UAHuntsville
THE UNIVERSITY OF ALABAMA IN HUNTSVILLE
Office for Enterprise Innovation and Sustainability

An Integrated Approach to Preventing Counterfeits in Defense Supply Chains

Presented at DMSMS 2009

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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.

Lipitor

Pfizer's blockbuster cholesterol drug is the world's bestselling prescription medicine, with $12.7 billion in sales last year.

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**

Source: Merck Chinese Counterfeit Drugs, May / June 2006
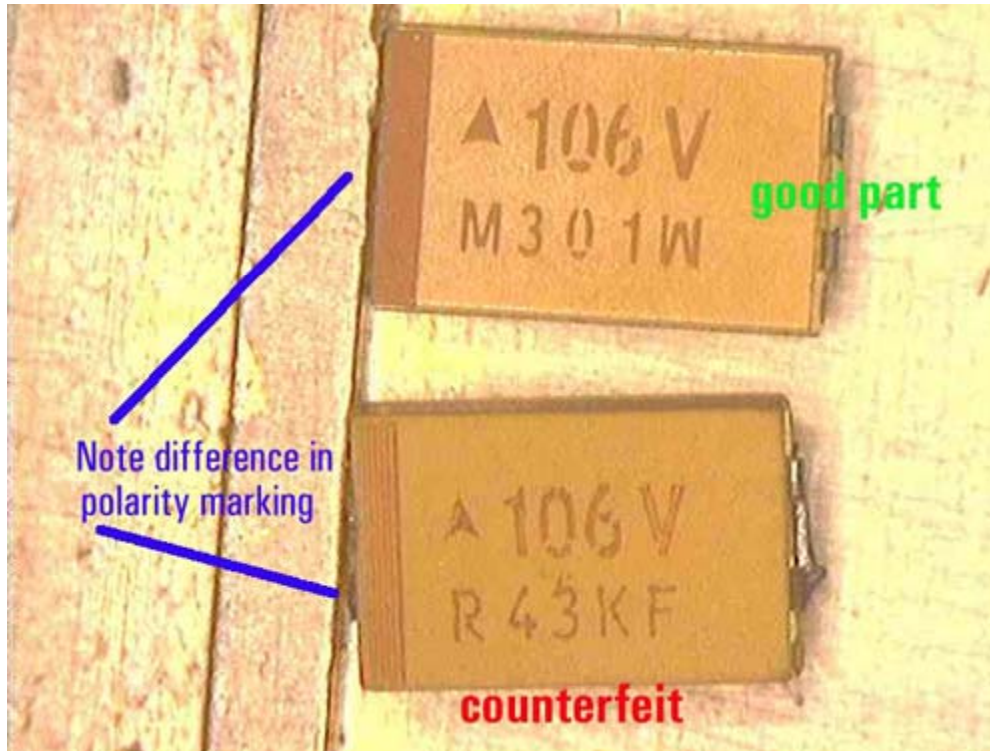
Pfizer Is Using RFID to Fight Counterfeit Viagra

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

Genuine

Pre-2003 breakers do not have white paint

I/ON
20
O/OFF
10 kA
120/240V~

A Genuine Circuit Breaker has a white painted amp rating on the toggle switch.

