their national legal systems, those measure necessary to ensure the application of the treaty. Following art. 14 in particular, the Member States should ensure that their legislation provides for adequate enforcement procedures to act against any infringement of the rights covered by the Treaty. The said enforcement procedures should comprise expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.

United Nations Convention against Transnational Organized Crime

More and more evidence exists with regards to the connections between counterfeiting and organized crime and the international community is monitoring this situation with a

growing interest. Therefore, specific attention should be given to the United Nations Convention against Transnational Organized Crime.

The Convention and two of its three Protocols – the first to Prevent, Suppress and Punish Trafficking in Persons, Especially Women and Children; and the second against the Smuggling of Migrants by Land, Air and Sea – were opened for signature during the Conference held in Palermo from the 12th to the 15th December 2000. On May 2001 the United Nations (UN) General Assembly approved the third Protocol – against the Illicit Manufacturing of and Trafficking in Firearms, Their Parts and Components and Ammunition.

The Convention and its Protocols constitute a milestone for international cooperation aimed at countering transnational organized crime. These legislative instruments overcome the terminological differences existing in the different ratifying countries and constitute a solid juridical basis for cooperation activities created among the Member States, in general, and their law enforcement authorities, in particular.

The first article of the Convention affirms that its purpose is to promote cooperation to prevent and combat transnational organized crime more effectively. The following articles contain provisions related to the most important transnational crimes – such as participation to a transnational organized criminal group, money laundering, corruption, the liability involved legal persons – as well as technical measures through which combat these phenomena – such as confiscation and seizure, extradition, mutual legal assistance, special investigative techniques, and protection of witnesses.

In those cases in which the crime of counterfeiting could be linked with organized crime activities, the punishment of the before mentioned crime would be more effective and will constitute a more efficient deterrent for the prevention of a repetition of the offence.

3. Actions at the European Union level

As clearly showed by the legislative *excursus* made so far, Intellectual Property is protected by a series of international normative instruments of which the Member States of the European Union (EU) are also a Party. Furthermore, the EU Legislator is strongly committed to further improve and harmonize the EU legislation on Intellectual Property and related rights[5]. In 2001 the European Union adopted Directive 2001/29/EC on the harmonization of certain aspects of copyright and related rights in the information society (known as the EU Copyright Directive, EUCD), whose aim was to keep the legal framework of the EU Member States in line with the international Conventions on the subject. The Copyright Directive falls within the scope of articles 47 (2), 55 and 95 of the Treaty of Rome and is also aimed at implementing the WIPO Copyright Treaty and the WIPO *Performances and Phonograms Treaty*[6], of which the European Union is a Party.

The ratio at the basis of the EUCD is the need to prevent and punish every kind of non authorized use of the works resulting from the activity of human intellect. In these regards the EUCD is aimed at keeping a high level of protection for copyright and related rights, considering also the needs arising from the diffusion of digital technology and providing for a harmonized protection at the Community level. This harmonized protection should confer to all the right holders, as identified in the Directive, the exclusive right to make accessible to the public their works protected by copyright as well as the materials that are protected by other rights.

In this regard the EU Legislator intervenes to identify the content of certain exclusive rights of economic use – as well as the extent of the related exceptions – and to provide for new forms of protection with regard to technological measures designed and used by right holders to prevent any non authorized act with respect to their work. Similar protection is also accorded to rights management information. This term indicates information provided by the right holder that identifies the work, the author or any other right holder, information regarding the terms and conditions of use of the work, or numbers and codes that represent such information.

Following what was previously contained in the WIPO Copyright Treaty, the Copyright Directive specifies the content of the rights of reproduction, communication to the public, and of distribution.

Regarding the right of reproduction, art. 2 confers to authors, performers, phonogram producers, producers, and broadcasting organizations, the "exclusive right to authorize or prohibit direct or indirect, temporary or permanent reproduction by any means and in any form of", respectively, their works, fixations of their performances, their phonograms, the first fixations of films in respect to the original and copies of their films, fixation of their broadcast[7].

For what concerns the right of communication to the public (art. 3) and the right of distribution (art. 4), the EUCD confers to the right holders the exclusive right to authorize or prohibit any communication or transmission to the public, by wire or wireless, of their work, copy of their work and of performances of performers. Moreover, the authors enjoy

the exclusive right to authorize or prohibit the distribution in any form of the original of their works or of copies thereof.

Regarding the exceptions to the before mentioned rights, contained in art. 5, the guiding principle is to avoid any prejudice to the technological development and to adapt the concepts of use and reproduction to the specificities of digital communication. Consequently, the Directive excludes the prohibition of temporary acts of reproduction which are transient or incidental and that constitute an essential and integral part of a technological process. These reproduction acts should, for instance, be performed with the sole purpose of enabling a lawful use of a work or other protected material and should not have an independent economic significance.

Member States retain the right to provide for further exceptions or limitations to the right of reproduction, the right of communication to the public, and the right of distribution (art. 5)[8].

Articles 6 and 7 are directly related with the implementation of the WIPO Copyright Treaty. They are aimed at ensuring adequate legal protection against the circumvention of the technological measures that are implemented by the right holders to prevent non authorized acts on their works protected by copyright, and to provide for adequate legal protection for rights management information. The term "technological measures" (art. 6.3) indicates, as already seen with regard to the WIPO Copyright Treaty, any technology, component or device that, in the normal course of its operation, is designed to prevent acts, with reference to a work, not authorized by the right holder of any copyright or related right[9]. The protection accorded by the EUCD relates to the necessity for the ratifying countries of providing adequate legal measures against the manufacture, import, distribution or sale of devices, products or components which: a) are promoted, advertised or marketed for the purpose of circumvention of the said technological measures; b) have only a limited commercially significant purpose or use other than to circumvent the technological measures; c) are primarily designed, produced adapted or performed for the purpose of enabling or facilitating the circumvention of the technological measures (art. 6.2).

