



# Defending Your Brand From Attack By Drug Counterfeiters And Illegal Diverters: New Strategies in China and Elsewhere

An FDA News Webinar

November 22, 2013

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# Disclaimers & Recommendations

- Fighting illegal counterfeiting activity is complicated and fact-specific. We will be simplifying almost everything
- This is descriptive information, not legal advice
- Please consult with your Company counsel if you have any questions or concerns about specific situations
- We are presenting as private attorneys and not as a representative of PSI.

# THE PROBLEM OF COUNTERFEIT DRUGS

# What Is a Counterfeit Medicine?

- Multiple, Similar Definitions
- World Health Organization:
  - » “A counterfeit medicine is one which is deliberately and fraudulently mislabeled with respect to identity and/or source.”
- Common Elements:
  - » Can apply to both branded and generic products
  - » May include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients
  - » May include fake packaging

# Counterfeit Medicines: Public Health Risk

- Unregulated
- Source Unknown
- Contents Unknown
  - » Not effective
  - » Passively and actively unsafe
- Storage, Tampering, Expiration Unknown
- Invisible for Recalls, Tracking of Adverse Reactions
- Lack of Treatment, Injury, and Development of Resistance
- Funding of Organized Crime—Est. \$75 Billion annually (2002-2003 data)

<sup>1</sup>Source: R. Cockburn (2005) The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers, PLoS/Medicine 2: e100.doi:10.1371/journal.pmed.0030100

# The Magnitude of the Counterfeit Problem: Some Quick Stats From PSI



- 2,000+ reported incidents of pharmaceutical crime in 2012
  - » Counterfeit
  - » Illegal diversion
  - » Major theft
- Crimes reported in 123 countries (out of 196)
- 40% of police seizures of “commercial” quantities—1,000+ doses
- Brands and generics, oral and injectable dosage forms

# Some Quick Stats From PSI: Target Therapies



- 523 Different Pharmaceuticals
- Top Therapeutic Areas:
  - » Anti-Infective (anti-malaria, antibiotic)
  - » Genito-urinary (ED)
  - » Central nervous system
- Greatest Recent Increases:
  - » Hormone therapeutic
  - » Central nervous system
  - » Musculo-skeletal
  - » Respiratory

# Some Quick Stats From PSI: Target Regions



- Regions linked to the most incidents of Counterfeiting, Illegal diversion, and theft
  - » Asia
  - » Europe
  - » Latin America
  - » North America



## Some Quick Stats: The Internet Problem

- Internet Pharmacies:<sup>1</sup>
  - » Only 3% Estimated To Be Acting in Compliance With U.S. Federal and State Regulations
  - » 83% do not require valid prescription
  - » 55% do not provide physical address
- Operation Pangea VI (June 2013)<sup>2</sup>:
  - » International operation focusing on illicit websites selling fake medicines
  - » Targeted websites, electronic payment systems, delivery services
  - » 9,000 websites shut down
  - » 9.8 million doses of counterfeit drugs seized

<sup>1</sup> Source: National Ass'n of Boards of Pharmacy Internet Drug Outlet Identification Program Progress Report January 2013

<sup>2</sup> Source: Interpol

# Drug Counterfeiting Is International Crime: Avastin® Case Study



- 2012 and 2013 Reports of Counterfeit Avastin® Entering Legitimate Distribution Chain in U.S.
  - » No API
  - » Doctors offering in-office injections bought from unauthorized distributors advertising legitimate “international” versions
  - » Orders processed through U.K. entity
  - » Which obtained the Product from Danish company
  - » Which obtained the product from a licensed Swiss company
  - » Which ordered the product from an unlicensed Egyptian company
  - » Which obtained counterfeit product from Turkey
  - » Through a Syrian broker
  - » For a \$400 savings