Counterfeit

I/ON
20
O/OFF
10 kA
120/240V~

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.
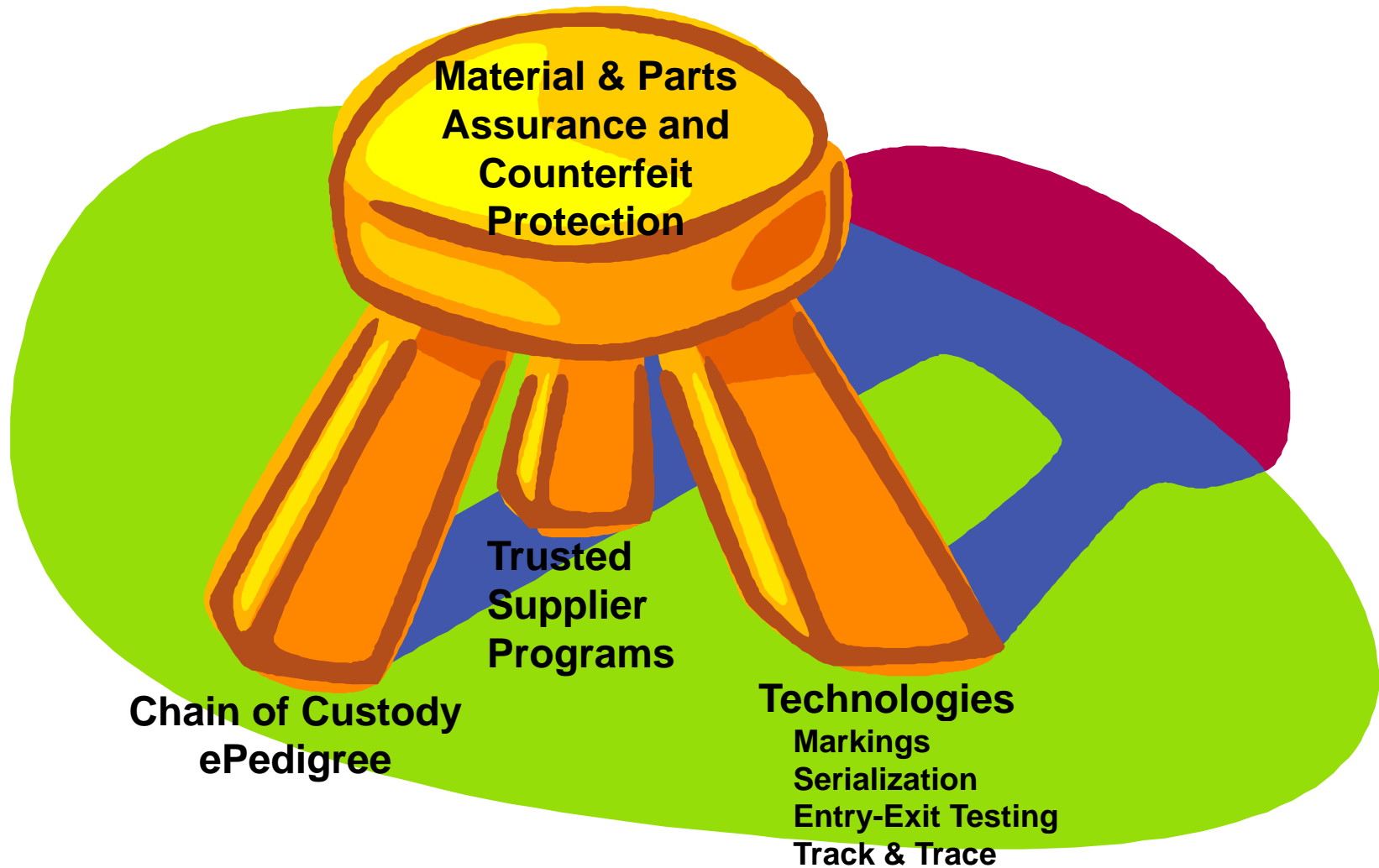
Cover Page News: Counterfeits in Defense Supply Chains

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

Trusted Supplier Programs

Chain of Custody ePedigree

Technologies
Markings
Serialization
Entry-Exit Testing
Track & Trace

14

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.

	Consumer Empowerment	Cost and Value	Forensics and Interdiction	Simplicity and Adaptabilty	Valued Added Features
Package, Markings, Seals	Marginal To Fail	Pass	Fail	Pass	Fail
Taggants	Fail	Fail	Pass	Mixed	Mixed
DMS DME ePedigree EPCIS	Pass	Pass	Pass	Pass	Pass

Unit Value ($) vs. Volume (Annual unit sales)