The concept of rights management information is defined by art. 7 as any information provided by the right holders which identifies the work or other protected materials under the Directive, the author or any other right holder, or information about the terms and conditions of use of the work or of other protected materials, or any number or codes representing such information.

With the aim of ensure an effective implementation of the WIPO Copyright Treaty, the EUCD calls the Member States for the provision of adequate legal protection against anyone who a) removes or modifies, without the authorization of the right holder, any rights management information; b) distributes, imports for distribution, broadcasts, communicates or makes available to the public, protected works from which the rights management information has been removed or altered without authorization. The said person must, however, know or have reasonable ground to know that by so doing she/he is

inducing, enabling, facilitating or concealing any infringement of any copyright or any related right.

With regard to the implementation of the EU Copyright Directive (foresaw not later than the 22nd December 2002) some examples are available: the United Kingdom adopted in 2003 the *Copyright and Related Rights Regulation*; France adopted in 2006 the *Loi sur le Droit d'Auteur et les Droits Voisins dans la Société de l'Information* (DADVSI); while Finland modified in 2005 the *Finnish Copyright Act* and the *Penal Code*.

For what concerns Italy, with art. 30 of law 39/2002 the Italian Parliament delegated to the Government the issuance of a legislative decree aimed at implementing the Directive. The decree in question is the D. Lgs. 68 of 9th April 2003, titled "Implementation of Directive 2001/29/CE on the harmonisation of certain aspects of copyright and related rights in the information society".

On March 2004, the European Union Institutions adopted the so called "*IPR enforcement directive*[10]" (hereinafter IPR Directive) focused primarily on the protection of IPRs. The preamble to the Directive explicitly recalls the obligations binding the EU Member States in consequence of their participation to the TRIPs Agreement, being the European Community itself a Contracting Party of the Agreement and not only the EU Member States. The intervention of the Community Institutions is in any case necessary to harmonize the relevant legislation and practice of the EU Member States, which remained different, for instance, for what concerns the procedure to be followed by the competent authorities to indicate provisional measures aimed at preserving evidence. The preamble anticipates a normative framework which presents points in common with the TRIPs Agreement, but the act owns, in this case, all the strength that Community legislation has towards the EU Member States.

Art. 1 defines the object and scope of the IPR Directive: the protection of IPRs, including also industrial property rights.

The extent of its application is specified by the following article, stating that the Directive has to be applied in any case concerning the infringement of an IPR in a Member State or in the Community, without any prejudice to the application of a more stringent protection in the case in which the later should be provided by other national or Community means.

Art. 3 (1) calls Member States for the adoption of remedies and procedures applicable to enforce IPRs. The said remedies and procedures should be effective, proportionate and dissuasive, they should not be applied in a manner to create barriers to commerce, and they should not be unnecessary complicated or costly, or entail unreasonable time-limits or unwarranted delays.

Art. 4 indicates that the rights holder, other persons authorized to use IPRs, or authorized collective bodies whose aim is to manage and defend the said eights, are the persons entitled to apply for requesting the protection of an IPR. Recalling art. 15 of the Berne Convention, the Directive embraces the presumption of paternity of the work to the advantage of the person who placed her/his name on the said work. Norms concerning the

acquisition and protection of proofs are very simalar to the ones contained in the TRIPs Agreement, also for what concerns the possibility to order provisional measures aimed at their protection. Thus, articles 6 and 7 of the Directive provide for: the power, held by the judicial authorities, to order the resistant to present the element of proof eventually at her/his disposal; the possibility to order provisional measures to protect the elements of proof *inaudita altera parte*, in the cases in which there exists the posbbility that the sad proofs could be compromised or destroyed; the possibility to subordinate the order of such measures to the lodging, on behalf of the requesting party, of a sum of money as an assurance towards the party against which the said measures should be ordered; the payment on behalf of the requesting parties to the of the alleged infringer of compensation for the damages suffered, in the case in which the ordered measures are revoked for any act or omission of the requesting party or in the case in which it is subsequently found that there has been no infringement.

The Directive, as the TRIPs Agreement, indicates the possibility for the judicial authorities, upon request of the claimant, to order the release of information to: a) the infringer or to any person b) found in possession of goods infringing an IPR, or c) commercially distributing such goods, or d) providing services used in infringing activities or e) to any other person indicated by the before mentioned subjects. With respect to the TRIPs Agreemen, however, the Directive presents a more detailed description of the subjects which bear the obligation to provide information. The same obligation is better defined with regard to its object and it must contain the names and addresses of the producers and of distributors of infringing goods as well as of all the subjects which participated to the illicit activity. It must also contain an indication regarding the units produced and distributed and the average sale price (art.8).

The provisions of art. 9 seem to be even more interesting. The said article provides for the power, held by the judicial authorities, to order provisional measures also to prevent an alleged infringement of an IPR or to forbid the continuation of an alleged infringing activity. To this aim the competent authoritis may order the subjects to maintain a certain behaviour or may seize the alleged infringing goods. In the case in which the alleged infringing activity is an activity conducted on a large scale, the competent authorities may also order the precautional seizure of movable and immovable property of the alleged infringer, including the blocking of her/his bank accounts and other assets. Ordering of such measures is subordinated to the demonstration on the part of the injured party of circumstances likely to endanger the possible recovery of damages. The said measure could be ordered *inaudita altera parte* and could be revoked. The latter could be the consequence of inaction on the part of the requesting party with regard to the initiation of proceedings to decide on the merit of the case, or could also be subsequent to the finding by the competent authorities that no infringement has occurred. In this case the requesting party could be ordered to pay the damages eventually suffered by the alleged infringer. In the case in which the judicial authorities find that an infringement occurred, the Directive, as the TRIPS Agreement, provides for the possibility to suspend, retire from the channels of commerce, or destroy the infringing goods at the expenses of the infringer (art. 10).

