

Fake it 'til we make it: regulating dangerous counterfeit goods

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The world's most lucrative industry?

The world's most lucrative industry may well be counterfeiting. According to some estimates, the trade in counterfeit goods accounts for 10% of all global trade and rakes in well over \$500 billion per year.¹ And counterfeiting extends far beyond handbags and watches: today, anything and everything from electrical fuses and car airbags to wine and prescription pharmaceuticals is counterfeited—posing a major risk to human health and safety. The global trade in dangerous counterfeit goods has grown directly alongside the trade in more traditional, 'low-risk' counterfeit goods.

The numbers are stark: counterfeit or falsified drugs directly cause 100,000 annual deaths in Africa alone, the World Health Organization estimates.² Interpol places the number above one million worldwide.³ Up to 30% of the world's medicine supply⁴—and an even higher proportion of drugs sold online⁵—are counterfeit.⁶

The danger is not limited to pharmaceuticals. Car manufacturer Aston Martin recently recalled 75% of its global fleet due to safety concerns over counterfeit plastic parts.⁷ A recent epidemic of counterfeit, shatter-prone, chemically treated 'decorative' contact lenses has been

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This article

- The lucrative global trade in dangerous counterfeit goods—everything from fake or adulterated pharmaceuticals to mislabelled electrical components—grows annually. Despite the obvious public health dangers posed by these products, most jurisdictions lack an integrated legal regime to prevent the flow of dangerous counterfeits.
- This article uses survey data gleaned from representatives to the ECTA to broadly characterize anti-dangerous-counterfeiting legal regimes in the US, EU, China and India. After setting out these archetypes, this article analyses certain 'best practices' including consumer education on the public health impact of dangerous counterfeits (particularly food and medicine), integrated product tracing systems and greater international coordination in enforcement efforts.
- The article seeks to add to a growing international conversation between law enforcement, non-governmental organizations and private stakeholders on the most effective means to curtail the growing dangerous counterfeit problem.

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1 See Michel Danet, 'Message from the WCO Secretary General, International Customs Day 2007' *World Customs Organization* (26 January 2007), <http://www.wcoomd.org/en/media/newsroom/2007/february/message-from-the-wco-secretary-general-international-customs-day-2007.aspx>. Statistics on counterfeiting are notoriously inaccurate because many counterfeit goods go undetected.

2 See Jocelyne Sambira, 'Counterfeit drugs raise Africa's temperature' *Africa Renewal* (May 2013) (citing WHO statistics). This figure only includes deaths caused directly by the drug poisoning—the figure is far higher when also accounting for deaths caused by reliance on fake (though not inherently dangerous) medicines. For instance, the International Policy Network estimates that 700,000 malaria and tuberculosis deaths each year—a significant portion of all fatalities from these diseases—could have been avoided if the victims had used proper and not counterfeit medicines. See 'Fake Drugs Kill Over 700,000 People Every Year – New Report' *International Policy Network* (2012), <http://www.policynetwork.net/health/media/fake-drugs-kill-over-700000-people-every-year-new-report>. This is the equivalent of 'four fully laden jumbo jets crashing every day.' Sambira, *supra* note 2.

3 Natalie Southwick, 'Counterfeit drugs kill 1mn people annually – Interpol' *In Sight Crime* (24 October 2013), <http://www.insightcrime.org/news-briefs/counterfeit-drugs-kill-1-million-annually-interpol>.

4 See *ibid*.

5 See eg, Melanie Haiken, 'Up to 77 Percent of Viagra bought online may be fake, and possibly dangerous, research shows' *Forbes* (12 September 2013) (noting that most erectile dysfunction medication sold online is counterfeit); Xu Wei and Chen Hong, 'Officials: majority of foreign drugs sold online fake' *China Daily* (9 May 2014), http://www.chinadaily.com.cn/china/2014-05/09/content_17494803.htm (noting that, depending on type, up to 75% of foreign drugs sold online in China are fake).

6 See generally Lawrence O Gostin et al, *Countering the Problem of Falsified and Substandard Drugs* 95–105 (2013), <http://www.nap.edu/catalog/18272/countering-the-problem-of-falsified-and-substandard-drugs> (presenting information on frequency of drug adulteration based on region and drug type).

7 See Derek Mead, 'How counterfeit plastic led to Aston Martin recalling 17,590 cars' *Motherboard* (6 February 2014), <http://motherboard.vice.com/blog/how-counterfeit-plastic-led-to-aston-martin-recalling-17590-cars>.

causing consumers permanent eye damage.⁸ And counterfeit semiconductors have become so commonplace that the United States has added a new anti-counterfeiting rule to its military procurement regulations after several recent incidents involving military equipment with counterfeit electronic parts.⁹

To turn the tide, consumer groups, industry stakeholders, international organizations and governments have begun proactively combating dangerous counterfeit goods.¹⁰ But due to their relative novelty, these anti-counterfeiting efforts have not been uniformly effective in stemming the rapid growth of the global counterfeit industry.¹¹

The authors of this article—through the European Communities Trade Mark Association (ECTA)—solicited information from private and governmental representatives in 35 countries about the character and scope of their efforts to combat dangerous counterfeit goods, and have analysed the responses. Part 2 of this article explains the survey methodology. Part 3 discusses how four major international trading areas—the United States, the European Community, China and India—combat dangerous counterfeits. Part 4 discusses enforcement issues revealed by the survey responses, and identifies best practices for detecting and mitigating the risk posed by dangerous counterfeits. Part 5 concludes with recommendations for further action.

