

The Challenge of Intellectual Property Enforcement for Agriculture Technology Transfers, Additives, Raw Materials, and Finished Goods against Product Fraud and Counterfeiters

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One often-overlooked aspect of intellectual property rights (IPR) strategy is the deterrence and enforcement against ‘irresponsible defendants’ including product counterfeiters. When applied to food, the consumer product fraud or product counterfeiting is referred to as food fraud, or economically motivated adulteration. While this problem is not unique to agriculture and food products, there are special circumstances and issues to consider. The objectives of this paper are to: (1) review the underlying fraud opportunities (complex and on a massive scale), including an exploration of types of fraudsters and types of fraud (near infinite); (2) review how globalization and source economies contribute to the problem; (3) review the complexity and challenges of enforcement for companies and agencies; and (4) introduce the ‘chemistry of the crime’ or the ‘crime triangle’, to shift the focus from reactionary intervention and response to proactive prevention. Five applicable case studies are included, bringing insights on the irresponsible nature of many of the fraudsters. Through its review of fraudsters and types of fraud, this study will provide information to assist with IP technology transfers and the effective enforcement of IPR. Product counterfeiting often poses a very serious public health and economic threat to agriculture and food products. There are very motivated, intelligent, resilient and aggressive fraudsters, but they can be deterred by companies or agencies focused on reducing fraud opportunities. Standard business practices—even identified best practices—often inadvertently contribute to fraud opportunities.

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Protecting intellectual property (IP) is extremely important to supporting and driving innovation.^{1, 2} ‘Intellectual property rights have been created to ensure protection against unfair trade practices.’³ The protection of intellectual property rights (IPR) could be academic credit for creating something new or it might be allowing an investor to recoup his research and development financial investment.^{4, 5} As the world becomes more complex, innovations will also become more complex, which, in turn, leads to research and development investments becoming more complex and more expensive. Whether pursuing publication in the highest level journal, or recouping the maximum financial return, innovators are attracted to seeking the highest rewards. Insufficient protection of IP will lead to fewer rewards, and some of the complex, innovative efforts will be driven to extinction. The innovators may relocate to regions where they can protect the IP they develop.

An example of innovation driven to extinction is a manufacturing company that worked for two years to develop a complex, innovative plastics extrusion die-head that could fill two moulds instead of one. The nature of the engineering design, as well as the temperamental plastic, combined with very stringent product performance, led to costly computer simulations and multiple pilot-production runs. Before the company could commercialize the product, there were copies in the marketplace. The company could no longer sell the product at a premium, so they could not recoup their research and development investment. While the industry and the country benefited from faster production and a higher quality product, that company cancelled their future research and development plans. While the one innovation created immediate benefits, the future marketplace will no longer receive multiple innovations from this company. The cost of prosecuting IP infringement was so exorbitant—if effective at all—that the company could not protect their innovation.

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The agriculture industry is familiar with IP patent protection—generally due to piracy, but there are trademark examples—generally referred to as counterfeit, but most often both are categorized together as counterfeit. It should be noted that the term counterfeit has a macro definition as product that is deceptive and a micro term that is a clear IP violation. The definition of counterfeiting can cause quite a bit of international debate and is being addressed by WHO and by ISO.⁶⁻⁹ When not considering currency counterfeiting, document forgery, artwork forgery, or digital piracy, the concept of counterfeiting is often equated to trademarks on luxury and consumer packaged goods. Agriculture and food examples include melamine in pet food to genetically modify food additives sold as a conventional product, urea in wheat, and diluted high-priced ingredients.¹⁰ Food fraud, or economically motivated adulteration, is a public-health food risk that is growing in awareness, concern, and danger.¹¹⁻²¹ In all cases, sloppy fraudster manufacturing or mishandling can lead to public health risks from contaminants including food allergens.^{22, 23}

The impact of food fraud incidents can include public health threats with devastating human and economic harm. For example, Peanut Corporation of America shipped and sold products which they knew had some level of *Salmonella* Typhimurium contamination—since the objective was personal financial gain, the motivation is categorized as food fraud. This incident led to over 700 illnesses and 9 deaths. The company had US\$ 12 million in personal liability insurance and, serving approximately 2 per cent of the US peanut product market, had an estimated US\$ 1 billion impact on the food industry, but they are now bankrupt.²⁴ Nationwide peanut butter demand dropped by 20 per cent, but luckily quickly recovered.²⁴