For what concerns the compensation for damages, art. 13 provides for two calculation standards. The first (art. 13, 1, (a)) assess the economic consequences suffered by the damaged party while the second (art. 13, 1 (b)) assess the economic value of the IPR and of the licenses.

The last articles of the Directive call the Member States to improve their cooperation and exchange of information also by publishing the relevant Court sentences and informing the Community Institutions about any problem encountered in the implementation of the Directive.

The EU legislative framework on the subject is improved by the Council Regulation 1383/2003[11], whose aim is to improve customs cooperation for the identification of goods infringing an IPR. In these regards, art. 2 of the Regulation proposes a distinction between "counterfeit" and "pirated" products. The term "counterfeit goods" will be used by the Regulation to identify those goods unlawfully bearing a trademark identical or very similar to the registered one, while the term "pirated goods" indicates goods which are or contain unauthorized copies of a work protected by copyright. The provisions of the Regulation, and especially those articles regarding customs actions, are also applicable to those products infringing: a) a patent registered in one of the EU Member States, and b) an indication of origin. Customs actions may be performed upon goods intended for export, import and transit (art. 1).

The said actions may be initiated by the national customs officers when there is the suspicion that the goods may infringe an IPR and may also be initiated after the presentation of an application for action by the right holder. In the latter case, the request should be sufficiently detailed describing, in particular, the goods in question and indicating the type of alleged infringement. Other information, if available, concern to the final destination of the said goods, the scheduled time for their arrival or departure should, the means of transport used, the interested countries, and the differences between the original and the infringing products. In addiction, the applicant has to present a declaration of assumption of responsibility for the damages eventually suffered by the party against which the customs action is requested. This declaration represents an assurance for the alleged infringer when the measures taken by the customs are revoked in consequence of an act or an omission on the part of the requesting party or in the case in which it is later found that no infringement occurred (art. 5 and art. 6). In these regards, art. 13 affirms that the competent customs office must receive communication of the initiation of judicial proceedings for the decision on the merits of the case within 10 working days from the day in which was received the notification regarding the suspension of the goods from the channels of commerce or of the seizure of the goods. In case of inaction on the part of the requesting party the alleged infringing goods are released. The suspension from commerce and the seizure are provided for by art. 9 of the Regulation in those cases in which a suspicion arises, after a customs control, that the controlled goods could infringe an IPR. Art. 11 affirms that, with the consent of the right holder whose who presumes that her/his rights are being violated, the alleged infringing goods suspended or seized may be destroyed. In this case a decision on the merits on the case has not yet been taken and there

is only the suspicion that the goods are infringing an IPR. For this reason the provision of art. 11 could be applied only if the customs authorities receive a written declaration, on the part of the owner or of the proprietor of the alleged infringing goods, indicating her/his favorable opinion for the destruction of the said goods. This declaration is presumed if the owner or proprietor does not oppose to the request of the destruction of the goods within the established time limits.

Art. 16 indicates the measures to which are subjected those goods that have been recognized to infringe an IPR after the end of judicial proceedings. In this regards, the said goods cannot enter the EU channel of commerce, cannot be exported and must be suspended in case in which they were already into commerce.

Implementation of Directive 2004/48/EC[12]

As stated above, the Directive pertains to the system of IPRs protection and imposes on Member State the obligation to harmonize their legislation with the provisions therein contained.

The deadline for the implementation of the Directive in each Member State had been fixed for 29 April 2006, although it has not been unanimously respected. For this reason, the Commission, in October 2006, formally asked to implement Directive 2004/48/EC to 12 Member States: Belgium, France, Germany, Greece, Latvia, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia and Sweden[13].

A selection of relevant examples:

Belgium

Two laws on civil and judicial matters, the *Loi relative aux aspects civils de la protection des droits de propriété intellectuelle* and the *Loi relative aux aspects de droit judiciaire de la protection des droits de propriété intellectuelle* (both of 10 May 2007), modify the protection of intellectual rights in Belgium quite significantly. Their first object is to transpose Directive 2004/48/EC into Belgian law. The reinforcement of civil sanctions will be even more significant as from 1 January 2008, when the judge will be entitled to ask for part of the plaintiffs' legal fees to the sentence.

Although the petition for descriptive seizure has been used in Belgium since the 19th century, the procedure of "*saisie en matière de contrefaçon*" has been expressly extended to all IPRs. The procedure is accessible to the right-holder her/himself and also to all those who are entitled to claim for counterfeiting in virtue of the specific law that is applicable.

One major change results from the transposition of Article 7 par.4 and 9 par.7 of Directive 2004/48/EC: this is the principle of compensating the party subjected to descriptive measures or to seizure when these measures are rescinded, cease to be applicable, or when it is determined subsequently that there was no counterfeiting or threat

of counterfeiting.

Cyprus

The Directive has been transposed with an Act of 28 July 2006, which, in its different chapters, amends the following legislation: section 123 (I), with regard to IPRs; section 121(I), with regard to trade marks rights; section 122(I), with regard to patents rights, and section 119 (I), with regard to designs rights.

Czech Republic

Thanks to the Law No. 221 of 2006, which came into force on May 26, 2006, from January 1, 2008 the Municipal Court of Prague will be the first instance court for Intellectual Property infringement matters. However there is no implementation of Article 14 of the Directive (*Legal costs*), because the current system does not censure that reasonable and proportionate legal costs and other expenses will be reimbursed to the right owner by the infringer.