The survey method explained

No jurisdiction has fully solved its dangerous counterfeit goods problem, but some have come closer than others. Indeed, given the vast disparities in manpower, capital and economic trajectory among different countries, there is probably no ideal model.

Because there is no perfect model to emulate, the goal of this article is to foster high-level discussions on the best practices for addressing the problem of dangerous fakes. As what constitutes a ‘dangerous counterfeit good’ is subjective, and the best practices to curb dangerous counterfeiting vary with the prevailing economic, demo-

graphic and political circumstances in a jurisdiction, our survey questions were deliberately open-ended. They allowed responders to address whatever issues they found most important, and to highlight the anti-dangerous-counterfeiting policies they deemed most effective. Such an approach allows many different perspectives to influence the debate. Almost as importantly, the gaps and silences in survey responses tend to reflect the gaps in anti-counterfeiting enforcement.

The world’s main dangerous counterfeit countermeasures

Dangerous counterfeit goods are both dangerous and counterfeit, so most jurisdictions combat them with a combination of consumer protection and intellectual property laws. This approach creates multiple layers of protection, but also increases the need for coordination.

The American system

Although the United States has few laws that explicitly target dangerous counterfeits, it excels in coordinating different types of private and public enforcement actions, resulting in a well-integrated anti-dangerous-counterfeiting programme.

The United States’ regulation of dangerous goods—counterfeit or not—incidentally regulates many dangerous counterfeit goods. For instance, the USA regulates all pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),¹² and regulates other common dangerous substances (such as lead and asbestos) under the Toxic Substances Control Act (TSCA).¹³

Dangerous counterfeit goods generally do not enter the market through normal channels of trade and thereby avoid the inspections and restrictions mandated by product safety laws, such as FIFRA and TSCA. To help close this loophole, the USA allows certain private actors to sue for counterfeiting under its Trademark Act.¹⁴ Those found guilty risk criminal penalties¹⁵ and

8 See ‘Federal agencies warn against counterfeit decorative contact lenses’ United States Immigration and Customs Enforcement (ICE) (23 October 2013), <http://www.ice.gov/news/releases/1310/131023washingtondc.htm>.

9 DFARS. Detection and Avoidance of Counterfeit Electronic Parts, 78 F.R.28780 (16 May 2013), <https://www.federalregister.gov/articles/2014/05/06/2014-10326/defense-federal-acquisition-regulation-supplement-detection-and-avoidance-of-counterfeit-electronic>; see also ‘Winning the battle against counterfeit semiconductor products’ *Semiconductor Industry Association* at 5–6 (August 2013), <http://www.semiconductors.org/clientuploads/directory/DocumentSIA/Anti%20Counterfeiting%20Task%20Force/SIA%20Anti-Counterfeiting%20Whitepaper.pdf> (discussing recent instances of counterfeit semiconductors causing fires or product malfunction in various consumer items and medical equipment).

10 See eg, *Countering the Problem of Falsified and Substandard Drugs* supra note 6 at 255–64 (proposing an international regime for regulating drug quality).

11 The incompleteness of these efforts is already starting to cause unforeseen collateral problems. For instance, ineffective and adulterated counterfeit antibiotics are accelerating the proliferation of drug-resistant diseases. See eg, Editorial: ‘Counterfeit drugs: a growing global threat’ *Lancet* 2012, 379:685; *Countering the Problem of Falsified and Substandard Drugs*, supra note 6 at 54–62. Similarly, the safety risks to civilians from counterfeit military hardware are obvious and acute.

12 See 7 USC §§ 136–136Y et seq (2007).

13 See 15 USC §§ 2601–2692 (1976).

14 See 15 USC §§ 1114, 1125(a) (2006).

15 See 18 USC § 2320 (1996).

massive damages.¹⁶ The potential for such large recoveries further motivates private companies to police the marketplace and conduct their own investigations into potential dangerous counterfeits.

Several other American laws and regulations also contain anti-counterfeiting provisions meant to promote cooperation between the public and private sectors. For example, the Tariff Act broadly prohibits importation of counterfeit goods, and allows entities whose rights are infringed by counterfeit goods to coordinate with customs officials to seize suspected counterfeits.¹⁷ The private companies record their trade mark registrations with the relevant agencies, usually Customs and Border Protection (CBP) or Immigration and Customs Enforcement (ICE), who then know what to look for when attempting to seize counterfeit goods at the border.¹⁸ The National Intellectual Property Rights Coordination Center further synchronizes administrative actions, and various organizations use this information to warn consumers of potentially dangerous counterfeits.¹⁹

The United States—like many other countries—supplements its general regime with specific legislation targeting dangerous counterfeit goods it deems particularly dangerous. For instance, the Food and Drug Safety Innovation Act²⁰ imposes significant obligations on manufacturers to avoid adulteration and enhances the penalties for counterfeiting drugs. Individual US states also often craft their own legislation to arrest the flow of particular dangerous counterfeits, such as car airbags.²¹

The European system

The European continent contains 50 countries, each with its own unique legal system. However, harmonizing influences—notably the European Union (EU)—have led many European countries to combat dangerous counterfeit goods in similar ways.