A recent trend has been to refer to this as food fraud, or economically motivated adulteration. Food fraud includes three types of public health risks:²⁵

- Direct: This food risk occurs when the user experiences imminent or immediate risk, which could be a lethal or acutely toxic contaminant
- Indirect: This food risk occurs when the user experiences risk after long-term exposure, such as the ingestion of chronically toxic doses, which then bio-accumulate, and
- Technical: This food risk is non-material in nature, for example, the patent infringement of a

seed or plant, or even documentation fraud, related to the label and a deliberate misrepresentation of country of origin or credence attribute.

The knowledge and ability to be clandestine and stealthy in a financially motivated fraud opportunity is a risk for other types of attacks. The ‘food defense’ discipline would cover an individual or organization using the supply chain to create harm or panic for someone else, such as in a terrorist attack.^{26, 27}

Counterfeiter networks have evolved in the same way as other crime networks have; they have evolved into swarms, or networks that form, disband, and reform for specific activities or opportunities.^{28, 29} There is a nearly infinite number of types of fraud and types of fraudsters.²⁵ Some are very simple and small, and some are very sophisticated and organized.²⁹⁻³¹ Many of the counterfeiters straddle the line between legitimate and illegitimate operations, as the opportunity presents itself.^{32, 33} In some instances, the fraudster will swap out a high value ingredient; may illegally replicate a biological plant; or may use legal goods to facilitate trade-based money laundering (TBML). Diversion—also referred to as parallel trade or gray market is really just product arbitrage—includes an exchange of product and ownership, which presents an opportunity for a fraudulent product to be introduced.³⁴ There is evidence of extensive organized crime involvement in all types of counterfeiting.³⁵ There is also evidence of industrial-scale counterfeiting operations.³⁶ In many cases, the counterfeiters produce products with a superior quality of product or packaging to avoid detection. In an extreme case, it may be assumed that the counterfeiters are criminals (not concerned with breaking laws), sociopaths (not concerned with cheating others), and/or not educated about the inherent public health or safety dangers.³⁷ The counterfeiters are often intelligent, resilient, well-funded, as well as clandestine, stealthy, and actively seeking to avoid detection.³⁸⁻⁴¹

Law school programs on IP technology transfer do not typically address defense against counterfeiters. Those programs assume criminal or civil defendants who can be identified, brought to court, prosecuted, incarcerated, have their assets seized, and can effectively be stopped from their IP infringement. Many programs focus on contract law interactions between legitimate corporations—‘responsible defendants’. Yet product counterfeiting often includes

‘irresponsible defendants’ who flee, obfuscate ownership of their assets and effectively launder their money out of reach, who have networks that can reform unnoticed, and who often are part of violent, criminal networks. ‘Because of these factors, litigation is often of marginal utility. It is fairly easy to ‘win’ cases against (a product fraudster); it is quite another to translate such victories into meaningful recovery.’³⁸ That being said, registering trademarks and patents should be considered in all countries, regardless of the level of sales of product in that country. While this does not mean the IP lawsuits would necessarily help, but at least counterfeiting would be technically illegal. If not registered it would not be illegal to produce products with the trademark or that infringe on a patent.

Globalization and Source Economies

The food fraud risk is a function of both individual company practices and general global practices.⁴² Influences include country-level practices of general fraud or corruption, and their flip-side—the strength of laws and prosecution of food laws and IP laws. The enforcement and prosecution of laws in all countries are important but strained as globalization leads to more production being consolidated while distribution is expanding farther around the world.⁴³⁻⁴⁵ In reality, it may be more dangerous to buy a product from a sloppy local manufacturer than from a trusted supplier half-a-world away. The growing global economy relies on the quick and efficient flow of goods around the world, and these very processes are co-opted by the fraudsters. Laws and regulations naturally lag in a rapidly changing marketplace.