- DMS/DME/RFID/EPCIS
- DMS/DME/RFID
- DMS/DME/ePedigree/RFID
- DMS/DME/ePedigree/2D barcode
- DMS
- DMS/DME
- Security Marks/DMS
- Security Marks
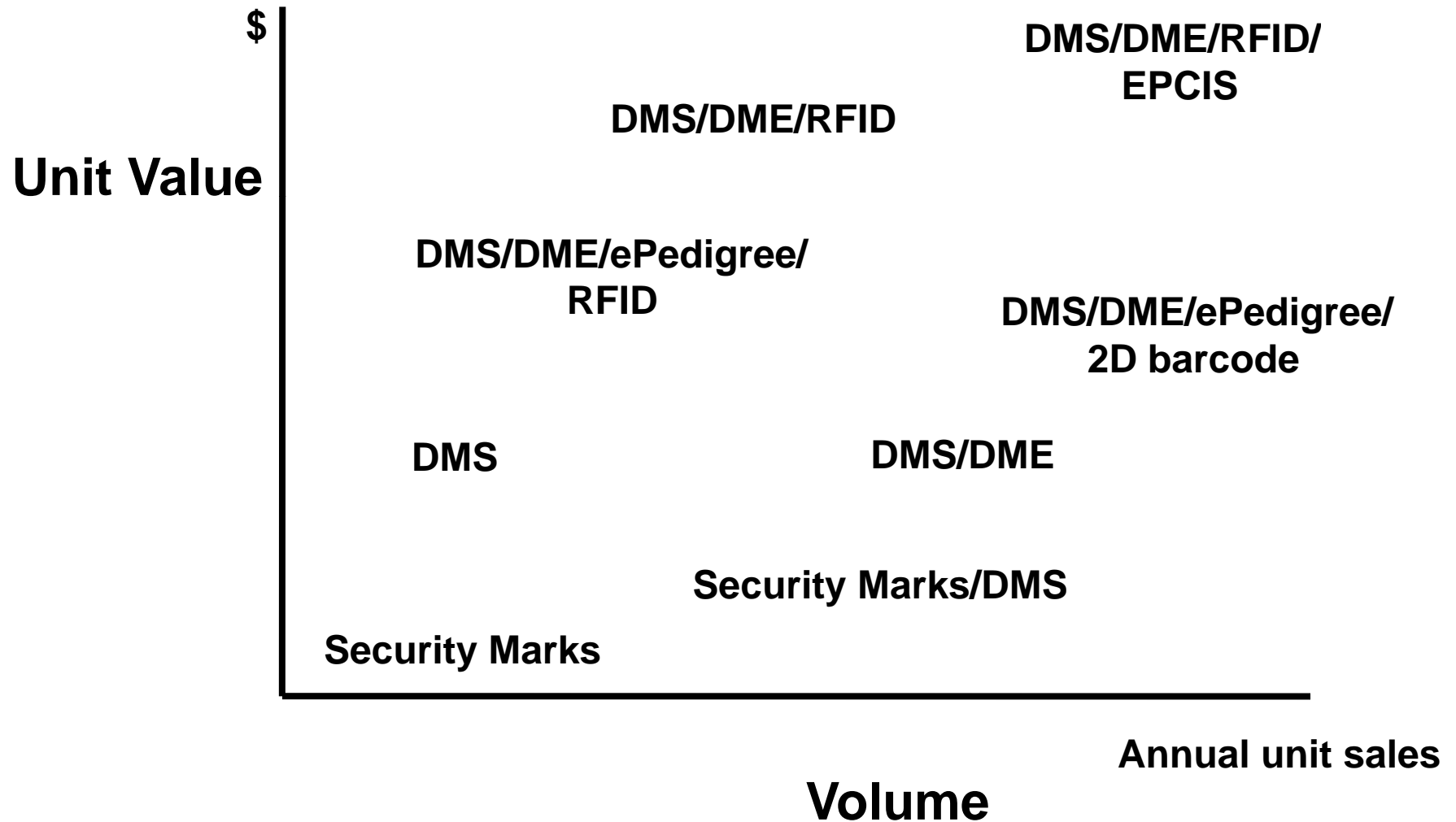
Value Added

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 Visibility

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.

24

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.