Like the United States, most European jurisdictions do not regulate ‘dangerous counterfeit goods’ specifically; rather, they regulate dangerous products and counterfeit products as separate, but overlapping, issues. Most European states enforce their prohibitions against dangerous goods through customs inspections (for imports) or in domestic laboratories, under domestic law (for goods produced internally). If the certifying state is an EU member, the products can then be distributed throughout the EU without further inspection.²² If a non-food product is dangerous to the environment, consumer health or national security, then the EU’s rapid response system, RAPEX,²³ allows for close coordination of enforcement efforts among EU member states.

European anti-counterfeiting laws have converged significantly because EU membership and various international treaties have encouraged such alignment.²⁴ Most EU states have laws providing for both criminal and private civil penalties for counterfeiting.²⁵ Private industries frequently hold events to educate enforcement officials on how to identify particular counterfeit products.²⁶

16 See 15 USC § 1117.

17 See generally 19 USC § 1526 (forbidding importation of goods that infringe on American intellectual property rights, authorizing their destruction and allowing rights holders to seek damages or injunction).

18 See generally ‘Record trademarks with customs and border protection’ *United States Patent and Trademark Office*, <http://www.uspto.gov/trademarks/notices/tmrecordcustoms.jsp> (accessed 21 September 2014) (advising trade mark owners to register their marks with CBP); see also ‘Intellectual property rights e-recording application’ *United States Customs and Border Protection*, <https://iprr.cbp.gov/> (accessed 21 September 2014) (indicating steps a trade mark owner must take to record their rights with CBP); ‘CBP seizes 500k in fake goods’ *United States Customs and Border Protection* (3 October 2014), <http://www.cbp.gov/newsroom/local-media-release/2014-10-03-000000/cbp-seizes-500k-fake-goods>; ‘Houston man charged with trafficking counterfeit “beats by dre” headphones’ *United States Immigration and Customs Enforcement* (10 October 2014), <https://www.ice.gov/news/releases/houston-man-charged-trafficking-counterfeit-beats-dre-headphones> (documenting counterfeit goods seizures aided by private industry). See Appendix A for a more extensive list of representative enforcement actions by US, European and international enforcement agencies.

19 See generally ‘About the IPR Center’ *National Intellectual Property Rights Coordination Center*, <http://www.iprcenter.gov/about-us> (detailing the role the IPR Center plays in coordinating US and international administrative enforcement actions and public–private education).

20 See 21 USC §§ 811–812 (2012).

21 See eg, Jonathon Ramsey, ‘Ohio enacts counterfeit airbag law’ *Autoblog* (31 December 2013), <http://www.autoblog.com/2013/12/31/ohio-enacts->

[counterfeit-airbag-law/](#) (noting that New York, Connecticut and Ohio have all passed laws banning counterfeit airbags).

22 See generally ‘A single market for goods’ *European Commission*, http://ec.europa.eu/internal_market/top_layer/goods/index_en.htm (last updated 10 July 2014) (observing that EU member states should only interfere with free flow of accredited goods across borders under exceptional circumstances).

23 See generally ‘Rapid alert system for non-food dangerous products’ *European Commission*, http://ec.europa.eu/consumers/archive/safety/rapex/index_en.htm (last updated 20 March 2014) (describing the general contours of the RAPEX system).

24 See eg, Paris Convention for the Protection of Industrial Property, as last revised at the Stockholm Revision Conference, 14 July 1967, 21 UST 1583; 828 UNTS 303 (harmonizing IP rights); Council Directive 2004/48, on the enforcement of intellectual property rights, OJ L195/16 (standardizing civil remedies for IP infringement); Council Regulation 765/2008, setting out the requirements for accreditation and market surveillance relating to the marketing of products, OJ L218/30 (setting forth market surveillance procedures); Regulation (EU) n 608/2013/EU of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council regulation (EC) n 1383/2003, JOEU 29 June, n L 181 (customs enforcement of intellectual property rights).

25 See Council Directive 2004/48 for civil measures.

26 See eg, ‘Our Partners’ *Office for Harmonization in the Internal Market*, <https://oami.europa.eu/ohimportal/en/our-partners> (accessed 19 August 2014) (after loading click on ‘User Groups’ tab) (listing the various private industry groups that regularly coordinate with OHIM).

If private companies provide specific information about an incoming infringing product shipment, European customs authorities will intercept the shipment.²⁷

The EU further harmonizes European anti-dangerous-counterfeiting laws with both directives that address specific goods, such as dangerous toys,²⁸ pharmaceuticals, pesticides,²⁹ food imitation³⁰ and medical devices,³¹ and with directives that harmonize legal procedures in intellectual property³² and product liability law.³³ Many European states also promulgate specific anti-dangerous-counterfeiting laws. For instance, many European nations have specific regulations concerning counterfeit food and tobacco.

In addition to the EU's internal efforts to promote harmonization and cooperation, European states and private entities participate prominently in global anti-counterfeiting efforts through organizations like Interpol,³⁴ Europol³⁵ and the United Nations.³⁶ Ultimately, the fact that one can even discuss Europe as a single unit (as opposed to 50 disparate ones) speaks to Europe's tremendous success in standardizing its counterfeiting laws. Its regional system is a blueprint for how to coordinate anti-counterfeiting laws on a global scale.