Transparency of the systems, processes, and flows of products is becoming ever more important to securing supply chains.⁴⁶ This transparency will also be helpful in ‘food defense’, or protecting the food supply from attacks.⁴⁷ A useful concept is the ‘Six T’s of supply chain quality management: traceability, transparency, testability, time, trust, and training.’^{48, 49} A frequent mantra in the anti-counterfeiting industry is ‘trust, but verify.’⁵⁰

There are many, multi-faceted security threats to the supply chain.^{47, 51, 52} Awareness of the types of fraud or counterfeiting can help in identifying those IP technology transfers, supply chain logistics, pricing and procurement practices that can reduce the fraud opportunity. The trans-border movement of proprietary goods for business is the very foundation of the world economy, whether for developed- or

developing-countries, regardless of that country’s level of IP assets. The first step is to understand the global economy’s basic drivers, the fraud opportunities, and then those company standard operating procedures or best practice process refinements that contribute to fraud opportunities. Global enforcement systems are based on the physical borders of countries and are merely hindrances to trans-border, trans-national organized crime organizations.

It is important to establish some key concepts about the illicit trade. Moises Naim, in his book, *Illicit: The Dark Trade*, states that in general illicit trade:

- is driven by high profits, not low morals;
- a political phenomenon—illicit traders cannot prosper without help from governments or accomplices in key public offices;
- is more about transactions than products—it has become customary to parse the illicit trades into separate product lines;
- cannot exist without licit trade—all illicit businesses are deeply intertwined with licit ones—traffickers have strong incentives to combine their illicit operations with legitimate business ventures;
- involves everyone—someone is buying; and
- cannot be enforced and prevented by governments alone.²⁸

The author has stated that illicit trade, including product counterfeiting, ‘...is also about a new form of politics in the twenty-first century.’²⁸ It is also difficult to rely on fiscally constrained countries to commit to the financial and human resources investments to combat this complex threat, ‘...let alone compensating their civil servants adequately, or even paying them in full and on time – all of which almost guarantees corruption.’²⁸ In 2004, the US Central Intelligence Agency stated the existence of ‘stateless zones’ in 50 countries—regions where there was little central government control.⁵³

Understanding that the fraudsters are not focused on products or IP violations, is important. The fraudsters are seeking the least risky opportunity to make the most money. This is not about IP, it is about making money; and there should be equal focus on enforcement and prevention.

The Challenge of IP Enforcement

IPR law, in itself, is extremely complex. IPR enforcement is hard enough when dealing with

responsible parties, such as between two upstanding corporations in a country with reliable law enforcement and prosecution in its court systems.

Laws and regulations are necessary for commerce to function efficiently. To maximize efficiency, compliance with the regulations facilitates smooth transactions, which reduce costs due to uncertainty or risk. ‘Trust in compliance also avoids cost that might otherwise be borne by the parties to the transaction.’³⁸ Key to this is the expectation of compliance, that the rules will be followed, and that the rule-breakers can be stopped.

When dealing with responsible parties, the process works. The system breaks down when dealing with fraudsters and counterfeiters, who are, in the worst but unfortunately very common case, criminals not concerned with breaking the law, sociopaths not concerned with cheating or demoralizing others, and/or uninformed and ignorant of risks inherent in the actions. Specifically, counterfeiters are often irresponsible defendants who hide or flee from prosecution and have laundered their assets out of reach of the courts. ‘Those (counterfeiters and diverters) who evade the laws do so with the expectation that they can reap substantial profits and the risk of incarceration—or even detection—is minimal.’³⁸

To add to the complexity, much of the IP infringement occurs all around the globe, and often with many parts of the crime perpetrated in multiple countries. It is not uncommon for a product counterfeiting network to include products or components produced in five countries, with assembly and distribution through five more.²⁸ Any prosecution that works to attack the actual production of the counterfeit product could include upwards of ten countries and their ten court systems.

There is a further complication of dealing with a wide-range of IP laws, enforcement, and prosecution. In some countries, IP protection is a low priority or cannot be relied upon for consistent intervention. It should be emphasized that government IP enforcement priority challenges all countries. For example, the US Trade Representative (USTR) publishes a ‘Special 301’ report of the countries identified for not effectively enforcing IPR in their Priority Watch List (PWL) and their Watch List (WL). The lists include 10 of the top 20 economies (G20) in the world, including Canada, Finland, Italy, Norway, and Spain (Table 1).

In addition, Transparency International is an organization that surveys and analyses government corruption. Many of the top IP technology transfer partner countries are represented in these two tables 1 and 2. Again, many G20 countries are prominent (Table 2).