Denmark

The Directive has been transposed with Act No. 1430/2005, which came into force on January 1, 2006.

The majority of the provisions of the Directive were already a part of Danish law prior to the implementation of the Directive. However, the Directive's rule on information, corrective measures and publication are new in Danish Law. Ex art.43 *subsection 3*, the right holder may obtain compensation for non-economical loss, which prior to the Directive was only possible under the Copyright Act. Moreover, Article 44 foresees that, in order to prevent further violations, the judiciary authority can apply inhibitory measures.

Finland

To proceed with the implementation of the Directive, on 21 July 2006 the following acts were amended: *Act to Safeguard the Evidence in Civil Actions concerning Intellectual Property Rights* (2000/344), *Copyright Act* (1961/404), *Trademarks Act* (1964/7), *Design Protection Act* (1971/221), *Patents Act* (1967/550), *Act on Plant Variety Rights* (1992/789), *Act on the Exclusive Right in the Layout-design of an Integrated Circuit* (1991/32), *Utility Model Act* (1991/800) e *Act on Trade Names* (1979/128).

Hungary

Implementation of TRIPS Agreement has almost completely changed the landscape of Intellectual Property enforcement in Hungary. Its ratification entailed a deep change in this legislative framework, making available various remedies which have been explicitly provided for the Directive of 2004.

In 2004 the *Hungarian Copyright Act* (76/1999) has been amended to implement Directive 2001/29/EC. Afterwards, Act. No.165 of 2005, entered into force on April 15, 2006, has

implemented Directive 2004/48/EC. This Law amends some articles of the *Hungarian Trade Mark Act*, of the *Act on Court Execution* and of the civil procedure code.

Article 2(1) of the Directive allows Member States to maintain or introduce such means of enforcement which are more favorable for right holders. The Hungarian legislation has made use of this one-sided flexibility in respect of e.g. the *presumption of authorship* (art. 5) and the measures for preserving evidence (art. 7 (1)), which should be available even before the commencement of proceedings on the merits of the case. The interpretation of Article 9 (1)(a)was hotly debated. This provision introduces a rather peculiar remedy that is often referred to in Hungary as the "counter-guarantee". Under the Directive, Member States have to ensure that the judicial authorities may issue against the alleged infringer, among other things, an interlocutory injunction intended to make the continuation of the alleged infringement of an IPR subject to lodging guarantees to compensate the right holder. It should be to the discretion of the court to order the lodging of "counter-guarantees" and permit the continuation of the alleged infringement if the applicant originally requested an interlocutory injunction.

The law provides the rights' holders and the courts with more tools during civil enforcement cases.

Specifically, it is possible to ask the court to devolve the goods to a third subject and, consequently, to order the respondent to withdraw the goods from the market.

The court can now oblige to stop the infringing activities not only the respondent, but also any other person involved in services which integrated the violation. Any person who owns infringing goods in a commercial quantity, should give information to the authorities about the companies which contributed to production and distribution.

Ireland

The Directive has been implemented with the *European Communities (Enforcement of Intellectual Property Rights) Regulations 2006 S.I. No. 360* of 2006, which entered into force on 5 July 2006. Similarly to United Kingdom, as a common law system, various Directive's provisions were already familiar in the Irish context, because Courts have broad discretionary power. The main innovations concern the mandatory aspects of the Directive[14], amongst them: the right to ask the Court to issue an ordinance to obtain information from people involved in suspected infringing activities (*Regulation 3*); the possibility to obtain an ordinance to seize or destroy the goods of the infringer, at his expense (*Regulation 4*), and the possibility, for the actor, to have the judgement published at the expense of infringer (*Regulation 5*).

Italy

The Directive 48/2004 was implemented in Italy with Legislative Decree No. 140 of March 16, 2006[15], which came into force on April 22, 2006.

This decree represents the last step in the process to harmonize the Italian legislation[16] to the European provisions on IPRs. In the framework of this process, it is notable that the

creation of the High Commissioner to fight against Counterfeiting, with the D.lgs. 35/2005, was converted into law by the Law No.80 of 14 May 2005.

Since the Directive involves IPRs and industrial property rights, the D.Lgs. amended both Law n. 633/41 on copyright[17] and the Industrial Property Code (*Codice della Proprietà Industriale-CPI*)[18].

The D. Lgs. made significant changes in the Italian legislation, introducing Art. 121 *bis* CPI. It allows the judicial authority order to give information, about origin and distribution networks of goods and services which are violating an industrial property rights, to the following subjects: the author of violation; every other person who owns goods, or have used or provided services, which are the object of the violation on a commercial scale; every other person indicated by other people as involved in the production or distribution of these products or services.

Information can include name and address of producers, manufacturers, distributors, providers and other previous holders of products or services, wholesale dealers, retail dealers, as well as information about quantity and price of products or services. It is a very important disposition, because it lets the judge collect the necessary information to understand and determine the dimension and the real range of the phenomenon.

Other criminal sanctions are foreseen for those who refuse to give this, or wrong information. (Article 127 CPI, which clearly recalls Article 372 of criminal code).

Another major provision is about the exhibition, on request of a part, of the bank, financial and commercial documentation of the counterpart (Art. 121 *comma 2bis* CPI). The aim is to give consent to the right holder in order to obtain significant information on the real dimension of the violation, in order to better protect his own rights.

Article 124 CPI ("Corrective measures and civil sanctions")[19] defines "sanctionary" powers of the judicial authority. The judgment which determines a violation of an industrial property right, can provide for: the inhibition from production, commerce and use of infringing goods; the withdrawal of infringing goods from commerce and distribution at the expenses of the violation's author; the temporary withdrawal form commerce if the judge determines that infringing goods are available for a legitimate use, with an adequate modification.