The Chinese system

Any discussion of Chinese law prohibiting dangerous counterfeiting must begin by acknowledging that some Chinese businesses are among the world's largest producers of adulterated and counterfeit products. Though the full extent of Chinese counterfeiting is unknown, recent high-profile incidents involving counterfeit or unsafe wine,³⁷ baby formula,³⁸ high-tech products³⁹ and aeroplane parts⁴⁰ hint at the scope of the problem, which is an open secret.⁴¹

The extent and profitability of Chinese 'fakes'⁴² constrain the potential effectiveness of Chinese anti-counterfeiting and dangerous product legislation. At the local and regional level, business and government are often so intertwined that the local enforcement bodies ostensibly responsible for enforcing anti-counterfeiting laws may themselves profit from the counterfeiting industry.⁴³ Chinese federal authorities face comparable moral hazards, in that they are further hamstrung by their reliance on these same corrupt local officials for information.⁴⁴ And because a majority of Chinese counterfeit goods are produced by legitimate factories working illegitimate 'third shifts,' it is frequently difficult to shut down operations

27 See generally O Vrms, 'Regulation 608/2013: towards a more effective Customs enforcement of intellectual property rights', (2013) BMM Bulletin 3, 118 and O Vrms, and M Schneider, *Enforcement of Intellectual Property Rights through Border Measures. Law and Practice in the EU*, 2nd ed. (2012), Oxford University Press (describing how private actors can file a customs detention order (CDO) to alert EU customs officials to potentially infringing shipments). Most of our responders that discussed private-public cooperation in interdiction required private entities to pay for all or part of the expenses, such as storage and destruction costs. This sort of barrier against private sector participation arguably chills customs enforcement efforts.

28 See eg, Council Directive 2009/48, on the safety of toys, OJ L 170/1 (legislating stringent toy safety standards).

29 See eg, Council Directive 91/414/EEC, concerning the placement of plant protection products on the market, OJ L/230.

30 See eg, Council Directive 87/357/EEC, on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers, OJ L/192 (requiring explicit labelling for products that imitate ingestibles).

31 See Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention).

32 See eg, Council Directive 2004/48.

33 See eg, Council Directive 2001/95, on general product safety, OJ L 11/4 (standardizing product safety standards throughout the EU).

34 See eg, 'Interpol operation nets fakes worth USD 50 million across Asia' *Interpol* (22 September 2014), <http://www.interpol.int/News-and-media/News/2014/N2014-179> (describing an Interpol-led anti-counterfeiting campaign resulting in hundreds of arrests worldwide).

35 See eg, 'Thousands of tonnes of fake food and drink seized in Interpol-Europol operation' *EUROPOL* (13 February 2014), <https://www.europol.europa.eu/content/thousands-tonnes-fake-food-and-drink-seized-interpol-europol-operation> (detailing a coordinated sting operation wherein law enforcement on four continents seized 1,200 tons of counterfeit food and a similar quantity of drinks from 33 different countries).

36 See eg, 'Counterfeit: don't buy into organized crime' *United Nations Office on Drugs and Crime*, <http://www.unodc.org/counterfeit/> (accessed 22 September 2014) (describing recent United Nations anti-counterfeiting educational material).

37 See eg, Jeff Leve, 'Massive Chinese counterfeit wine ring busted with 7,000 fake cases' *The Wine Cellar Insider* (30 August 2013), <http://www.thewinecellarinsider.com/2013/08/massive-chinese-wine-counterfeiting-ring-busted-7000-fake-cases/>.

38 See eg, Tania Branigan, 'Chinese figures show fivefold rise in babies sick from contaminated milk' *The Guardian* (2 December 2008), <http://web.archive.org/web/20081205093042/http://www.guardian.co.uk/world/2008/dec/02/china>.

39 See eg, Christopher Magoon and Katie Martin, 'China's copycat phenomenon: fake apple stores still booming in southern China' *Tea Leaf Nation* (4 June 2013), <http://www.tealeafnation.com/2013/06/chinas-copycat-phenomenon-fake-apple-stores-booming-in-southern-china/>.

40 See US Senate Armed Services Committee, *Inquiry into Counterfeit Electronic Parts in the Department of Defense Supply Chain*, Washington: Government Printing Office (2012), <http://www.levin.senate.gov/newsroom/press/release/senate-armed-services-committee-releases-report-on-counterfeit-electronic-parts> (accessed 19 August 2014).

41 See eg, '2013 USTR Report to Congress on China's WTO compliance' *United States Trade Representative* (2013) at 7, <http://www.ustr.gov/sites/default/files/2013-Report-to-Congress-China-WTO-Compliance.pdf> (noting that American businesses lose \$48 billion annually to Chinese counterfeiters).

42 See Yu Hua, 'The true cost of chinas fakes' *New York Times* (9 June 2014), http://www.nytimes.com/2014/06/10/opinion/you-hua-the-true-cost-of-chinas-fakes.html?_r=0.