Beyond the base complexity of the IP challenges and the international nature of the laws, the priorities and capabilities within many of the leading

Table 1—USTR Special 301 Priority Watch List and Watch List⁵⁴

Priority Watch List	Watch List
(n=13, *G20=6)	(n=33, *G20=4)
Algeria	Brazil*
Argentina*	Finland
Canada*	Italy*
Chile	Mexico*
China*	Norway
India*	Spain
Indonesia*	Turkey*
Pakistan	
Russia*	
Thailand	
Venezuela	

Note: Eighteen of forty-six countries listed here, top twenty countries (G20) are noted with an (*).

Table 2—Selection of Transparency International Corruption Index for 2010 – G20 and Special 301 PWL or WL listed countries⁵⁵

Rank	Country/Territory	CPI 2009 Score (10 is highest, 1 is lowest)
1	New Zealand	9.4
6	Finland (301 WL)	8.9
8	Canada (G20)(301 PWL)	8.7
11	Norway (301 WL)	8.6
14	Germany (G20)	8.0
17	Japan (G20)	7.7
17	United Kingdom (G20)	7.7
19	United States (G20)	7.5
24	France (G20)	6.9
30	Spain (301 WL)	6.6
61	Turkey (G20)(301 WL)	4.4
63	Italy (301 WL)	4.3
75	Brazil (G20)(301 WL)	3.7
79	China (G20)(301 PWL)	3.6
84	India (G20)(301 PWL)	3.4
89	Mexico (G20)(301 WL)	3.3
106	Argentina (G20)(301 PWL)	2.9
110	Indonesia (G20)(301 PWL)	2.8
146	Russia (G20)(301 PWL)	2.2
178	Somalia	1.1

Notes: New Zealand is the top-ranked country and Somalia is the lowest ranked; countries are included only for reference. Special 301 Priority Watch List and Watch List countries are noted with (301 PWL) and (WL)

technology transfer country partners vary widely. When the fraudsters and counterfeiters enter the enforcement equation, the challenges of IP enforcement become astronomical. The challenges have become so daunting that there must be a shift in focus from reactionary intervention and response, to the proactive prevention of the fraud opportunity. It should be remembered that ‘the goal of a (company’s) litigation strategy is to deter (product fraudsters) from targeting the company—not necessarily to put them out of business.’³⁸

Preventing Fraud Opportunities

There are entire academic criminology disciplines dedicated to understanding criminals (traditional criminology) and criminal opportunities (environmental criminology, including Situational Crime Prevention). Yet, it is novel to directly apply chemistry of the crime and the crime triangle concepts to IPR theft prevention and to anti-counterfeit strategy.^{21, 56} To reduce the extremely complex impact of IP infringement, it is important to first understand the nature of the specific types of fraud and associated risks, and second, to take actions to reduce the specific fraud opportunities.

There should be an emphasis on a holistic review of the entire risk rather than to just seek a simplistic magic bullet from the arsenal of a single discipline. Packaging components, product authentication, traceability, market monitoring, IP litigation, supply chain tightening, distributor control, and other measures are all important components of the overall anti-counterfeit strategy. There are many standard business operating procedures, or even best practices, which can contribute to fraud opportunities. The very systems used to refine the focus against risks such as specific traditional food safety incidents, inherently create gaps in the less-monitored adjacent areas. The fraudsters are human actors who are intelligent, resilient, opportunistic, and work very hard to find creative ways to circumvent or dupe the detection and deterrence systems. Anti-counterfeit strategy should be considered a chess match rather than a one-time fix.

With a nearly infinite number of fraud and fraudsters, as well as with products moving quickly around the globe, the intervention task is daunting, to say the least. To be able to implement countermeasures within systems that are controlled, and to do so in a way that will actually be somewhat measureable in their outcomes (admittedly very

qualitative; how can one measure the number of terrorist attacks that were deterred in the terrorist planning stages?), the shift should be towards prevention and reducing the fraud opportunities.

To understand the fraud opportunity, each incident should be analysed for a specific product, group of products, market channel, and type of consumer, company, industry, and country. Those incidents provide insights on who is perpetrating the fraud, with what technologies, on what scale, with what partners, through which channels, to which consumer, with what public health and economic risk, and using what modus operandi. When this process is used, specific countermeasures can be assessed for their integrated effective and efficient detection and deterrence of this specific incident. Different types of fraud and fraudsters can be grouped and classified for more broad-ranging countermeasures.

