An Integrated Approach to Preventing Counterfeits in Defense Supply Chains

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Some Counterfeits Are Easier To Spot Than Others

......Did they mean Adidas?
Other Counterfeits are Almost Impossible to Visually Detect

Counterfeit duplication of the packaging for an injectable drug.
COUNTERFEIT. Despite its impressive resemblance to the real pills on the right, the fake Lipitor on the left likely contains little to no active ingredients, putting patients at risk of conditions such as heart disease. In 2003, the U.S. Food and Drug Administration ordered at least 100,000 bottles of Lipitor recalled after consumers complained about bitter-tasting pills, which turned out to be fakes, and large recalls were ordered in Britain in 2005 and 2006.
Approved Fosamax  Counterfeit Fosamax

FOSAMAX®
ONCE WEEKLY 70 mg TABLETS
4 tablets

FOSAMAX®
ONCE WEEKLY 70 mg TABLETS
4 tablets

Source: Merck Chinese Counterfeit Drugs, May / June 2006
Pfizer Is Using RFID to Fight Counterfeit Viagra
An advertisement for a fake iPhone that is being sold in China.
Technological advances have allowed hundreds of small Chinese companies, some with as few as 10 employees, to churn out what are known here as shanzhai, or black market, cellphones, often for as little as $35 apiece. This fake Louis Vuitton-branded phone was available at a mobile phone market in Shenzhen, China.
Genuine and Counterfeit Capacitors
A Genuine Circuit Breaker has a white painted amp rating on the toggle switch.

Genuine
Pre-2003 breakers do not have white paint

Counterfeit
A’PEXi is concerned about the potential damage that the counterfeit Turbo Timers may cause. Poor circuit design, incomplete programming, use of inferior materials, and inconsistent manufacturing processes could lead to car malfunction, short circuits, electrical fires, electrocution, and possible physical injury and are not recommended for use.

Key features of the A’PEXi Auto Timer, such as the Parking Brake Safety Protection and Air/Fuel Ratio Monitor functions are non-operational on the counterfeit units.
Cover Page News: Counterfeits in Defense Supply Chains
Pervasive & Dynamic Problem

- Cuts Across Industries
- Impacts Low Value and High Value Products
- Affects Low-Tech and High-Tech Products
- Dynamic and Evolving Battle of Wits
  - “Trying to Stay One Step Ahead”
- A Multi-Pronged Approach Seems Strongest
Multi-Vectored Approaches

- Material & Parts Assurance and Counterfeit Protection
- Chain of Custody ePedigree
- Trusted Supplier Programs
- Technologies
  - Markings
  - Serialization
  - Entry-Exit Testing
  - Track & Trace
The First Leg:
Trusted Supplier Programs

• DMEA
  • Trusted Foundry
  • Trusted IC

• Purchase from Original Manufacturer or from Distributor, Reseller or Aftermarket Supplier Who is Authorized or Franchised by Original Manufacturer

• Independent Brokers Must Sometimes Be Used
  • Traceability and Custody Documentation
  • Testing, Inspection, Analysis
  • Purchasing Processes
The Second Leg: Anti-Counterfeiting Technologies
Path to Success

- Solution must be appropriately chosen
  - Robustness, longevity, acceptable cost;
- Solution must be effectively promoted in marketplace; Customers Must be Aware;
- Technology must be implemented at appropriate level
  - Implemented at the most elemental level, saleable unit.
Anti-Counterfeiting Technologies

• Packaging, Marking & Seals
  • Holograms and security seals;
  • Overt and hidden images;
  • Package modification.

• Taggants
  • Forensic Taggants
    • Optical taggants
    • Chemical taggants
    • Nanotaggants

• Mass Encoding
  • Digital Mass Serialization: Human Readable/Barcode/RFID
  • Digital Mass Encryption: Human Readable/Barcode/RFID
  • Serialization With ePedigree: 2D Barcode/RFID
  • Serialization With EPCIS: 2D Barcode/RFID
Five Criteria for Success

- Customer empowerment;
- Cost and value;
- Forensics and interdiction;
- Simplicity and adaptability; and
- Value added features.
<table>
<thead>
<tr>
<th>Package, Markings, Seals</th>
<th>Consumer Empowerment</th>
<th>Cost and Value</th>
<th>Forensics and Interdiction</th>
<th>Simplicity and Adaptability</th>
<th>Valued Added Features</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Marginal To Fail</td>
<td>Pass</td>
<td>Fail</td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>Taggants</td>
<td>Fail</td>
<td>Fail</td>
<td>Pass</td>
<td>Mixed</td>
<td>Mixed</td>
</tr>
<tr>
<td>DMS DME ePedigree EPCIS</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
<td>Pass</td>
</tr>
</tbody>
</table>
Value Added
Investment Required