On compensation of damages, it has to be taken into account the new Article 125 CPI (" Compensation of damages and restitution of profits of the author of the violation")[20]. It is therefore possible to ask, among others, also for a compensation of moral damages suffered by the right holder. As for the criteria, the possibility of a lump sum is foreseen. This amount will be evaluated on what the author of the infringement should have paid if he received a license from the right owner. In any case, the amount of compensation cannot be less than what was evaluated for the stopped profit; there could be an integration with the reversion, partial or complete, of profits made by the author of infringement. The compensation is no longer calculated only on the basis of the suffered loss, but also taking into account the profit of the counterfeiter.

The new Article 144 *bis* CPI ("Conservative seizure") completes the discipline regarding

compensation of damages. It foresees that when the damaged part denounces circumstances able to prejudice compensation of damages, the judicial authority can order the conservative seizure of goods and real estate of the suspected author of infringement, included the block of the bank accounts and other goods, up to the compensation of the presumable damage amount. Since a similar measure has been already foreseen in the civil procedure code (Art.671), the new Article can be interpreted as a clear will to promote and guarantee the use of these remedies in actions against the infringement of IPRs.

The D. Lgs., Article 131, c. 1 bis, states that the proceeding should be initiated by 20 working days or 31 calendar days. The deadline will accrue from the ordinance pronunciation or communication. If this deadline is not respected, the precautionary provision will loose its effectiveness. This principle doesn't apply to urgent measures ex Art. 700 of the Civil Procedure Code or to other cautionary provisions able to anticipate the effects of the judgment.

Lithuania

On June 8 2006 Parliament passed a law amending and supplementing the Law on Trademarks. The changes were designed to harmonize the Law on Trademarks with EU Directive 2004/48/EC. One of the essential means of the enforcement of legal rights is damages and their reimbursement. According to the Laws of Lithuania, there exists a mixed type of remuneration of damages. The following types of damages exist in Lithuania: losses, compensation and non-economic damages. The Directive insists on the compensation, because previously, due to the calculation method employed, it was much more of a punitive nature than a compensatory one.

The compensation was based on the lawful sale-price, which is the market retail price, the ultimate price of the good including taxes multiplied by the number of the products sold. Compensation may be increased by 200% or by 300% if the infringer has committed the infringement deliberately[21]. However, taken into account the proposed amendments to the Law on Trademarks, such increase of compensation will be declined and in case of deliberate and intentional infringement the request on double compensation may be filed.

The Directive (Article 13.2) establishes that Member States may lay down a liability for persons not knowingly engaging in an infringing activity (without a fault). In Lithuania such provision is not implemented. Fault is an obligatory condition for the application of liability; therefore this is an essential condition for application of the institute of remuneration of damages in the enforcement of Intellectual Property. However, taken into account the proposed amendments to the Law on Trademarks, the IPR holders may request compensation even in cases when the infringer was acting without the fault of not knowing about the infringement.

Malta

The Act N°20 of 2006, Enforcement of Intellectual Property Rights (Regulation) Act, has implemented the Directive.

Romania

The legislation on copyright is entailed in the **Copyright Act** of 1996, several times amended in the following years[22] up to the Emergency Ordinance N. 123/2005, which entered into force on 21 September 2005 with the purpose of implementing Directive 48/2004/EC.

Although far from ideal, there are some positive elements: the Copyright Office (ORDA) no longer has direct enforcement authority in criminal cases; penalties for copyright infringement were increased; jurisdiction for criminal piracy cases were moved to the higher level tribunals in hopes of expediting cases; the principle of having a unique collecting society for all right holders was eliminated; the statutory royalty caps for the broadcasting and cable transmission rights of copyright and related right holders were eliminated.

The 2005 Ordinance was voted in the Parliament and become Law N°329 of 2006, which made the Copyright Law compliant with the Romanian Criminal Code, which will enter into force in September 2008.

Spain

The Directive has been transposed by Law No.19 of 5 June 2006. It primarily amends the Law on Civil Procedure N°1/2000, as well as specific legislation, namely: the consolidated version of **Intellectual Property Act** approved by Royal Legislative Decree No. 1/1996; the **Patent Act**, No. 11/1986; the **Trade Mark Act**, Law No. 17/2001; and the **Industrial Design Protection Act**, Law No. 20/2003.

Regarding the Law N° 1/2000, the right to information is regulated by new preliminary procedures.

The main change to the specific legislation has been the amendment of the provisions dealing with damages, which have been brought into line with the Directive (Article 13), with two standards of calculation. In addition, damages shall expressly include the expenditures affected by the right holder on investigations to compile evidence of the infringement.

The wording of the articles dealing with the damages is new: a definition of moral prejudice has been included, to coexist with the notion of damage to prestige of the IPRs introduced earlier by the **Trade Mark Act** of 2001. Damage to a right's prestige was formerly held in addition to purely economic losses, whereas under the current wording taken from the Directive, moral prejudice would seem to be in addition to economic loss only where the first standard for calculating damages (art. 13, c. 1 (a): negative economic consequences suffered by the injured party) is employed, but not where the second standard (art. 13, c. 2 (b): the amount of royalties or license fees) is used. This will be something for the courts to elucidate, because if this strict interpretation is followed, instead of extending the protection accorded to right holders as intended by the law, the revision world, paradoxically, be a step backwards compared to the system previously in force.

Another amendment, based on Article 9 of the Directive, common to the specific legislation is intended to broaden the range of available actions designed to prevent fresh infringements, in particular destruction and impoundment of the means and instruments used to commit infringement.

Lastly, the time period for filing the main complaint when interim measures have been requested before the main complaint has been filed has been shortened to 20 working days, compared with the former time period of two calendar months.