In general, the types of food fraud cover IP infringement in each component of: incoming goods, outgoing goods, information (including trade secrets and technology transfer), and products completely outside the legitimate supply chain (Fig.1).

There is an important role played by supplier agreements and standards in procurement contracts. International standards exist, and more are under development, from the likes of the International Standards Organization (ISO) and the US Pharmacopeia/Food Chemicals Codes (USP/FCC). ISO is expanding work against fraud through the work of Technical Committee 247 Fraud Countermeasures and Control. USP/FCC is expanding work in food ingredient intentional adulteration, as well as in economically motivated adulteration. It is important that these standards expand to clearly define the expected honest business practices. It is also important that these new internationally recognized standards support new regulations and are included in business contracts. If IP laws are not

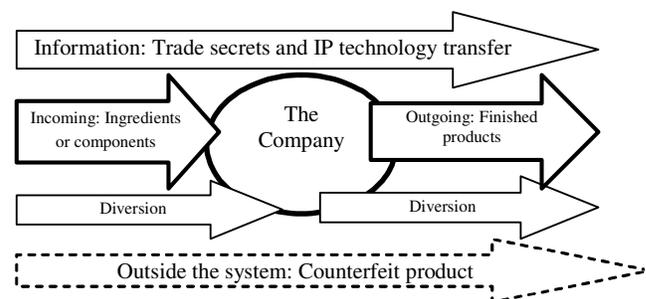


Fig. 1—Types of food fraud – In- and outside the legitimate supply chain⁵⁷

enacted, and if fraud is not clearly defined, then what may be considered fraud by the brand owner manufacturer may not be illegal in a criminal or commercial sense.

Case Studies

To provide some examples of ‘irresponsible defendants,’ five cases of food fraud or product counterfeiting will be reviewed. Although not all of the cases are agriculture- or food-related, they provide excellent insights into the nature of fraud and fraudsters. The reviews provide examples of the extent of the operations, evolution from legitimate businesses to illegitimate, as well as the diligence these fraudsters maintain to avoid detection or capture.

Hiding in the Jungle and an Attempt to Bribe Officials

This case provides an example of how a small group of fraudsters can create an entire network from manufacturer through direct customer sales; the massive amounts of money that can be made; and an example of a defendant who launders their money and flees.

Jared Wheat created a series of businesses, which culminated with Hi-Tech Pharmaceuticals. He established a production facility in a house in Belize, where he received active ingredients, and then had a small staff produce counterfeit, finished pharmaceuticals. He marketed and sold the product through Internet websites that claimed to be Canadian pharmacies. The legitimate, genuine active ingredients were reported to be from India and China, which is logical since those are the two largest producers of all active pharmaceutical ingredients. It was reported that he had ‘hundreds’ of customers and that over US\$ 100 million was deposited in his personal bank account.⁵⁸ The operation was somewhat sophisticated in procuring the active ingredient, but the packaging was very unprofessional ‘sandwich bags’ and ‘two pieces of ordinary paper crudely glued together.’⁵⁸

Overall, the indictment noted 45 counts against him. The US Drug Enforcement Agency (DEA) raided the business together with the Belizean Police, but Wheat fled to Mexico and began to transfer his money to Panama.⁵⁹⁻⁶² Later, it was reported that the defendant tried to bribe Belizean officials to ‘to get rid of these charges.’⁵⁸ Belizean officials withdrew all criminal charges against him at that time. He eventually returned to the US and was arrested without incident, at his home in suburban Atlanta.

This case is important because it provides an example of how simple it is to create an organization, the stealthy access to customers via the anonymity of the Internet, willingness and ability of defendants to apparently bribe officials, and the willingness of the fraudsters to flee. He was sentenced to 4 years in prison and the forfeiture of US\$ 3 million of his reported US\$ 100 million in ill-gotten gain.

Escaped Prosecution and Funded Terrorism

This case provides an example of the nature of some of the fraudsters, specifically a defendant who escaped before being caught; elaborate nature of multiple operations; and how terrorist operatives or sympathizers are involved in revenue-generating fraud.

