

MICHIGAN STATE
UNIVERSITY

To: Office of Management and Budget, Executive Office of the President,
Intellectual Property Rights Enforcement Coordinator, Victoria A. Espinel
Intellectualproperty@omb.eop.gov

Re: Part I – Assessing the Economic Impact,
Comments on the “Coordination and Strategic Planning of the Federal Effort
Against Intellectual Property Infringement: Request of the Intellectual Property
Enforcement Coordinator for Public Comments Regarding the Joint Strategic
Plan. [DOCID:fr23fe10-127]

Date: March 24, 2010

This is a response to the request for comments for **Part I – Assessing the Economic Impact of IP violations** for the “Coordination and Strategic Planning of the Federal Effort Against Intellectual Property Infringement: Request of the Intellectual Property Enforcement Coordinator for Public Comments Regarding the Joint Strategic Plan. We will submit separate comments for **Part II – Recommendations for Accomplishing the Strategic Objective**.

This represents the opinion and insight of the individual authors and not of the overall Programs, Schools, Colleges, or University.

These comments expand on the previously submitted Comments on Guidance Document FD&C Act/505D – Pharmaceutical Security [Docket No. FDA-2009-D-0001], Draft Guidance for Industry on Standards for Securing the Drug Supply Chain-- Standardized Numerical Identification for Prescription Drug Packages; Availability [Docket No. FDA-2009-D-0001], and the public record comments for Product Tracing Systems for Food; Public Meeting; Request for Comment [Docket No. FDA-2009-N-0523]

Part I – Assessing the Economic Impact of IP Rights Violations

We have conducted preliminary reviews and research on this topic:

- It is important to note that there are several global or US estimates of the impact of counterfeiting and/or piracy that have taken on an almost mythical stature. When many of the “hard facts” are assessed, most are rooted in qualitative assessments, at best. We reviewed over 50 statements of the economic impact and found most to be rooted in only a hand-full of primary references. Many of the primary references include very clear statements that the estimates are no more than educated guesses or that there do not seem to be any methodologies to develop an overall estimate. Nevertheless, it is well known from thousands of examples that counterfeit and substandard products are a tangible and substantial public health and economic threat to the global and US economies.



436 Baker Hall

School of Criminal Justice

Michigan State University

East Lansing, Michigan

48824-1302

p. 517-884-0520

f. 517-432-1787

<http://www.a-cappp.msu.edu>

- We do understand the regulator and legislator need for a quantitative based assessment, specifically to rank public health and economic risks, and to assign priorities. When developing a methodology, it is important to consider the needs of all the stakeholders, and specifically how the assessment will specifically be used in risk mitigation and risk communication.
- To create the economic assessment, it is our hypothesis to apply other proofs or theorems created for similar analysis, specifically in the field of economics but firmly rooted in mathematics and statistics.
- We believe that the most effective way to manage this ever changing data set, and the overall emerging and evolving threat, is to assign a dedicate set of researchers.

We thank the IPEC for the opportunity to review and comment on the Joint Strategic Plan. This is an extremely interdisciplinary threat with very complex and organized fraudsters. To develop efficient and effective countermeasures will require a strong public/private partnership. At Michigan State University and within the Anti-Counterfeiting and Product Protection Program (A-CAPPP), we are pleased to participate in the process and to contribute to the research.

Sincerely,

John Spink, PhD, CPP (Certified Packaging Professional)
Associate Director & Assistant Professor
Anti-Counterfeiting and Product Protection Program (A-CAPPP)
School of Criminal Justice
Michigan State University
SpinkJ@msu.edu
517.884.0520
www.a-cappp.msu.edu

MICHIGAN STATE
UNIVERSITY

To: Office of Management and Budget, Executive Office of the President,
Intellectual Property Rights Enforcement Coordinator, Victoria A. Espinel
Intellectualproperty@omb.eop.gov

Re: Part II – Recommendations for Accomplishing the Strategic Objective
Comments on the “Coordination and Strategic Planning of the Federal Effort
Against Intellectual Property Infringement: Request of the Intellectual Property
Enforcement Coordinator for Public Comments Regarding the Joint Strategic
Plan. [DOCID:fr23fe10-127]

Date: March 24, 2010

This is a response for to the request for **Part II – Recommendations for Accomplishing the Strategic Objective** for the “Coordination and Strategic Planning of the Federal Effort Against Intellectual Property Infringement: Request of the Intellectual Property Enforcement Coordinator for Public Comments Regarding the Joint Strategic Plan. We will submit separate comments for **Part I – Assessing the Economic Impact of IP violations**.

This represents the opinion and insight of the individual authors and not of the overall Programs, Schools, Colleges, or University.

These comments expand on previously submitted Comments on Guidance Document FD&C Act/505D – Pharmaceutical Security [Docket No. FDA-2009-D-0001], Draft Guidance for Industry on Standards for Securing the Drug Supply Chain--Standardized Numerical Identification for Prescription Drug Packages; Availability [Docket No. FDA-2009-D-0001], and the public record comments for Product Tracing Systems for Food; Public Meeting; Request for Comment [Docket No. FDA-2009-N-0523].

Part II – Recommendations for Accomplishing the Strategic Objective

Consistent with our previous comments to Federal Register Notice requests for comments and in open meetings, we recommend a focus on the real business drivers to minimize the fraud opportunity with the litmus test of our actions of “are we disrupting the chemistry of the crime?”