Law 19/2006 definitely improves the system of protection before the trial, because it let the violation be prosecuted in the fastest and most efficient way.

United Kingdom

The Directive has been implemented with the **Statutory Instrument, Intellectual Property Regulations N°1028** of 2006[23], which has amended the **Registered Designs Act** 1949 and the **Patents Act** 1977 and other various pieces of legislation. The Directive applies to the United Kingdom, and given the different legal systems in England and Wales, Scotland and Northern Ireland, the changes required to implement the Directive vary across the United Kingdom. Many of the provisions in the Directive are dependent on court rules, civil procedures, and common law rather than Intellectual Property law. Court rules and procedures are consolidated in England and Wales by means of the **Civil Procedure Rules** (CPR). The CPR does not apply in Northern Ireland, but any changes made to the CPR will be replicated in Northern Ireland by equivalent procedures.

Specific implementation was required in Scotland for: a) the discipline of disclosure of information. Article 4 of the **Statutory Instrument**, Order in Scotland for disclosure of information, attains at the disclosure of information by the person suspected of infringement of an IPR; b) the publication of judgments. Article 5 of the **Statutory Instrument, Order in Scotland for publication of judgments**, establishes that the court may, at request of the pursuer, order appropriate measures for the dissemination and publication of the judgment to be taken at the defender's expense.

The **Regulations**[24] grant the exclusive licensee of a registered design similar rights and remedies to the proprietors of registered designs. Article 4 (a) of the Enforcement Directive requires member State to provide the same remedies to, amongst others, exclusive licensees as they provide to right owners, but only as far as national law permits. Thus there is not a Community obligation to provide such rights to exclusive licensees, and granting them a right of action goes beyond the requirements of the Directive.

For the assessment of damages, **Regulation 3, Schedule 2**, paras 2 and 3, sets out the general approach required by Article 13.

As stated in a document published by **Fédération Internationales des Conseils en Propriété Industrielle-Commission d'Étude et de Travail** (CET) in March 2007, the following European countries have partially implemented the Directive: Austria (art.6 not implemented); Greece (only for copyright matters); Estonia; The Netherlands (although the Directive is not formally implemented yet, it is already applied by the Courts).

4. FUTURE INTERNATIONAL LEGISLATION DEVELOPMENTS ON THE FIGHT AGAINST COUNTERFEITING

Counterfeiting and piracy, and infringements of Intellectual Property in general, are a constantly growing phenomenon which nowadays have a international dimension, since they are a serious threat to national economies and governments.

In addition to the economic and social consequences, counterfeiting and piracy also pose problems for consumer protection, particularly when health and safety are at stake.

Finally, this phenomenon appears to be increasingly linked to organized crime because of the lucrative nature. Additional provisions to strengthen and improve the fight against counterfeiting and piracy are therefore necessary to supplement Directive 2004/48/EC. In addition to the civil and administrative measures, procedures and remedies provided for in Directive 2004/48/EC, criminal penalties also constitute, in appropriate cases, a means of enforcing IPRs.

2004 Directive was hastily passed before the Fifth Enlargement of the European Union of May 1, 2004. It did originally include criminal sanctions provisions, but this rather controversial part was omitted in order to be able to meet the deadline of May 1, 2004. There was still the possibility for the States, as cited in recital 28, to provide for criminal sanctions in specific cases[25].

A start was made on harmonization with the entry into force of the TRIPS agreement (Article 61) which lays down minimum provisions on means of enforcing trade-related IPRs. These include the implementation of criminal procedures and criminal penalties, but there are still major disparities in the legal situation in the Community which do not allow the holders of IPRs to benefit from an equivalent level of protection throughout the Community.

In July 2005, the European Commission presented the double proposal for a Directive and a framework decision to strengthen the criminal law framework to combat Intellectual Property offences[26]. It is often called IPRED2, *Second Intellectual Property Rights Enforcement Directive*.

The Commission has adopted on April 26, 2006[27] a proposal for a directive to combat Intellectual Property offences that amends the proposal approved by it on 12 July 2005. It is thus responding to the Court ruling of 13 September 2005 in Case C-176/03, according to which criminal law provisions necessary for the effective implementation of Community law are a matter for Community law. Consequently, the framework decision was withdrawn and its provisions have been carefully integrated in the modified directive's proposal.

The proposed directive shall apply to all types of crime related to infringements of IPRs.

As with the 2004 IPR directive, the current proposal embraces all, IPRs, entailing a horizontal disposition.

Article 3 obliges Member States to consider all intentional infringements of an IPR on a

commercial scale as a criminal offence, whether it is an actual infringement, an attempt at infringement, or aiding and abetting or inciting such an offence.

Article 4 concerns penalties: besides imprisonment (4 years for infringements committed by a criminal organization or which entail a severe risk for public health and security) for natural persons (as defined in Article 2), the Directive lays down a range of penalties to be imposed on both natural and legal persons, such as fines and the seizure of goods belonging to the offender, including the infringing goods and the materials, implements or media used predominantly for the manufacture or distribution of the goods in question. The fine should be at least of 100,000 EUR or 300,000 EUR, in case there is a proven link with a criminal organization or a risk for public health and security. The proposal lets Member States make harsher provisions in case a risk for serious counsequences, as consumers' death or infirmity, arises.

In October 2006 the *Justice and Home Affaire Council* discussed the proposal of the Commission, underlining the subsidiarity principle and adding that the harmonization of criminal law should be the last tool[28].

In April 2007[29] the European Parliament voted the Directive with a series of amendments: for example, to exclude private individuals from the scope of the Directive, so long as they do not generate any profit from the use of the product. Smaller offences will also remain under national civil law.

