

2. The Means

The Art of Multiplying Visible and Invisible Markings

There are different ways to combat counterfeiting. From the use of simple holograms to ultra-sophisticated and invisible technologies, anti-counterfeiting techniques today cover different levels of security based on drug companies' requirements. "There is both a need for tamper-evident packaging as well as product authentication along the supply chain," says Paul Julia, Trade and Marketing Manager at CCL Label. "In the field of anti-counterfeiting," he adds, "the trend is to mix visible and invisible markings on the packaging to ensure correct and quick identification at borders thanks to one and increased safety thanks to a second level of verification."

Levels of Security

To illustrate, CCL Label has developed a safety label for the erectile dysfunction (ED) drug, Viagra (sildenafil), from Pfizer in the United States, which combines three anti-counterfeiting technologies. Among these is the latest CCL Label's SecureShift, an ink that has been used for many years for securing the printing of currency and passports. It uses Optically Variable Pigment technology, which can be used on labels and packagings such as blisters, boxes, closures, including foil induction seals, shrink sleeves and molded plastics. To add, Pfizer has also put on each Viagra box labels a RFID (Radio Frequency Identification) tag, following an initiative by UK's GSK which has begun placing security tags on all bottles of its HIV medicine, Trizivir, distributed in the United States. The National Association of Boards of Pharmacy listed GSK's HIV treatment as one of 32 medicines most prone to possible counterfeiting and diversion. Both initiatives follow the FDA's (Food And Drug Administration) call for the pharmaceutical industry to develop RFID-related processes, which the US regulatory body promotes as a general tool in years to come to deter counterfeiting. In Europe, the Finnish Orion Pharma is now adopting a strategy and communicating openly on it which aims to replace classical barcodes on its drug products with RFID tags. The current trial targets the drug maker's Marevan bottles for tracking in the

Scandinavian countries. If traceability becomes mandatory in the US, the company is convinced that it would have to add RFID tags to all its packages sold on the US market.

The Whole Supply Chain

According to Kirsi Viskari, Manager of Intelligent Solutions at Stora Enso, the Helsinki-based paper packaging company which participates in Orion Pharma's trial, the Orion Pharma pilot project has an exceptional scope as it covers the whole supply chain, all the way from the product and packaging manufacture to wholesale and consumer distribution. Real-time tracking and authentication of the products increases the safety, reliability and efficiency of the supply chain. It is true that RFID projects cover much more than anti-counterfeiting targets, and also offer interesting tracking services. However, there are still many obstacles to a more generalized use of RFID on a large scale, including the difference in standards between the US and Europe and the cost associated with adopting the required infrastructure.

Some prefer to go with proprietary technology such as those at ATT (Lamy) which has already been chosen by Packart and Rotanotice (Ileos) for their folding cartons and leaflets, but also Bopack for pharmaceutical labeling. According to ATT, the integration of three codes in the pre-press files of a packaging – a classical bar code, a DataMatrix and a Seal Vector, which contains the identity of the company – guarantees product identification up to the final step. Finally, any pharmacist store can authenticate a product while scanning the packaging Seal Vector and compare it to the original data mentioned on the drug company's website.

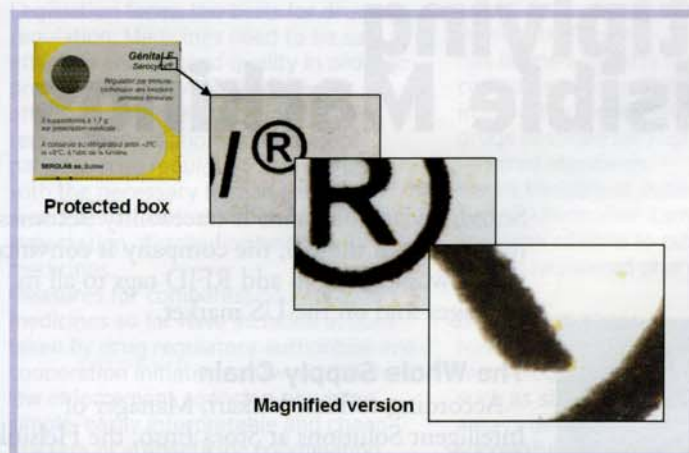
Invisibility and Transparency

Invisible to the eye and transparent in its integration on industrial processes – these are the two adjectives which characterize today's advanced anti-counterfeiting technologies. The Cryptoglyph technology from Alp Vision is one noteworthy example. Frederic Jordan and Martin Kutter founded the company in 2001 in the field of digital security printing and data security.



MIXING OVERT AND COVERT FEATURES
Schreiner ProSecure's SecuMed labels combine options of seven security features to prevent product anti-counterfeiting. For overt features, holograms and color-shifting inks are used along with holographic strips customized with 2D or 3D effects, dynamic structures and micro or nano texts. Other features use color-shifting films and thermo-reactive inks which change color when in contact with body heat. In complement, covert features include digital watermarks and specific UV luminescence, invisible pigments and traceless taggants.

Technology CRYPTOGLYPH TECHNOLOGY IN 3 POINTS



The technology patented by Alp Vision has successfully been integrated into blisters. The Swiss company is currently studying its application to glass vials.

1) INVISIBLE MICRO-POINTS

The Crypto (=encryption) glyph (=marks) technology from Alp Vision consists of the printing of invisible micro-points over the entire surface of the primary or secondary packaging, such as the blister foil, which are impossible to replicate or erase. These micro-points contain encrypted information which can be only deciphered by using the encrypted key. The micro-points are invisible to the eye and are integrated into the package design before printing.