43 See eg, Mark Turnage, 'Most counterfeit goods are from China' *Business Insider* (25 June 2013), <http://www.businessinsider.com/most-counterfeit-goods-are-from-china-2013-6> (noting that it is an open secret that counterfeiters bribe local Chinese government officials to ignore their operations).

44 See *ibid.*

that produce counterfeit goods.⁴⁵ Finally, the sheer size of China's market and the scope of its counterfeiting problem make enforcement difficult.⁴⁶ Even well-intentioned product safety and anti-counterfeiting watchdogs are overworked and of limited effectiveness.

Against that background, China, like other major regimes, regulates 'dangerous counterfeit products' through a bifurcated scheme that regulates counterfeit products and dangerous products separately. These legal regimes, however, are often difficult for foreign businesses to access.⁴⁷

Moreover, a lack of coordination between specific administrative agencies inhibits enforcement. Infringement claims against registered or 'well-known' Chinese trade marks and other marks are investigated by different agencies, none of which has the authority to regulate dangerous products.⁴⁸ Furthermore, as the statutes of limitation on infringement claims and many product safety claims are two years or less, litigants must choose the right forum or risk losing the opportunity to bring their claims.

Although civil litigants can recover statutory damages under Chinese anti-counterfeiting law without proving actual damages, criminal penalties are another matter. For a counterfeiter to be subject to criminal penalties, the prosecution must generally meet certain thresholds of actual damage.⁴⁹ Under the best circumstances, actual damages are hard to prove, and when the counterfeited goods are themselves inexpensive (such as foodstuffs), their actual value may not even reach the predicate threshold for criminal liability.⁵⁰ This effectively immunizes many dangerous counterfeiters from criminal prosecution for injuries their counterfeiting has caused.

China has a variety of laws regulating dangerous products, but all subject to a caveat. Chinese consumers

have a tremendous demand for cheap (frequently dangerous) goods, and various Chinese government policies actively encourage manufacture of inexpensive products. Because a dangerous counterfeiting control programme would be at cross-purposes with other Chinese economic policies, legislation seeking to control dangerous products frequently follows—rather than prevents—crises. The paradigmatic example of this was the Chinese tainted milk scandal.⁵¹ In 2008, melamine-tainted milk powder produced by a well-known Chinese dairy manufacturer killed four infants and made hundreds of thousands of others ill.⁵² Both the dairy and the Chinese government knew of the issue beforehand, but legislation was passed only after the crisis.⁵³ Moreover, the regulatory response was arguably dysfunctional—part of the government's response was to effectively loosen the definition of 'milk', lowering required protein levels to remove the incentive for corrupt producers to add melamine (a protein substitute) to their milk powder.⁵⁴ Though such an approach might address the melamine problem, it does not make the public healthier. All told, China's legal protection against counterfeit and dangerous goods—though improving—still lacks transparency, consistency and effectiveness.

The Indian system

Although far from perfect,⁵⁵ the Indian anti-counterfeiting and anti-dangerous products regimes balance consumer protection with the need for administrability. Despite India's size and relative poverty, aspects of its system have garnered international praise from a variety of sources.⁵⁶

India joins many other jurisdictions in regulating dangerous counterfeits through legislation against dangerous

45 See eg, Dan Harris, 'Not exactly counterfeit—new balance shoes and China's "third shift"', *ChinaLawBlog* (1 May 2006), http://www.chinalawblog.com/2006/05/not_exactly_counterfeit_new_ba.html (describing the 'third shift' phenomenon and chronicling New Balance's travails in trying to shut down a third shift counterfeiter).

46 For instance, Chinese authorities recently arrested 2,000 people for counterfeiting drugs without significantly denting the flow of counterfeit drugs in China. See David Barboza, '2000 arrested in China in crackdown on counterfeit drugs' *New York Times* (5 August 2012), http://www.nytimes.com/2012/08/06/world/asia/2000-arrested-in-china-in-crackdown-on-counterfeit-drugs.html?_r=2&.

47 See generally Gloria Q Wu, 'Anti-counterfeiting guide in China' *Lexology* (4 June 2012), <http://www.lexology.com/library/detail.aspx?g=e65c3880-053b-474e-ae4a-3f7d9e8630a2> (describing Chinese customs interdiction procedures).

48 See *ibid.*

49 See *ibid.*

50 See *ibid.*

51 See generally Vivien Lim, 'Tainted milk: unraveling china's melamine scandal' *ThinkBusiness* (1 March 2013), [http://thinkbusiness.nus.edu/articles/item/118-tainted-milk-unravelling-china%E2%80%99s-melamine-](http://thinkbusiness.nus.edu/articles/item/118-tainted-milk-unravelling-china%E2%80%99s-melamine-scandal)

scandal (providing background on the melamine scandal and discussing government and big-industry complicity in various Chinese dangerous-product scandals).

52 *Ibid.*

53 *Ibid.*

54 See 'China lowers dairy protein levels to curb melamine' *China Daily* (15 July 2010), http://www.chinadaily.com.cn/china/2010-07/15/content_10107670.htm.

55 See generally 'Guide to protection of intellectual property rights in India 2014' *Office for Harmonization in the Internal Market* (2014), <https://oami.europa.eu/ohimportal/documents/11370/80606/Guide+to+protection+of+intellectual+property+rights+in+India> (accessed 26 August 2014) (describing weaknesses in Indian IP enforcement, focusing on difficulties securing and enforcing patents).