Source: Rx-360 Supply Chain Security White Paper, April 30, 2013

# International Response

- WHO
- IFPMA, PhRMA, and EFPIA
- Interpol
- NGOs
  
- PSI, Partnership for Safe Medicines, VIPPS
- Secure Legitimate Supply Chain
- Improve Data Collection
- Promote Enforcement and Awareness
- Enhance Regulatory Authority

# BUILDING AN EFFECTIVE PRODUCT INTEGRITY PROGRAM

# Counterfeit Drugs: Risks and Costs

- Responsibility to Protect Public Health
- Reputation/Damage to Brand
- Costs
- Liability

# Building an Effective Product Integrity Program



- Investigation
- Enforcement
- Technology
- Internal Legal
- Resources
- Executive Support

# Creating a Product Integrity Program

- Build an anti-counterfeiting/product integrity team
  - » Designate individual with anti-counterfeiting responsibility
  - » Interdisciplinary: Security, Legal, Packaging, Logistics, Marketing, QC-QA, Sales
  - » Provide adequate resources
- Develop and use anti-counterfeiting features
  - » Overt and covert
  - » Beware of vendor promises!
  - » SOPs for detection of counterfeits

# Creating a Product Integrity Program

- Implementing the plan
  - » Supply chain security
  - » Theft
  - » Contracts with suppliers and customers
  - » Audits
  - » Proactive engagement of law enforcement
  - » private civil actions



# ANTI-COUNTERFEITING EFFORTS: U.S. LEGAL ISSUES AND ACTIONS

# Criminal Laws Are Broken by Drug Counterfeiting



- Law Enforcement Typically Requires Direct and Substantial Public Health Threat
- Higher Success Rate, Greater Deterrence
- Peerless Evidence Gathering Resources, Especially Internationally
- Limited Manufacturer Control, Recovery
- Get to Know FDA OCI, National Intellectual Property Rights Coordination Center

# Civil Laws Are Broken by Counterfeiting



- Many Alternatives, With Lower Burden of Proof
- Substantial Financial Recovery Possible
- Manufacturer Maintains Control
- Limitations on Evidence Gathering
- Challenges to Establish Jurisdiction Over Foreign Defendants

## Civil and Criminal Proceedings in Parallel

Why pursue both civil and criminal actions?

Synergy generated by parallel civil and criminal proceedings:

- Criminal proceeding can generate evidence for the civil case, and vice versa. E.g., in *Louis Vuitton Malletier S.A. v. LY USA, Inc.*, defendants produced only 40 pages of documents. But LV was able to obtain other evidence from seizures by U.S. customs officials. 676 F.3d 83 (2d Cir. 2012).

## Civil and Criminal Proceedings in Parallel

***But***, parallel proceedings must not violate defendant's right to due process.

Generally no due process violation if:

- Defendant in civil case knows about the parallel criminal investigation.
- Defendant in civil case is represented by a lawyer.
- Plaintiff has not misled defendant regarding its knowledge of the criminal proceeding or investigation.
- Plaintiff offers prosecution with the fruits of its investigation, instead of “fishing” for evidence that would be useful for the prosecution.

# Private Civil Enforcement

But whom do you sue?



## Additional Hurdles



And even if you can identify the players --

Can you get jurisdiction over them?

Can you serve them with a complaint?

Do you have strong claims of IP misuse?

Can you get the evidence to prove it?

Can you identify recoverable assets?

## What Laws Protect Against Counterfeiting?



# Using IP Laws to Combat Counterfeits

## Trademark protection

Trademark Counterfeiting; 15 U.S.C. § 1114, Trademark Infringement; 15 U.S.C. § 1114, Trademark dilution; 15 U.S.C. § 1125, False advertising; 15 U.S.C. § 1125 (a), State law claims – unfair competition, trademark infringement, trademark dilution, etc.