25

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

Widget #110056

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

29

Enterprise Operating Model Master Scenarios

Widget #110056

Object BOM

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

Assembly M

Sub Assembly BOM

Component BOM

Manufacture BOM

Material BOM

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

Information BOM

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

Certification

Training Materials

Testing Outputs

Plans

Equipment Plans

System Structure With Nodes at Suppliers

Data Vault

The publish & subscribe information network
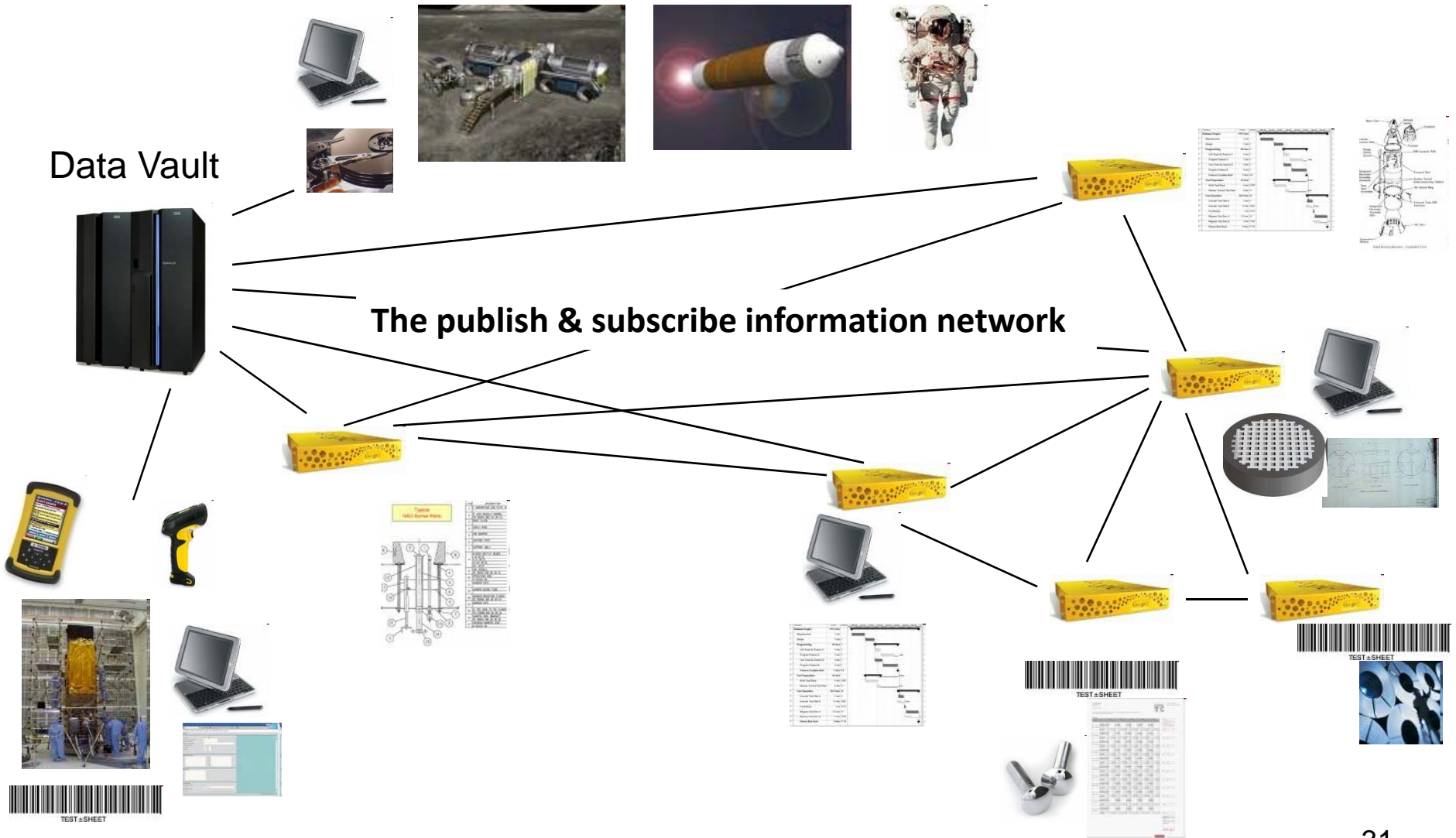
Enterprise Participant Concept
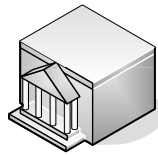
MDA

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   Tier 3 Supplier   Tier 3 Supplier   Tier 3 Supplier