56 See eg, Office Memorandum, 'Award of WCO certificate of merit 2014' *India Ministry of Finance* (27 January 2014), http://www.cbec.gov.in/deptt_offcr/misc/wco-meritlist2014.htm (listing Indian recipients of World Customs Organization awards); *Guide to Protection of Intellectual Property Rights in India 2014*, *supra* note 55 at 7 (discussing ease of seeking compensation for trade mark and copyright infringement in civil courts).

products and anti-counterfeiting laws.⁵⁷ However, due to India's vast size and limited budget, Indian customs—to a greater extent than most countries—cannot inspect every single shipment of goods into the country. Accordingly, India supplements its random inspections by requiring shipments of 'inherently dangerous cargo' to submit to additional scrutiny. India streamlines enforcement by requiring that specific types of dangerous cargo enter India only via certain ports. Such a rule allows for specialization among customs officials, and establishes easy grounds for suspicion of any dangerous cargo that enters through the wrong port. India coordinates internally through advanced track-and-trace procedures for certain dangerous products.

India supplements its official procedures by inviting extensive private involvement. It has broad anti-counterfeiting laws that contemplate both civil and criminal liability.⁵⁸ Private parties can also ask domestic laboratories or customs to test particular lots of potentially dangerous goods, and can register their trade marks for five years with Indian customs, thus alerting customs officials to suspected infringement and empowering them to act against it.⁵⁹

Like many other countries, India supplements its general scheme with policies regulating goods of special concern, particularly agricultural products. And it actively encourages regulated industries to self-regulate voluntarily, which has resulted in numerous private standard-setting bodies that are more responsive and more protective than enacted laws.

Survey insights and best practices

Our respondents represent different countries and various professional backgrounds, but most raised the same concerns and described similar practices. A few of these observations—shared by several responders—were especially informative as to both the scope of the dangerous counterfeiting problem and potential ways forward.

Ingestible dangerous goods are more prominent in anti-dangerous-counterfeiting programmes than equally dangerous inedible goods

Without fail, survey respondents focused on ingestible substances—food, drink, tobacco or medicines—as the main dangerous products worth regulating. Although most governments regulate dangerous chemicals, electronics and firearms, responders frequently did not include these

kinds of product regulations in their answers; though the dangers of these products are well-known, they are not foremost in the public consciousness. Going forward, more effort needs to be expended educating both government officials and the public about non-ingestible dangerous counterfeit products.

Successful consumer education efforts should highlight personal safety risks of dangerous counterfeit goods

The Italian respondent wisely observed that many efforts to educate consumers about counterfeit goods have failed in part because of how the message was framed. Counterfeiting aids unlawful activity and harms legitimate businesses, but many consumers are unmoved by such appeals to their better nature. Indeed, the whole reason that counterfeiting is so lucrative—and, in some instances, so dangerous—is that consumers want goods far cheaper than the legitimate market will bear. The most effective educational efforts portray the product as undesirable by focusing on the gruesome health and safety consequences of using poorly made counterfeit goods. Anti-counterfeiting public education and outreach efforts should thus focus on the personal—not social—risks of using dangerous counterfeit goods.

Integrated product tracing systems could leverage network effects to aid enforcement

A product that is dangerous to a Chilean person is just as dangerous to a Danish or Indian person; laws differ, but the nature of dangerous products remains the same. Similarly, a counterfeit product is a counterfeit product wherever it is sold—only the legal consequences differ.

Recognizing that danger from products transcends borders, the European Union's RAPEX system allows for the speedy and streamlined sharing of information across borders. India, the United States and others have their own systems to accomplish similar ends within their own borders.

Any system that trades in information—which RAPEX and its national equivalent systems surely do—becomes exponentially more potent as it leverages network effects. Since dangerous products are equally dangerous in all jurisdictions, anti-dangerous-products enforcement would become more efficient if the disparate systems were integrated. An integrated system aimed at tracking and tracing dangerous products could coexist in harmony with different substantive national laws. Everyone is warned of the products, but no jurisdiction has to act on the

57 See eg, *Guide to Protection of Intellectual Property Rights in India 2014*, supra note 55 at 5 (listing specific legislation to protect patents, trade marks, copyrights, industrial designs, seeds and geographic indicators, and to protect consumers from potentially harmful substances including cosmetics, drugs and food adulterants).

58 See *ibid* at 3, 7 (noting large awards offered in civil anti-counterfeiting litigation).

59 See *ibid* at 7–8.

warnings. An international *counterfeit* tracing system would likely yield benefits similar to an international dangerous product tracing system.

Cooperative international anti-counterfeiting efforts have been largely successful and should be expanded

The authors were struck by how similarities in anti-counterfeiting and dangerous products enforcement regimes vastly outweighed the differences—both substantively and procedurally. These similarities are probably attributable to the tremendous (and largely effective) extent of international dialogue and cooperation on global IP and product safety issues, both by governments and private associations. Prompting and strengthening these engagements is critical to the global effort to combat dangerous counterfeit goods.⁶⁰

Legislation should guide and complement private enforcement efforts

Consumers bear the brunt of dangerous and counterfeit goods; they are the ones who become ill or are harmed by shoddy products. And if those consumers lose confidence in the legitimate brands that are counterfeited, lawful private businesses—and even industries—suffer the long-term effects of lost consumer goodwill. When these businesses fail, everyone loses.