- Purpose is to prevent consumer confusion of source of origin
- Protects against uses that cause confusion or cause mistake or deceives
- Also protects against false designation of origin, misrepresenting characteristics, qualities, geographic origin
- Criminal penalties also exist

# Using IP Laws To Combat Counterfeits

## Copyright protection

Copyright Infringement; 17 U.S.C. § 501

- Purpose is to protect creative works
- Criminal penalties also exist

## Patent protection

Patent infringement, 35 U.S.C. § 271

- Purpose is to protect against unauthorized offering for sale, sale, use and/or importing of patent composition or method
- Requires presence of patented substance

# Remedies for Sales Associated With IP

## Trademark infringement

- Disgorgement of infringer's profits
- Damages and lost profits
- Royalty
- Damages may be trebled if bad faith
- Injunctive relief
- Ex parte seizure of goods
- Cost of action in exceptional case

## Trademark Counterfeiting

- Adds statutory damages of up to \$100K for ordinary infringement; up to \$1MM per mark for willful infringement

# Remedies for Sales/Offers for Sale of Product Associated With IP



## False Advertising

- Corrective advertising
- Lost profits
- Profits lost by reason of false advertising
- Cost of corrective advertising
- Damages from harm to good will
- Injunctive relief

## Patent Infringement (if some patented compound present)

- Lost Profits
- Reasonable Royalty
- Lost Profits may be trebled if willful
- Injunctive relief
- Attorney's fees in exceptional case