Minimal Counterfeit Protection: Markings/Packaging

Moderate Counterfeit Protection: Serialization/Entry-Exit Testing

Heightened Counterfeit Protection: Serialization/ePedigree Supply Chain History

Maximum Counterfeit Protection: Serialization/RFID Supply Chain Visibility/Configuration Management

Superior Counterfeit Protection: Serialization/RFID/EPCIS Supply Chain History
A Basic Approach Using Serialization

- Unique Serialization
- Entry and Exit Point Validation
- Provides Increased Protection in Near-Term
- Does Not, However, Contribute to Supply Chain Visibility
A Basic System

- Based on item level serialization.
- Encrypted serial numbers carried by 2D matrix barcode and/or human readable.
- Serial number is created at “Point of Entry” (manufacturer) and validated at “Point of Exit”.
- Serial number is validated by manufacturer when queried by Exit Point. (Can be done by email, web access, text message, etc.).
- Represents the most basic and straightforward approach to securing the supply chain.
- Other approaches can build on this system by adding track and trace and pedigree features.
Reference Implementations

• Philip Morris International
  • Law enforcement agencies, companies and consumer can authenticate packages of cigarettes.
  • 12 digit unique bar code is printed on the pack.
  • Codes can be transmitted and verified using telephone, text message, email and web-sites.
  • PMI does not store the code, but provides decoding of the code.

• Roche India has implemented mass serialization anti-counterfeiting technology, using bar codes.
  • Consumer confirms the authenticity of the product.
  • Every unit of sale has 16 digit alpha-numeric security code.
  • SMS(text message) or email is used for authentication.
  • Roche maintains the database of the unit codes.
Basic System Summary

• Provides mass serialization approach to prevent counterfeiting.
• Cost-effective solution as compared to other alternatives.
• Reference implementations available from pharmaceutical and non-pharmaceutical industries.
• Barcode based solution is very cost competitive to RFID.
Track and Trace Technology
Overview of Approach

• Two Pronged Attack Builds On IUID;
• 2D Barcode Data Matrix and/or RFID;
• Track and Trace System with Search Capability;
• The Third Leg: ePedigree for Backup Assurance of Historical Path.
The basic concept is for every object in the program to be uniquely identified and maintained

Physical Information
Bill of Materials
• Manufacturing work centers
• Raw material used
• Sub-components used
Location
Condition
Testing results
certifications

Component Information
Production routing
Component heritage
Raw materials heritage
Certification BOMs
Manufacturing SPC / SQC data
Manufacturing video
Design documents
Version controls

Programmatic Information
Timeline / schedule
Budget
Dependencies
Sourcing
Certifications
Contractual deliverables
Enterprise Operating Model
Master Scenarios

An object BOM (Bill of Material) is a compilation of all the activities and materials relevant to the object.

Object BOM

An Information BOM is the compilation of all the relevant documents related to an object.

Information BOM

Every activity and movement relevant to the object generates an information document.

Material BOM

Component BOM

Sub Assembly BOM

Assembly BOM

Manufacture BOM

Certification

Training Materials

Testing Outputs

Equipment Plans

Plans

Example Widget: #110056
System Structure With Nodes at Suppliers

Data Vault

The publish & subscribe information network
Enterprise Participant Concept

- MDA
- MainStreet Applications System Ops / Admin
- Prime
- Tier 1 Supplier
- Tier 1 Supplier
- Tier 1 Supplier
- Tier 2 Supplier
- Tier 2 Supplier
- Tier 2 Supplier
- Tier 2 Supplier
- Tier 3 Supplier
- Tier 3 Supplier
- Tier 3 Supplier
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Ability to Track and Trace for Control Decreases
The Third Leg:
Electronic Digital Pedigrees
Secure Digital ePedigree

Signed manufacturer pedigree
(Initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)

Secure Nested XML Pedigree Standard
Established by GS1/EPC Global
ePedigree Is Built Up As Part Moves Through Supply Chain
<table>
<thead>
<tr>
<th>Product Information</th>
<th>Pedigree Serial Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transmitter</td>
<td>Terific Transceivers</td>
</tr>
<tr>
<td>License Number</td>
<td>01-00001 NC</td>
</tr>
<tr>
<td>Transaction Number</td>
<td>2479006700054</td>
</tr>
<tr>
<td>Date of Transaction</td>
<td>02 Oct 2007</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Seller</th>
<th>Quality Missile Parts</th>
</tr>
</thead>
<tbody>
<tr>
<td>License Number</td>
<td>01-00002 FL</td>
</tr>
<tr>
<td>Date of Transaction</td>
<td>23 Oct 2008</td>
</tr>
<tr>
<td>Seller</td>
<td>Missile R Us</td>
</tr>
<tr>
<td>License Number</td>
<td>01-00001 NC</td>
</tr>
<tr>
<td>Date of Transaction</td>
<td>03 Sep 2007</td>
</tr>
</tbody>
</table>