Ability to Track and Trace for Control Decreases
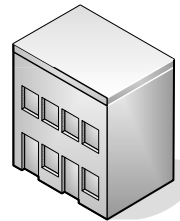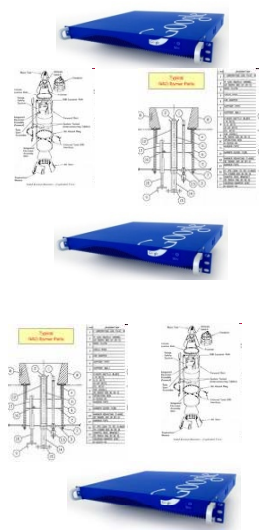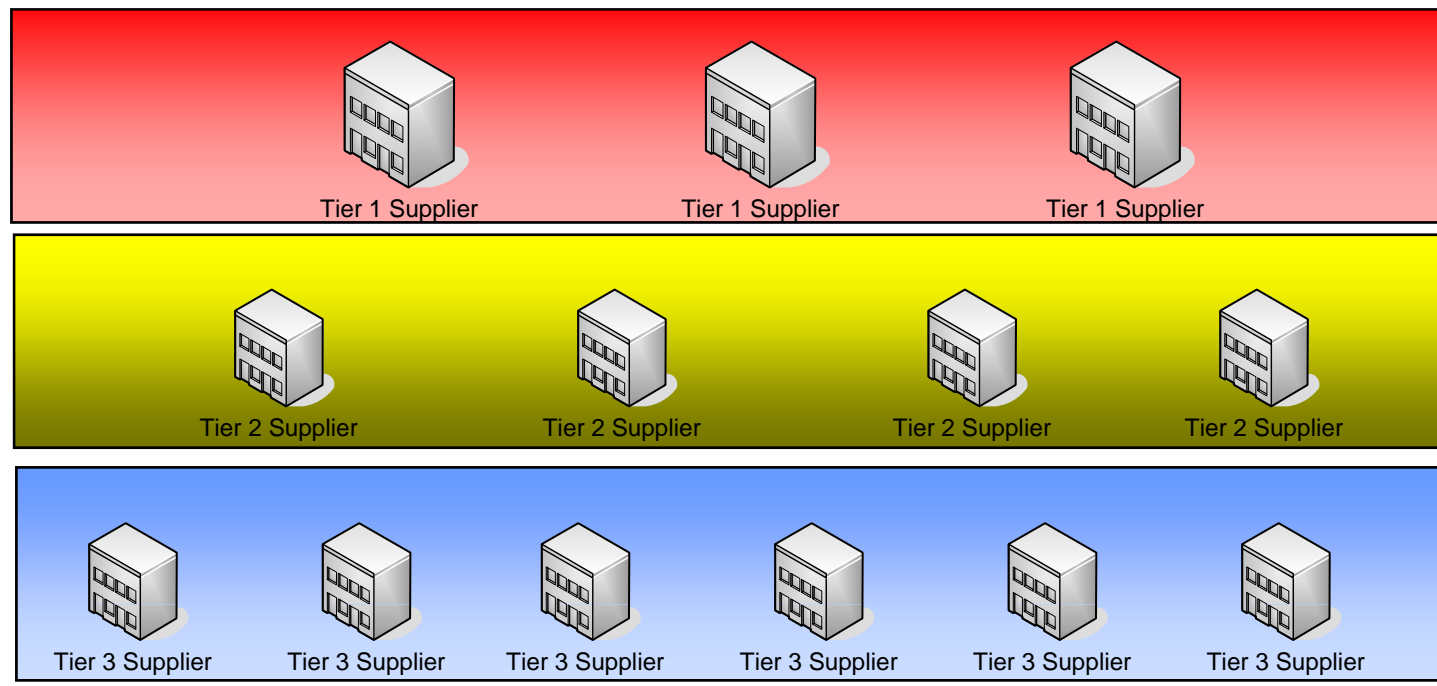
The Third Leg:
Electronic Digital Pedigrees