# Investigating Canadian Internet Unauthorized Sales

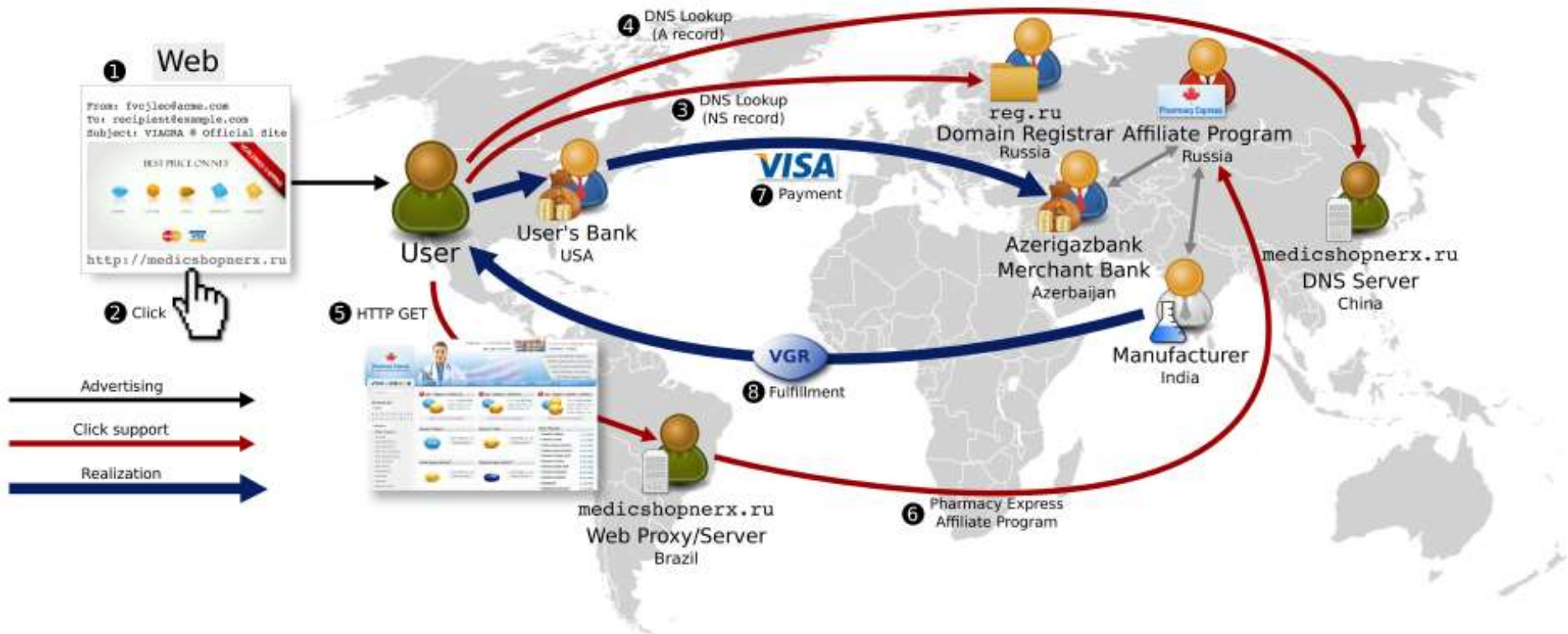


## Goals

- Identify substantial retailers in order to have maximum impact and to improve likelihood of deterring manufacturers
- Select targets based upon best available combination of Lanham Act Claims and likely personal jurisdiction (in the U.S.)
- Learn how foreign manufacturers operate, with the goal of obtaining injunctions to slow/stop flow of imports

# The Special Problem of the Internet

# The Ecosystem of the Internet



\*From "Click Trajectories: End-to-End Analysis of the Spam Value Chain," Dr. Kirill Levchenko et al

## Three Different Levels to Attack

### Follow the money

- Lowest hanging fruit
- Jurisdictional challenges
- Even if ultimately not successful, can be disruptive

### Follow the electrons

- If done correctly, can be highly disruptive

### Follow the product

- The home run (identify the manufacturer)
- The most difficult of the three options



## Follow the Money

Lowest hanging fruit in that relatively easy to identify, but jurisdiction and liability difficult to establish

- *UnSpam Technologies v. Chemuk*, slip op., No. 1102406 (4th Cir., May 3, 2013) (VA court lacks personal jurisdiction over foreign banks used for payment for counterfeit sales by Canadian Pharmacy)
- *Perfect 10 v. Visa Int'l Serv. Ass'n*, 494 F. 3d 788 (9th Cir. 2007) (case against Visa and Mastercard based on processing credit card payments to infringing websites dismissed because neither contributed nor induced infringement)

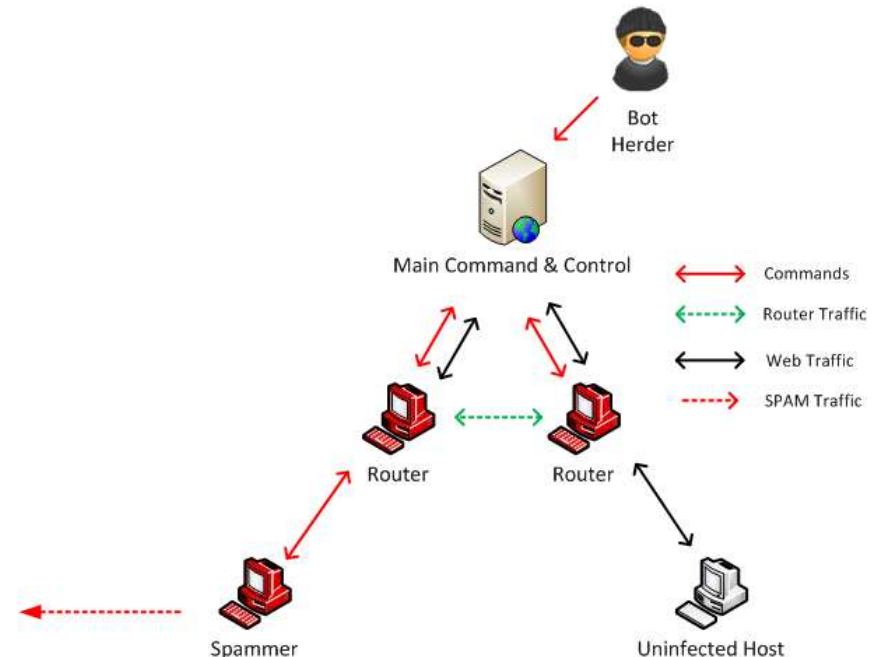
## Follow the Money

Cases against banks and payment processors do sometimes however survive motions to dismiss, and may even be held liable:

- Gucci Am., Inc. v. Frontline Processing Corp., 721 F. Supp 2d 228 (S.D.N.Y. 2010) (motion to dismiss contributory infringement claims against credit card processors denied where defendant reaches out to “high risk merchants” and knows of chargeback investigations)
- Tiffany LLC v. Dong, 2013 WL 4046380 (S.D.N.Y. Aug. 9,, 2013)(credit card processing defendant that processes payments from counterfeit websites after being served with TRO and PI against websites liable for contributory infringement)

# Follow the Electrons: Disable Technical Infrastructure Used by Rogue Pharmacies

- Fundamental technical infrastructure is a “weak link”
- Botnet command and control servers (domains / IP addresses) – the valve to billions of spam emails
- DNS servers used to resolve thousands of rogue pharma domains.
- Disabling such infrastructure doesn’t just stop one operation, it deals with many all at once.
- Technical operations like this are the place where brands can get most “bang for their buck” in enforcement activities.



# Follow the Electrons: Disable Technical Infrastructure Used by Rogue Pharmaceutical Operations



## Sufficient civil legal regimes:

- Trademark law (Lanham Act), copyright law
- Computer Fraud & Abuse Act and state law versions
- CAN-SPAM Act
- Trespass, unjust enrichment, negligence, unfair competition and other tort theories

## Sufficient procedural mechanisms:

- *Ex parte* TRO/preliminary injunction process (take it down without prior notice)
- Alternative service of process on international John Does
- This all pushes bounds of Due Process
- (But, to the Defendants, I say – tough luck!!!)
- Give them every chance to show up and argue about turning off their infrastructure
- Default judgment – final injunction

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Alexandria Division

FILED  
IN OPEN COURT  
SEP 22 2011  
CLERK, U.S. DISTRICT COURT  
ALEXANDRIA, VIRGINIA

MICROSOFT CORPORATION, a  
Washington corporation,

Plaintiff,

v.

DOMINIQUE ALEXANDER PATTI, an  
individual; DOIFREE GROUP S.R.O., a  
Czech limited liability company, JOHN  
DOES 1-22, CONTROLLING A  
COMPUTER BOTNET THEREBY  
INJURING MICROSOFT AND ITS  
CUSTOMERS

Defendants.

Civil Action No: 1:11-cv-1017

**FILED UNDER SEAL**

EX PARTE TEMPORARY RESTRAINING ORDER AND  
ORDER TO SHOW CAUSE RE PRELIMINARY INJUNCTION

The Honorable James L. Robart

1 FILED \_\_\_\_\_ ENTERED \_\_\_\_\_  
2 LODGED \_\_\_\_\_ RECEIVED

3 SEP 13 2011

4 AT SEATTLE  
CLERK U.S. DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON DEPUTY

5 BY \_\_\_\_\_

6

7

8 UNITED STATES DISTRICT COURT

9 WESTERN DISTRICT OF WASHINGTON

10 AT SEATTLE

11 MICROSOFT CORPORATION,

12 Plaintiff,

13 v.