**Lot 004_20091023_153742 Expiration: 01 Jul 2019 Quantity: 1**

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Sample Pedigree
# Pedigree Standard

*Product/Transaction Data in One Secure Source*

## Pedigree Data

<table>
<thead>
<tr>
<th>1. Product ID #</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Serialized Product Title</td>
</tr>
<tr>
<td>3. Lot #</td>
</tr>
<tr>
<td>4. Expiration Date</td>
</tr>
<tr>
<td>5. Exact Quantity</td>
</tr>
<tr>
<td>6. Product Serial #s</td>
</tr>
<tr>
<td>7. Financial Link (Invoice, PO)</td>
</tr>
<tr>
<td>8. Transaction Date</td>
</tr>
<tr>
<td>9. Trading Partner Identification</td>
</tr>
<tr>
<td>10. Transaction Validation</td>
</tr>
</tbody>
</table>

## Pedigree Security

| 1. **Standard, universal format** that supports interoperability, serialization, and future extensions |
| 2. **Digital signatures** to protect each transaction’s integrity and stop people from refuting the pedigree content |
| 3. **Digital certificates** to verify distribution authorization by each party on the pedigree |
| 4. **Self-authentication** for fast, secure chain of custody tests |
1. Pedigree is initiated by Terrific Transistors and signed with a digital certificate issued by an DOD authorized Certificate Authority.

2. Pedigree is received by Quality Missile Parts (QMP) and authenticated. Pedigree system verifies no tampering or adulteration. QMP receiving supervisor certifies the pedigree with his digital signature.

3. QMP sells the part to Missiles R Us (MRU). Prior to shipping the pedigree is digitally signed by QMP’s shipping supervisor.

4. MRU receives pedigree, verifies no tampering/ adulteration and signs the pedigree.

5. MRU transfers product to warehouse-pedigree certification performed as above.

Nested digital signatures
Securing the Pedigree

- Receipt of electronic pedigree by ePedigree system verifies:
  - Current transaction digitally signed
  - Each prior transaction unaltered and digitally signed
  - Signed content includes the original hash and reference to the public key for verification
- Each transaction is electronically authenticated by recipient’s ePedigree system
  - Verify each signature
  - Verify each layer of signed content to ensure it was not altered since digitally signed
  - Each ‘nested’ transaction is signed (certified)
- Each digital certificate is issued to a specific individual representing the organization
ePedigree Transmission & Security

• Secure transmission must provide for document immutability, non-repudiation, and must be secure and authenticated;
• Secure transmission methods such as secure FTP or AS2 are used to send and receive pedigrees between supply chain partners;
• Stored pedigrees contain hashes and digital signatures for compliance, but also guard against unauthorized modification and contain an implicit audit trail; and
• AS2 transport is recommended for transmitting and receiving pedigrees with supply chain partners, providing non-repudiation and message integrity in addition to a secure data stream.
Digital Certificates in ePedigrees

- The digital signatures used in the pedigree schema comply with several of the FIPS (Federal Information Processing Standards) standards;
- An E-Pedigree system should provide the necessary Public Key Infrastructure (PKI) for managing digital certificates used to sign electronic pedigrees for electronic certification of pedigrees. This includes use of X.509 certificates, FIPS 186-2 digital signature system, FIPS 180-2 hash function, and FIPS 140-2 cryptographic module.
- The use of FIPS for the digital signatures qualifies them as legally binding signatures just as if an individual had signed a paper legal document with pen in hand.
- There is an important distinction between digital signatures used to encrypt a document simply to keep it private, and the signatures in an electronic pedigree document, where the signature is used to legally bind an individual or company to the contents of the document.
**ePedigree Is Pushed Forward Through Supply Chain**

ePedigree Does Not Provide Track and Trace Capability But It Provides Important, Secure Documentation of Movement in Supply Chain and Establishes Historical Path and Precludes Entry of Counterfeits.
Summary

• Greater oversight and visibility into the entire supply chain network (SCN) enables true Supply Chain Management;
• Linking of physical assets and supporting documentation enables Product Lifecycle Management;
• Information tracking and secure data storage for all parts and materials supports Product Lifecycle Management;
• Material and part tracking through final assembly supports complete reconciliation of EBOM and MBOM;
• Obsolescence Plan and Technology Refresh Contributes to on-going Readiness;
• Central, secure data repository/vault enables management and oversight; and
• Track and Trace Plus ePedigree Creates High Protection Against Counterfeits