Secure Digital ePedigree

Signed manufacturer pedigree

(Initiated by manufacturer, after the wholesale distribution, signed by both manufacturer and wholesaler)
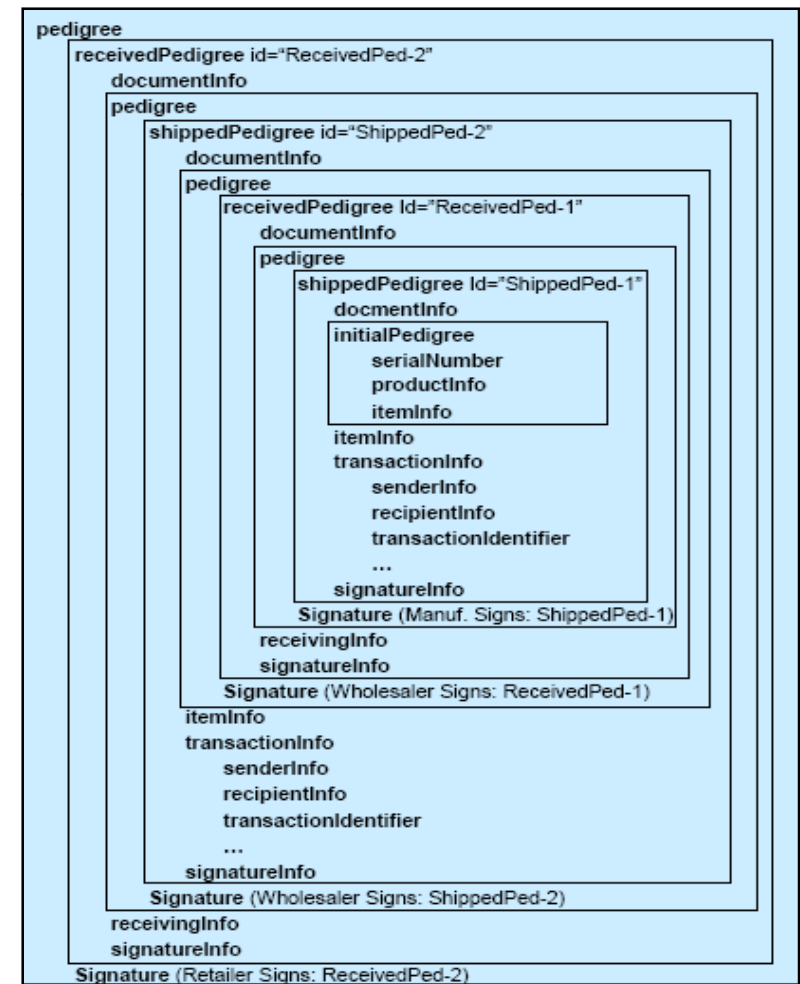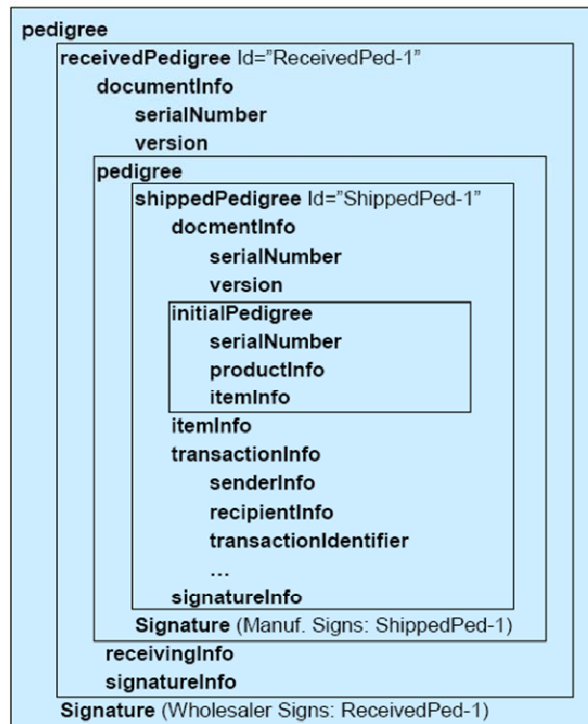
Secure Nested XML Pedigree Standard Established by GS1/EPC Global

Left diagram:
```
pedigree
  receivedPedigree Id="ReceivedPed-1"
    documentInfo
      serialNumber
      version
    pedigree
      shippedPedigree Id="ShippedPed-1"
        documentInfo
          serialNumber
          version
        initialPedigree
          serialNumber
          productInfo
          itemInfo
        itemInfo
        transactionInfo
          senderInfo
          recipientInfo
          transactionIdentifier
          ...
        signatureInfo
        Signature (Manuf. Signs: ShippedPed-1)
    receivingInfo
    signatureInfo
  Signature (Wholesaler Signs: ReceivedPed-1)
```