- To expand efficiency and effectiveness, we recommend coordinating interagency initiatives to address the overall public health and economic risk. This could be done by considering all product fraud beyond just intellectual property rights violations. Examples of fraud events that are broader than IP include cargo theft, tax avoidance smuggling, illegal diversion, unauthorized refill or remanufacturing, food adulteration or misbranding, and tampering such as date-code altering.



436 Baker Hall
School of Criminal Justice
Michigan State University
East Lansing, Michigan
48824-1302
p. 517-884-0520
f. 517-432-1787
<http://www.a-cappp.msu.edu>

- To follow successful initiatives in areas such as medicine and criminology, we recommend an expansion of the science- and evidence-based decision making based on research for IP.
- To help reduce the supply-side demand, the consumer awareness outreach and training program should be expanded. This work should expand on current best practices and innovations such as in the health-risk communication field.
- There should continue to be an education and training component for businesses, specifically with a focus on increasing transparency of supply chains and also of reducing inadvertent business risks that may occur in procurement processes.
- To increase the efficiency of working with international Customs partners, an expanded research agenda is recommended on why countries do, or do not, enforce or prosecute IP laws. Beyond Political Science, Criminology, and Criminal Justice, this is a function of Social Anthropology as well as Business and Organizational Anthropology.
- Before anything else, it is critical to establish intellectual property rights laws and anti-fraud laws globally. Without IP laws, counterfeiting is **not** illegal.

Supplemental Comment Topics

- **Supplemental Comment Topics – 1** (Improve coordination between, and efficiency of, agencies):
 - Education and Training – We propose continued Executive Education on the basics of IP and of Anti-Counterfeit Strategies. (We are already in discussions with the Intellectual Property Rights Center to coordinate combining and expanding our programs.)
 - Research – Core to effective and efficient policy is to understand the nature of the risk and of the risk factors. We recommend expanding a science and evidence-based research agenda to support the IPEC and all agencies. (We are currently in discussions with food agencies and task forces to begin research projects or dedicated research groups in Economically Motivated Adulteration, or Food Fraud.)
- **Supplemental Comment Topics – 8** (Standardization): We feel standardization is a key to global efficient implementation of global technology and general policy initiatives. We support the International Standards Organization (ISO) and the work of Technical Committee TC 247 Fraud Controls and Countermeasures, which includes Project Committee PC 246 Authentication Tools.
- **Supplemental Comment Topics – 11** (effectiveness of agencies), i. Office of the U.S. Trade Representative IP attaché: The USTR representatives have a tremendous challenge to coordinate and manage this complex topic. Continuing to liaison with industry and academics will continue to improve understanding of the real business drivers which can motivate international businesses or countries, themselves, to change. As was mentioned earlier, the most important

task is to make sure that IP laws are established globally – counterfeiting must be illegal before there can be a focus on enforcement and prosecution.

- **Supplemental Comment Topics – 12** (Coordinate training): We recommend expanding University-based education and training programs and certifications. Also, to expand these training programs globally. When the underlying risks (including economic losses) of product fraud are clearly understood, then real business drivers support the strengthening of IP enforcement and prosecution. Specifically addressing “c. enhance industry participation,” we are expanding our MSU led Anti-Counterfeit Strategy Executive Education and our open-enrollment on-line graduate course “VM840 Anti-Counterfeit and Product Protection.” (This course is included in the MSU Public Health Program Certificate in Counterfeit Pharmaceuticals and in the future MSU Certificate in Anti-Counterfeiting Criminology.) There should continue to be an education and training component for businesses, specifically with a focus on increasing transparency of supply chains and also of reducing inadvertent business risks such as in the procurement process.
- **Supplemental Comment Topic – 19** (reduce demand): To help reduce the supply-side demand, a strong consumer outreach program should be conducted. This work should expand on current best practices and innovations in the health-risk communication field. (We currently have student pilot survey research underway and new industry-university projects proposed.)

This is an extremely interdisciplinary topic that is extremely complex, and there is no magic solution. The fraud and the fraudsters are intelligent, resilient, patient, well funded and very motivated. The human actors are clandestine, stealth and seeking to avoid detection. These fraudsters try to exploit the very systems we put in place to increase our own prevention, intervention, and response countermeasures. The public health and economic risk of counterfeiting and sub-standard product will still be significant even with strong global IP laws, enforcement, and prosecution. Developing efficient and effective countermeasures will require a strong public/private partnership. At Michigan State University and within the Anti-Counterfeiting and Product Protection Program (A-CAPPP), we are pleased to participate in the process and to contribute to the research.

Sincerely,

John Spink, PhD, CPP (Certified Packaging Professional)
Associate Director & Assistant Professor
Anti-Counterfeiting and Product Protection Program (A-CAPPP)
School of Criminal Justice
Michigan State University
SpinkJ@msu.edu
517.884.0520
www.a-cappp.msu.edu

With Michigan State University Collaborators:

Michael Rip, PhD
Director, Program in Public Health
College of Human Medicine
School of Criminal Justice

Doug Moyer, MS
Lead Instructor, Counterfeit Medicines
Program in Public Health
College of Human Medicine