14 JOHN DOES 1-11 CONTROLLING A  
COMPUTER BOTNET THEREBY  
INJURING MICROSOFT AND ITS  
CUSTOMERS,

15 Defendants.

16

17

18

11-CV-00222-ORD

Case No. 2:11-cv-00222

**~~RESTRICED~~ ORDER GRANTING  
DEFAULT JUDGMENT AND  
PERMANENT INJUNCTION**

# Go Deep: Target An Online Operation And Pursue Robust Investigation



## Different Approaches

- Civil Litigation (John Doe or otherwise) as platform for workup of law enforcement referral
- Test local law in jurisdictions with developing legal regimes (have to pick the right test case, domestic victims are good)
- Push litigation toward developing legal standards that require more accountability of “complicit” online service providers
- Take down infrastructure or take away something they need through legal process (ex parte seizure, servers etc) may force them show up and defend

## What This Requires

- Lots of relationships to work the locks in various countries
- Experienced investigation team (knows where and how to look)
- The law is almost secondary to the practical investigation issues. If you’ve got identities and evidence, there’s always a legal theory

# Another Idea

## Whack-A-Mole – But Immensely Scaled



Thousands of “throwaway” domains promoting rogue pharmaceuticals through search and spam methods

- Seems insurmountable. Cease and desist perceived as futile.
- May be true, on balance

However, “cease and desist” takedown program shouldn’t be ruled out

- Must be scaled sufficiently to operate like a big, efficient machine
- Must have global escalation procedures by which hosts / registrars / domain owners actually hear from local lawyers if they don’t comply – must create enough hassle that it works.
- These efforts have a track record of success.

# Follow the Product: Linking Physical Supply To Rogue Affiliate Programs



- Another approach of the “go deep” strategy is to identify connections between physical supply and the affiliate programs / marketers.
- Robust enforcement against the online affiliate programs can provide information that bolsters case against gray market manufacturers and counterfeiters.
- Evidence of wrongful marketing into US by the suppliers can increase the “heat” in trademark or false advertising enforcement against physical product.

# Anti-Counterfeiting Enforcement in China



# Anti-Counterfeiting Enforcement in China: Central Government Efforts



## Manufacturers Seek to Promote Law Enforcement Activity Against Counterfeiters

- At the Central Government level
  - » State Food & Drug Administration (“SFDA”), Ministry of Health (“MOH”); General Administration of Quality Supervision, Inspection and Quarantine (“AQSIQ”), Ministry of Public Security (“MPS”) (Gao Feng, Director General of Economic Crime Investigation Department), General Administration of Customs (“GAC”), General Administration of Industry & Commerce (“AIC”), China Consumers’ Association; central media such as CCTV 3.15 Program.
- Locally, agencies of the above at local level

# Anti-Counterfeiting Enforcement in China: The Old Model for Local Law Enforcement



- Pharmaceutical companies engage investigative firms, or law firms which supervise investigation firms, to find counterfeit source
- Pharmaceutical companies & law firms/investigation firms mobilize local Administration for Industry & Commerce (“AIC”) & police to make raids and arrests
- Pharmaceutical companies bring civil actions mainly to protect patents; civil actions following criminal prosecutions in order to secure monetary recoveries infrequent

# Anti-Counterfeiting Enforcement in China: A New Model For Law Enforcement



- Pharmaceutical companies authorize investigation firms at either low or no cost to find counterfeit source
- Pharmaceutical companies and investigation firms mobilize local AIC & police to take raids
- Investigation firms engage law firms on contingency to file civil lawsuits
- Investigation firms and law firms share recovered damages, if any

## How the New Model is Different

- No payments by pharmaceutical companies that might be questioned
- Civil actions used as fundraising device

- Does the New Model Change Things?
- Need to Respect and Advance Chinese Anti-Corruption Policy
- Need to Comply With Western Anti-Corruption Statutes
- Promotion of Law Enforcement at Level of Central Government Remains Viable Alternative

## U.S. Foreign Corrupt Practices Act Issues

- Does the New Model Trigger the “Business Purpose” Test?
- To Whom or What are any Payments Being Made?
- Status of Manufacturer Knowledge
- Responsibility if suspected payments to police by third parties

## U.S. Foreign Corrupt Practices Act Issues

- Significance of Possible Payments to Police Made From Litigation Proceeds
- Elements of “Corrupt” Acts
- Availability of “Facilitation Payments” Defense

# Discussion

## Experiences and Alternatives