Hassan Hodroj was reported to be a ‘Hezbollah weapons-procurement officer,’ and was among a crew of sixteen defendants identified in a 31-count Grand Jury Indictment.⁶³ The wide range of crimes included gun-running, manufacturing and selling fake passports, distributing counterfeit and stolen currency, selling stolen goods, selling counterfeit goods, and falsifying government documents.⁶³ Counterfeit products comprised US\$ 5,000 of the US\$ 2,535,000 listed in the indictment. ‘The crew, and accomplices, had ties to other operations, including a multi-million dollar Hezbollah cigarette-smuggling ring.’⁶⁴ The crew travelled on fake British and Canadian passports, and Hodroj fled from the US for Lebanon before he could be captured. He has not been reported captured and there is no additional information on the status of the US-based crime group.

This is an example of the often elaborate nature of fraud organizations, the potential for the fraudsters to have an extremely violent nature, and an explicit example of the use of multiple passports and escaping justice. He was sentenced to 15 years in prison *in absentia*.

Document Counterfeiting, Quality Fraud, and Price Fixing

This case study provides an example of the extent of fraud and deception even with diligent enforcement and prosecution, willingness to launder money and flee, as well as the extent and longevity of fraud when there are no incidents of public health incidents.

The CEO of SK Foods, Frederick Scott Salyer, was indicted in a 20 count criminal complaint perpetrated over ten years, in twenty two states, and to over fifty customers.⁶⁵ The newspaper articles discuss tremendous personal, individual financial, and business financial duress for Salyer, which appear to partially have led to the willingness to commit the fraud.¹¹ This motivation for personal financial gain is

classified as food fraud, and this case included many types of counterfeiting including document fraud. He conspired with others and bribed purchasing managers and quality inspectors to accept lower quality tomato paste, to pay above market prices, or to wrongfully obtain competitor pricing. The fraud included falsifying Certificates of Analysis. They also conducted fraud such as selling product as organic that was not organic.⁶⁶ Although no final estimate was provided, with the fraud escalating over ten years and fifty customers, the result could easily be over US\$ 100 and it is conceivable to be as much as US\$ 500 million. The indictment noted over US\$ 330,000 in bribes and two specific deals were listed that netted premium prices of US\$ 1.6 million and US\$ 2 million.⁶⁷ The fraudulent product was reported to have often been sold for up to a 30 per cent premium.¹¹ The original indictment was expanded to include the Racketeer Influenced and Corrupt Organizations Act (RICO) which gave Salyer, a maximum penalty of 20 years, fine of up to US\$ 250,000, and forfeiture of all assets related to the activity.⁶⁸

Salyer was arrested while reentering the US since he had a flight booked back to Europe the next day. He had transferred ‘millions’ to banks in the Caribbean and Lichtenstein. He also had started to pursue permanent residence in countries with low risk of extradition such as Uruguay, Paraguay, Andorra, and France. ‘Mr Salyer apparently intended to become a fugitive from justice.’⁶⁵ He was not offered bail until he had served eight months in jail and after he had posted a US\$ 6 million bond.⁶⁸ The case is currently ongoing and no final sentence has been decided.

In this fraud, the product often did not meet US and FDA specifications for human consumption. The product was noted to be mainly low quality, so the lack of public health outbreaks reduced the opportunity for the fraud to be uncovered sooner. For example, illnesses and positive tests for salmonella uncovered the food fraud much sooner in Peanut Corporation of America case.

This is an example of how legitimate businesses and their leaders can be tempted from legitimacy into fraudulent practices, the ease with which quality control systems can be circumvented, and the extent of money laundering and willingness to flee.

Distributor Evaded Court and Stayed in Business

This case provides an example of how difficult it can be to prosecute—or even conduct discovery on—

an international IP infringement case, even when the individuals and companies are operating in plain sight.

In May 2004, the US FDA issued a recall notice for counterfeit Prolene surgical mesh.⁶⁹⁻⁷² Robert Nicholson, a federal prosecutor, was quoted stating that this is believed to be the first known identification of a counterfeit medical device – but certainly not the last.^{73,74} While a scientific study did not find a significant difference in the performance of the counterfeit to the genuine product,⁷⁵ other studies did find that the product was not sterile and included four types of bacteria.⁷⁶ It was unequivocally a counterfeit product by any definition of IP, since the trademark holder did not authorize or manufacture the product.