The upshot is that private businesses that have the most to lose from rampant counterfeit and adulterated products generally have the greatest means and motivation to curtail counterfeiting. Anti-counterfeiting and dangerous product legal regimes should engage the assistance of these interested, knowledgeable and well-funded private businesses in enforcement efforts. It appears that every jurisdiction surveyed envisages public–private partnerships on IP enforcement, whether through private legal action, cooperation between businesses and customs officials or educational efforts. Some regimes—such as China (which limits damages for counterfeiting) or Ukraine (where private entities foot the entire bill for intercepting shipments)—inhibit private enforcement, thus limiting their potential effectiveness. When possible, such barriers to private enforcement should be eliminated.

Concluding remarks

Expensive, brand-named products become expensive, brand-named products in part because of their superior

materials and manufacture; you get out what you put in. Every day, more and more people become consumers, and these new consumers are generally not wealthy. Yet many want the same products as the global wealthy. To them, the appeal of counterfeits is immense, and as such the counterfeit problem is only going to grow.

Governments have the tools to respond, but too often individual jurisdictions go it alone, employing unilateral strategies to combat coordinated international counterfeiting networks. We may not know what the best enforcement approach is, but that is not it. International organizations should identify potential best practices and start a conversation as to how to best implement these practices across jurisdictional boundaries. The public health and safety consequences of the problem are simply too great to ignore.

Appendix: Representative enforcement actions

Alone or coordinated, spontaneous or planned, government agencies tasked with preventing the flow of dangerous counterfeits seize infringing goods every day. The enforcement actions described below are representative:

1. After a multi-year investigation by numerous US law enforcement agencies including the FBI, Immigration and Customs Enforcement (ICE), Homeland Security Investigations (HSI), Internal Revenue Service (IRS) and the Department of Defense (DoD), the owner and four employees of Oregon-based defence contracting firm Kustom Products, Inc. pleaded guilty on 18 July 2014 to fraudulently obtaining 750 DoD contracts valued in excess of \$10 million. Of these, one of the most egregious—and the one that ultimately led to their prosecution—related to counterfeit aviation locknuts used in military fighter jets. Kustom Products supplied these counterfeit locknuts in 2008—sourced from a known Texas-based counterfeiter—but military supply chain protocols identified the fakes. Upon investigation, Kustom Products claimed to have delivered locknuts from the ‘wrong bin’. However, when asked to replace the counterfeit parts, Kustom Products sourced identical locknuts from the same manufacturer. Under the plea agreement, the defendants forfeited all proceeds attributable to the fraud, as well as various vehicles, \$365,000 and real property.⁶¹
2. Pursuant to an ICE investigation, an indictment was filed on 12 September 2014 charging two defendants

60 See eg, *Countering the Problem of Falsified and Substandard Drugs*, supra note 6 at 255–64 (recommending a unified international code of practice, overseen by the WHO and engaging private stakeholders, to combat the dangers posed by falsified medicines).

61 ‘Oregon defense contractor pleads guilty to multimillion dollar scam’ *ICE* (18 July 2014), <http://www.ice.gov/news/releases/1407/140718portland.htm>.

with ten counts related to a conspiracy to smuggle four million misbranded and counterfeit pills into the United States. According to the indictment, from 2007–2010 Marla Ahlgrimm, a pharmacist from Madison, Wisconsin and Balbir Bhogal, a Las Vegas pharmacologist, illicitly contracted to acquire the pills from an Indian drug counterfeiter. The defendants allegedly purchased the pills to supply a Costa Rican online pharmacy, but actually sold them directly to consumers in the United States.⁶²

3. On 27 January 2014, based on findings from an investigation by HSI, Hao Yang of Harrisburg, Pennsylvania pleaded guilty to trafficking in counterfeit goods, including counterfeit military-grade circuits and avionics equipment. Pursuant to his plea deal, he forfeited \$59,000 in cash, a 2010 Acura and various counterfeit items worth \$280,720. He faces a maximum of 10 years in prison.⁶³
4. In a series of recalls dating back to May 2013, Aston Martin has recalled 17,590 vehicles due to faulty plastic throttle pedal arms. In a 15 January 2014 letter to the US National Highway Transportation Safety Administration, Aston Martin revealed that the defects stemmed from counterfeit plastics used by a third-tier supplier. Although engineering specifications supplied to Hong-Kong-based Fast Forward Tooling required the use of brand-name DuPont plastics, Fast Forward Tooling instead acquired its plastics from Dongguan-based Synthetic Plastic Raw Material Co. This recall affects nearly all 2008–2014 Aston Martin models.⁶⁴
5. On 12 June 2013, 34-year-old Jason Jordan pleaded guilty to conspiracy to traffic in counterfeit goods. Between July 2010 and August 2012, Jordan imported and sold counterfeit Ford, GM, Honda and Toyota airbags over the internet, grossing nearly \$450,000. As part of a plea agreement, Jordan would forfeit \$57,000 in seized cash, pay a judgment of \$100,000 to the government and pay restitution in the amount of \$444,180.28. Prosecutors recommended a prison sentence of 31 months. The safety

risks inherent in counterfeit airbags were considered in the sentencing proposal.⁶⁵