Right diagram:
```
pedigree
  receivedPedigree id="ReceivedPed-2"
    documentInfo
    pedigree
      shippedPedigree id="ShippedPed-2"
        documentInfo
        pedigree
          receivedPedigree Id="ReceivedPed-1"
            documentInfo
            pedigree
              shippedPedigree Id="ShippedPed-1"
                docmentInfo
                initialPedigree
                  serialNumber
                  productInfo
                  itemInfo
                itemInfo
                transactionInfo
                  senderInfo
                  recipientInfo
                  transactionIdentifier
                  ...
                signatureInfo
                Signature (Manuf. Signs: ShippedPed-1)
            receivingInfo
            signatureInfo
            Signature (Wholesaler Signs: ReceivedPed-1)
        itemInfo
        transactionInfo
          senderInfo
          recipientInfo
          transactionIdentifier
          ...
        signatureInfo
        Signature (Wholesaler Signs: ShippedPed-2)
    receivingInfo
    signatureInfo
  Signature (Retailer Signs: ReceivedPed-2)
```

ePedigree Is Built Up As Part Moves Through Supply Chain

Sample Pedigree

Pedigree Standard

Product/Transaction Data in One Secure Source

Pedigree Data	Pedigree Security
Product and Transaction Specifics	

Pedigree Data	Pedigree Security
1. Product ID # 2. Serialized Product Title 3. Lot # 4. Expiration Date 5. Exact Quantity 6. Product Serial #s 7. Financial Link (Invoice, PO) 8. Transaction Date 9. Trading Partner Identification 10. Transaction Validation	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.
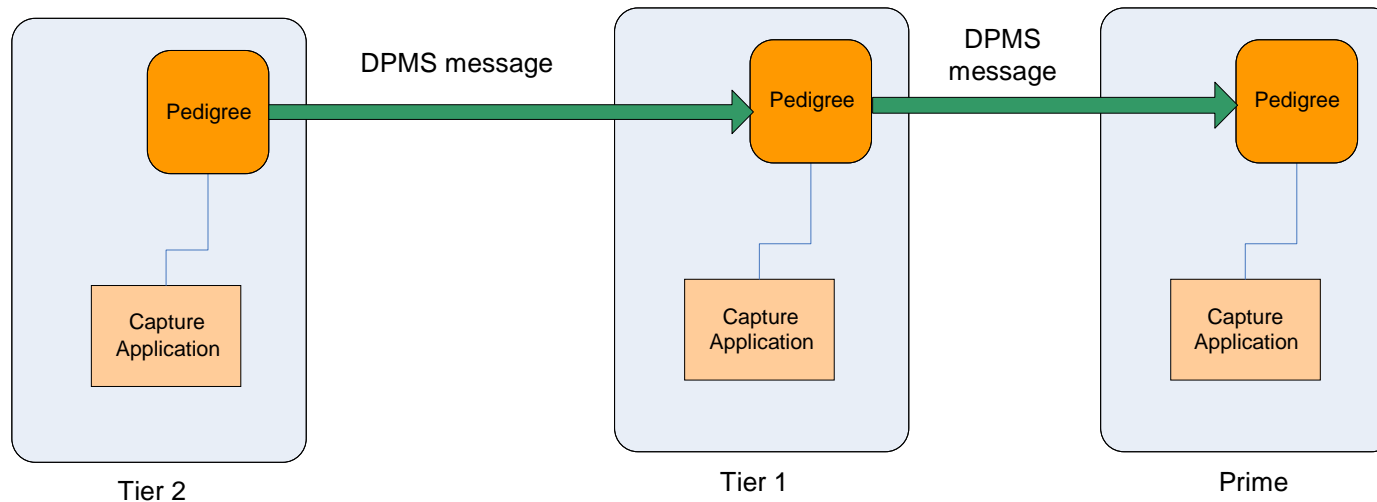
Digital Certificates in ePedigrees

- 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

DPMS message

DPMS message

Pedigree

Pedigree

Pedigree

Capture Application

Capture Application

Capture Application

Tier 2

Tier 1

Prime

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