Patents on inventions have also been left out of the Directive on the basis that such breaches are more difficult to verify and that civil law remains the most appropriate instrument for prosecuting this type of infringement.

Currently the text is waiting to be read by the European Council (to get the "common position").

The Directive will come into force only if approved by Member States.

Since counterfeiting is such a dangerous and always increasing phenomenon, counterfeiting of medicines is specifically one of the greatest concerns for international legislators. This particular kind of pharmaceutical crimes, often executed by various types of criminal organizations, shows its severity in affecting the weakest subjects, such as people affected by serious pathologies, with a range of consequences from grave health complications to lethal effects.

The Council of Europe has shown always more commitment in fighting counterfeiting and it is currently working on the preparation of a binding international agreement to further facilitate inter-state cooperation[30]. Currently there are some main Council of Europe bodies that are dealing with this issue: the *Committee of Experts on Pharmaceutical Questions* (P-SP-HP) and its *Ad hoc Group on Counterfeit Medicines*[31], the *European Directorate for the Quality of Medicines*[32] (EDQM) and the *European Committee on Crime Problems* (CDPC).

Notes

1 Some countries adhere only to the Madrid Agreement or to the Madrid Protocol while others, including Italy, are members of both.

2 The cost related to the filing of Marks at the International Bureau of Intellectual Property is usually inferior to the amount deriving from the sum of all the national registration fees that ought to be paid in case of single registration in different countries.

3 Paris Act of July 24, 1971, of the Berne Convention for the Protection of Literary and Artistic Works, 1886.

4 For the purpose of the WIPO Treaty, Rights Management Information means: "information which identifies the work, the author of the work, the owner of any right in the work, or information about the terms and conditions of use of the work, and any numbers or codes that represent such information, when any of these items of information is attached to a copy of a work or appears in connection with a communication of a work to the public". WIPO Copyright Treaty, art. 12 (2).

5 EU legislation actually into force: 1.COPYRIGHT: Council Directive 91/250/EEC of 14 May 1991 on the legal protection of computer programs (Official Journal of the EU L 122, 17/05/1991 p. 42); Council Directive 92/100/EEC of 19 November 1992 on rental right and lending right and on certain rights related to copyright in the field of intellectual property (Official Journal of the EU L 346, 27/11/1992 p. 61); Council Directive 93/83/EEC of 27 September 1993 on the coordination of certain rules concerning copyright and rights related to copyright applicable to satellite broadcasting and cable retransmission (Official Journal of the EU L 248, 06/10/1993 p. 15); Council Directive 93/98/EEC of 29 October 1993 harmonizing the term of protection of copyright and certain related rights (Official Journal of the EU L 290, 24/11/1993 p. 9); Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases (Official Journal of the EU L 77, 27/3/1996, p. 20); Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society (Official Journal of the EU L 167, 22/6/2001, p. 10) ; Directive 2001/84/EC of the European Parliament and of the Council of 27 September 2001 on the resale right for the benefit of the author of an original work of art (Official Journal of the EU L 272, 13/10/2001, p. 32); 2. INDUSTRIAL PROPERTY: -Patents & Supplementary protection certificates- Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (Official Journal of the EU L 213, 30/7/1998, p. 13); Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (Official Journal of the EU L 182, 02/07/1992, p. 1); Regulation (EC) No 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products (Official Journal of the EU L 198, 08/08/1996, p. 30); Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for pediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Official Journal of the EU L 378, 27/12/2006, p. 1), amended by Regulation (EC) No 1902/2006 of the European Parliament and of the Council (Official Journal of the EU L 378, 27/12/2006, p. 20); Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (Official Journal of the EU L 157, 09/06/2006, p. 1) ;-Industrial designs- Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs (Official Journal of the EU L 289, 28/10/1998, p. 28); Council Regulation (EC) No 6/2002 of 12 December 2001 on Community designs (Official Journal of the EU L 3, 05/01/2002, p. 1), amended by Council Regulation (EC) No 1891/2006 of

December 18 2006 (Official Journal of the EU L 384, 29/12/2006, p. 79); Commission Regulation (EC) No 2245/2002 of 21 October 2002 implementing Council Regulation (EC) No 6/2002 on Community designs (Official Journal of the EU L 341, 17/12/2002, p. 28); Commission Regulation (EC) No 2246/2002 of 16 December 2002 on the fees payable to the Office for Harmonization in the Internal Market (Trade Marks and Designs) in respect of the registration of Community designs (Official Journal of the EU L 341, 17/12/2002, p. 54); -Trademarks-First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks (Official Journal of the EU L 40, 11/2/1989, p. 1); Council Regulation (EC) No 40/94 of 20 December 1993 on the Community trade mark (Official Journal of the EU L 11, 14.1.1994, p. 1), amended by Council Regulation (EC) No 422/2004 of 19 February 2004 (Official Journal of the EU L 70, 09/03/2004, p. 1); Commission Regulation (EC) No 2868/95 of 13 December 1995 implementing Council Regulation (EC) No 40/94 on the Community trade mark (Official Journal of the EU L 303, 15.12.1995, p. 1), amended by Commission Regulation (EC) No 1041/2005 of 29 June 2005 (Official Journal of the EU L 172, 05/07/2005, p. 4); Commission Regulation (EC) No 216/96 of 5 February 1996 laying down the rules of procedure of the Boards of Appeal of the Office for Harmonization in the Internal Market (Trade Marks and Designs) (Official Journal of the EU L 28, 6.2.1996, p. 11), amended by Commission Regulation (EC) No 2082/2004 of 6 December 2004 (Official Journal of the EU L 360, 07/12/2004, p. 19); Commission Regulation (EC) No 2869/95 of 13 December 1995 on the fees payable to the Office for Harmonization in the Internal Market (Trade Marks and Designs) (Official Journal of the EU L 303, 15/12/2002, p. 33), amended by Commission Regulation (EC) No 1687/2005 of 14 October 2005 (Official Journal of the EU L 271, 15/10/2005, p. 14).