2) DETECTION SOFTWARE

They are camouflaged within the imperfections found in all printed material structures, which is one of the unique aspects of the patented technology. The detection software is based on advanced signal detection capabilities that have very low-signal-to-noise ratios and built-in conceptual redundancies.

3) SIMPLE SCANNING BY MOBILE PHONE

The detection process can be performed using a standard flatbed scanner or even using a mobile phone equipped with a digital camera. To avoid having the encryption key made available in the field, a digital image of the packaging is sent to a processing system located in a secured area, via mobile transmission networks. Once analyzed in this safe and secured area, the result is sent back to the field controller via SMS or another modern communications means. This two-way communication process ensures the full security of the encryption system and allows instant consolidation of the field track and trace verification tests.



Their idea was to hide invisible information inside digital images and apply the techniques on an industrial printing scale. Hence the name Cryptoglyph (Crypto = encryption, glyph = marks). The originality? The invisible marking is enabled through the use of visible ink on standard printers (offset, rotogravure, digital printing, etc.). As a result, the micro-encrypted points are difficult to distinguish in the material, even with a magnifying glass, as the dots are confused with the imperfections found in all printed material structures. Today, industrial printers like Constantia Packaging and Rondo,

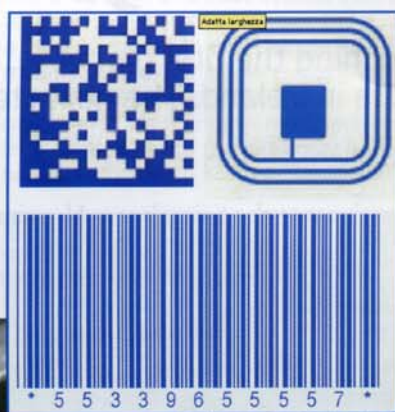
in the field of blister foils, have already added Cryptoglyph to their security processes. According to Alp Vision, the technology surpasses other technologies such as the 2D DataMatrix bar codes because, by definition, the bar code requires contrasts in visible black-and-white and other covert and overt features as it does not require any special security element as special ink, tag or the like. To go a step further, Alp Vision is currently working on laser gravure printing adapted to glass vials to enlarge its technology's applications.

MARION BASCHET-VERNET

RFID

ORION PHARMA'S RFID TAGGING ON BOTTLES

In cooperation with Stora Enso, the Finnish drugmaker is testing individual RFID (Radio Frequency Identification) tracking for its Marevan bottles, an anticoagulant sold globally to treat blood clots, as they move from the factory to the patient-consumer.



1) RFID LABELING

Stora Enso is working with Finland's Orion Pharma to individually RFID tag its Marevan bottles of drugs. In the beginning, the Finnish packaging manufacturer, Jaakoo-Taara, attached UMP Raflatac 13.56 MHz passive tags to the individual bottles, to the interior bottom of the paper cartons. When Orion Pharma fills the bottles with pills at its production site, it encodes each tag with a unique serial number for the carton, as well as the batch number and the expiry date for the medicine. Then handheld wireless RFID readers from Piccolink and equipment from Feid Electronic participate to encode the tags at its factory. Once a batch of drugs is ready for shipment, individual items are packed in cases and an 868 MHz Raflatac Dipole passive UHF RFID tag is applied to each case encoded with a unique ID number.

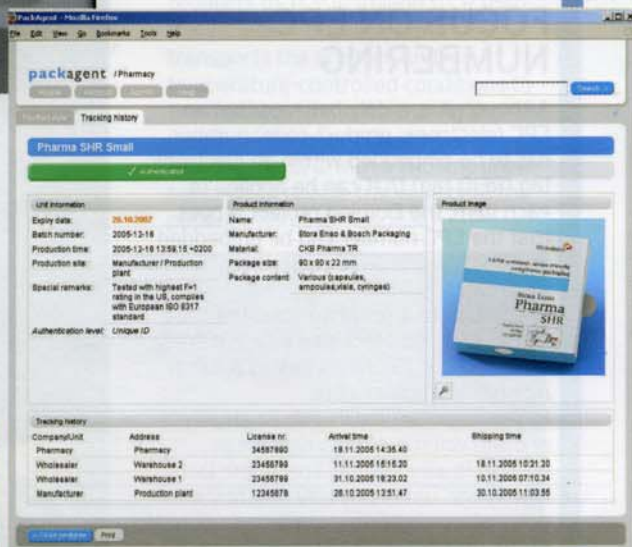
2) KEEPING TRACK OF THE SERIAL NUMBER

Matching information about the contents of each case is kept in the PackAgent software of Stora Enso, which helps identify the cartons throughout the supply chain by identifying each tag's serial number. Prior to shipping the cases from its facilities, Orion reads the case tags to keep track of where each batch is going. At this reading in the distribution chain, data is transferred to PackAgent software, either via a WLAN or a cable connection directly to a PackAgent server or by means of an Internet connection linked to the server.



3) AT THE WHOLESALER'S

When the case arrives at the facilities of the wholesaler Oriola (Orion Group), a portal reader SAMSys Technologies reads the case tags. The data is then sent to the PackAgent software to authenticate the products and record their location. Oriola distributes to pharmacies in Finland, with a separate subsidiary delivering the drugs to Estonia. For this trial, cases for shipping were designed to hold the approximate amount of medicine required by each pharmacy, allowing Oriola to store cases without unpacking them while awaiting the pharmacies' orders. As each order comes in, Oriola pulls the requested quantity from storage, reading the case tags as the order leaves its facilities.



4) IN THE PHARMACIST STORE

The pharmacies unpack the individual bottles from the cases using a desktop RFID reader to read the HF tag attached to each bottle's carton to make certain the correct package has been delivered to the right place. At the point of sale, the pharmacist reads the carton's tag one last time to authenticate the drug.