6. On 6 August 2013, two men were arrested and charged with conspiring to smuggle and traffic in counterfeit and misbranded prescription medicine, including Viagra. The investigation, conducted by HSI and partners, identified the two men as engaged in smuggling large shipments of Viagra from China to the US. The suspects were apprehended when one of them delivered approximately 17,000 counterfeit and misbranded Viagra tablets to an undercover agent who successfully infiltrated the counterfeit pharmaceutical trafficking organization.⁶⁶
7. In a joint operation conducted with French customs, the United States Custom and Border Patrol (CBP) seized 480 shipments of counterfeit critical computer components between 1 November 2012 and 30 April 2013. Operation Core Systems continued a line of joint operations between French and US Customs officials, and served to highlight the threat to businesses and public safety from counterfeit computer parts.⁶⁷
8. Between 28 March and 8 April 2013, US CBP officials seized 14,904 toasters bearing counterfeit Underwriter's Laboratories (UL) safety marks. UL performs vigorous safety tests on products to determine potential risks from fire, shock and other health hazards, meaning the toasters with counterfeit UL marks are potentially dangerous to consumers. The seized toasters had a market value of \$297,931.⁶⁸
9. Between 5 May and 11 May 2014, an INTERPOL-led anti-counterfeiting programme involving private stakeholders and representatives from ten European, Asian and North American countries netted over \$50 million of counterfeit products. The programme resulted in the seizure of various types of counterfeit goods, including cigarettes, cosmetics, alcohol, electronics and electrical parts, and led to hundreds of arrests.⁶⁹
10. On 19 March 2012, EUROPOL arrested individuals in the UK, Spain, Romania and the Netherlands for importing counterfeit drugs from Singapore and

62 '2 Charged with smuggling counterfeit pharmaceuticals' *ICE* (15 September 2014), <http://www.ice.gov/news/releases/1409/140915newyork2.htm>.

63 'Man pleads guilty to counterfeit goods' *ICE* (27 January 2014), <http://www.ice.gov/news/releases/1401/140127baltimore.htm>.

64 Kyle Stock, 'Bad gas pedals force Aston Martin to recall 17,590 fancy cars' *Bloomberg Business Week* (6 February 2014), <http://www.businessweek.com/articles/2014-02-06/bad-gas-pedals-force-aston-martin-to-recall-17-590-fancy-cars>.

65 'Washington state man pleads guilty to trafficking in counterfeit air bags' *ICE* (12 June 2013), <http://www.ice.gov/news/releases/1306/130612yakima.htm>.

66 '2 men arrested for smuggled counterfeit viagra from China to Houston and Chicago' *ICE* (6 August 2013), <http://www.ice.gov/news/releases/1308/130806houston.htm>.

67 'CBP, French customs seize critical counterfeit electronic components' *CBP* (22 May 2013), <http://www.cbp.gov/newsroom/national-media-release/2013-05-22-040000/cbp-french-customs-seize-critical-counterfeit>.

68 'CBP seizes nearly 15,000 toasters with counterfeit safety markings' *CBP* (18 April 2013), <http://www.cbp.gov/newsroom/local-media-release/2013-04-18-040000/cbp-seizes-nearly-15000-toasters-counterfeit-safety>.

69 'Interpol operation nets fakes worth USD 50 million across Asia' *Interpol* (22 September 2014), <http://www.interpol.int/News-and-media/News/2014/N2014-179>.

China. The counterfeits included both generic and name brands, and were laced with various poisonous filler ingredients.⁷⁰

11. On 22 May 2014, a coordinated effort between Interpol and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) resulted in the seizure of over \$29 million of counterfeit pharmaceuticals and 10,603 websites. The effort was conducted as part of Operation Pangaea VII, Interpol's anti-counterfeit pharmaceutical programme, and is believed to be the largest-ever crackdown on illicit pharmaceuticals.⁷¹
12. As part of a massive Interpol–Europol-coordinated effort conducted in December 2013 and January 2014, over 1,200 tons of counterfeit food, and 430,000 litres of counterfeit drink were seized from locations in 33 countries. The seizures notably included 131,000 litres of oil and vinegar, 45 tons of dairy products, 60,000 bottles of fake champagne and 685 tons of poorly preserved or mislabelled seafood. The operation, dubbed Opson III, also resulted in arrests in Spain, France, Vietnam, Thailand and the Philippines.⁷²

70 'Europol busts international ring of fake pharma distributors' *Organized Crime and Corruption Reporting Project* (19 March 2012), <https://www.reportingproject.net/occrp/index.php/en/ccwatch/cc-watch-briefs/1428-europol-busts-international-r>.

71 'Thousands of Illicit online pharmacies shut down in the largest-ever global operation targeting fake medicines' *Interpol* (22 May 2014), <http://www.interpol.int/News-and-media/News/2014/N2014-089>.

72 'Thousands of tonnes of fake food and drink seized in Interpol-Europol operation' *EUROPOL* (13 February 2014), <https://www.europol.europa.eu/content/thousands-tonnes-fake-food-and-drink-seized-interpol-europol-operation>.