6 WIPO Performances and Phonograms Treaty (WPPT), adopted in Geneva on December 20, 1996.

7 Art. 2 "Member States shall provide for the exclusive right to authorise or prohibit direct or indirect, temporary or permanent reproduction by any means and in any form, in whole or in part: a) for the authors, of their works; b) for performers, of fixations of their performances; c) for phonogram producers, of their phonograms; d) for the producers of the first fixations of films, in repsect of the originals and copies of their films; e) for broadcasting organizations, of fixations of their broadcasts, whether those broadcasts are transmitted by wire or over the air, including by cable or satellite." EU Copyright Directive.

8 These exceptions and limitations include: use for the sole purpose of illustration for teaching or scientific research, indicating the source and including the author's name; reproduction by the press, communication to the public or making available of published articles on current economic, political or religious topics, as long as the source, including the author's name, is indicated; quotation for purposes such as criticism or review, provided that they relate to a work which has already been lawfully made available to the public and that the source, including the author's name, is indicated, and that their use is in accordance with fair practice, and to the extent required by the specific purpose; uses, for benefit of people with a disability, directly related with the disability and that are not of a commercial nature; use for purposes of public security or to ensure the proper performance or reporting of administrative, parliamentary or judicial proceedings. EU Copyright Directive.

9 These measures are deemed effective only in the case in which the use of a protected work is controlled by the right holder through application of an access control or protection process which achieves the protection objective, such as encryption or a copy control mechanism.

10 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of Intellectual Property Rights.

11 Council Regulation (EC) No 183/2003 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.

12 Updated at 20 August 2007. The exam of the national implementation of the EU legislation was completed by direct consultations with some of the EU Member States.

13 Europe, Press Release, IP/06/1354.

14 The non-mandatory provisions of the Directive are contained in the IP (Miscellaneous Provisions) Bill.

15 "Attuazione della Direttiva n. 2004/48/CE sul rispetto dei diritti di proprietà intellettuale ", published on Gazzetta Ufficiale of 7 April 2006, n. 82.

16 Law 168/2003 created 12 Specialized Sections of Tribunals (Bari, Bologna, Catania, Firenze, Genova, Milano, Napoli, Palermo, Roma, Torino, Trieste e Venezia). These courts, also defined as "Community marks and patents' tribunals" have jurisdiction not only for marks, patents, utility models, new plants' varieties, designs, models and copyrights, but also for all others industrial property rights as defined by the new Code, as, for example, geographic indications, names of origin, distinctive signs others than marks, etc.

17 Arts.1-13 of Decree n.140/2006.

18 CPI-legislative decree 10 February 2005 n. 30, entered into force on 19 March 2005.It harmonizes in one text the legislation on marks, patents, models and reserved information. Arts.14-21 of Decree n.140/2006.

19 Arts.10 and 15 of the Directive.

20 Art.13 of the Directive.

21 Consultation of the Supreme Court of Lithuania on February 22, 2002.

22 Law 258/2004 tried to harmonize the Law in force with the European Directives and WIPO treaties.

23 This instrument implement the following communitarian acts: (a) Directive of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights (2004/48/EC) (OJ L157, 30.4. 2004 p.45, a corrigendum was published in OJ L195, 2.6.2004 p.16) ("the Enforcement Directive"); (b) Agreement establishing the World Trade Organisation (including the Agreement on Trade-Related Aspects of Intellectual Property Rights (Cm. 3044-6, 3080, 3263-4, 3268-9, 3271, 3275-7 and 3282) ("TRIPS") which was specified as a Community treaty by SI 1995/265; (c) Directive of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs (98/71/EC) (OJ L289, 28.10.98 p. 28) ("the Designs Directive"); (d) Council Regulation of 12 December 2001 on Community designs (EC) Regulation No. 6 of 2002 (OJ. L3, 5. 1. 2002 p.1) ("the Community Design Regulation"); and (e) European Economic Area Agreement ("EEA Agreement").

24 Schedule 1, section 24F of Regulations directly amends the Registered Designs Act 1949 .

25 Recital 28, Directive 2004/48/EC: "in addition to the civil and administrative measures, procedures and remedies provided for under this Directive, criminal sanctions also constitute, in appropriate cases, a means of ensuring the enforcement of intellectual property rights."

26 COM (2005) 276 final, July12, 2005, Proposal for a EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE on criminal measures aimed at ensuring the enforcement of intellectual property rights- Proposal for a COUNCIL FRAMEWORK DECISION to strengthen the criminal law framework to combat intellectual property offences {SEC(2005)848}.

27 COM/2006/0168 final, Amended proposal for a Directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights.

28 Council Justice and Home Affairs: Criminal measures aimed at ensuring the enforcement of intellectual property rights (5 - 6 October 2006), p.23.

29 European Parliament legislative resolution of 25 April 2007 on the amended proposal for a directive of the European Parliament and of the Council on criminal measures aimed at ensuring the enforcement of intellectual property rights (COM(2006)0168 – C6-0233/2005 – 2005/0127(COD)).

30 European Committee on Crime Problems, Feasibility Study for a Council of Europe Convention on Counterfeit Medicines/Pharmaceutical Crime, Document prepared for the Directorate General of Legal Affairs, Strasbourg, 5 January 2007. Please, see also the recommendation to the European Parliament of April 2007: Recommendation 1794 (2007), The quality of medicines in Europe.

31 It is based on a Partial Agreement of 18 Member States, but it's open to everybody.

32 It provides the European Pharmacopeia, which standardize medicines at the international level.