There is quite extensive detail in the indictments, identifying how the product was integrated into the legitimate supply chain, and how it circumvented authentication and testing protocols. Originally, the wholesale distributor, Q-Med Corporation, bought the plastic meshing from an unnamed overseas seller later identified as Globe Traders, and resold it to a large national medical distributor that supplies to the surgeons, according to federal officials and the FDA.⁷⁴ Later, the supply chain was as Wilmington Surgical Center from their distributor, Owen & Minor (an authorized distributor of Prolene⁷⁷), from the national wholesale distributor Q-Med, who procured the product from outside of authorized channels from Globe Traders of Mumbai India.⁷⁸ (It is interesting to note that Ethicon, the genuine product manufacturer was not listed as a defendant.) The case stated that Q-Med was ‘negligent and breached the applicable standard care’ and ‘participated in the purchase of medical devices (including the counterfeit mesh) in the ‘gray market’ or caused, aided, and abetted the said participation, when under all the circumstances it is unreasonable to do so,’ and also that buying on the gray market caused ‘foreseeable’ conditions of risk.⁷⁸ It was alleged that Globe Traders was the manufacturer of the counterfeit product—not just a ‘parallel trader.’ Five years after the original recall, Global Traders was identified in a September 2009 FDA import alert for ‘Prolene Mesh II’.⁷³

This provides an example of the complexity of the global supply chain, as well as the difficulty in prosecuting—or even conducting discovery of—international suspects. The case is also an example of an alleged counterfeiter who was not stopped.

Tax-Avoidance Smuggling Expanding to Food Fraud

This case provides an example of the complexity of tax-avoidance smuggling which resulted in a

counterfeit statement of country-of-origin and included product with unsafe ingredients. This network expanded to diluted product and created an opportunity for additional counterfeit product to be introduced into commerce.

A group of fourteen business people from China and Germany were charged in the US with a forty-four criminal count indictment for country of origin fraud for honey.⁷⁹ The conspiracy indictment was for 'entering transshipped Chinese-origin into the United States' and included anti-dumping violations, tax avoidance smuggling, adulterated food, shipping documentation violations, and obstructing justice. The Chinese-origin honey was falsely declared as originating from countries other than China, including Russia, India, Indonesia, Malaysia, Mongolia, Philippines, South Korea, Taiwan, and Thailand. The country-of-origin fraud (origin-laundering) of hiding the Chinese origin was to avoid US anti-dumping duties of over 200 per cent of the product value. This is considered adulterated under the FDA Food, Drug, and Cosmetics Act due to not being 'safe, wholesome, sanitary, and properly labeled.' The product was found to include 'unsafe' antibiotics of Ciprofloxacin and Norfloxacin, Chloramphenicol, and Furazolidon. The entire known fraud was estimated at US\$ 39,589,775. The scheme included multiple shipping containers of 55-gallon drum product; one purchase order included fifteen shipping containers transshipped through the Philippines.^{80, 81} The accused admitted to fraudulent activities including importing US\$ 8 million in honey that was blended with 20-30 per cent artificial sugar to upgrade the product to obtain a higher price⁸²⁻⁸⁴, besides, evading anti-dumping duties.

This case is an example of the technical complexity of fraud, the extent of some of the legitimate organizations perpetrating the fraud, ability for many of the leaders to move quickly around the world and possibly launder their proceeds, the potential inadvertent public health threats, as well as how the financial fraud can expand to food fraud.

Conclusion

IP technology transfer and expansion into global markets is necessary for any company to achieve large-scale success, but the growth is not without correspondingly expanding and emerging risks. Governments, agencies and courts have a daunting task, if they are to reduce fraud opportunities against

these clandestine, stealthy and irresponsible defendants using reactionary enforcement and prosecution.

While product counterfeiting often conjures up luxury goods and branded consumer products, the case studies demonstrate fraudulent practices that create fraud opportunities for agriculture IP technology transfer, bulk products such as seeds or plants, concentrated chemicals that are mislabeled or diluted, country of origin or appellation fraud, and all include the potential for trademark counterfeiting of the branded manufacturer.

Protecting IP rights against fraudsters and product counterfeiters is such a challenge that it is critical for a company to make a strategic shift from intervention and response, to prevention. To protect IP, it is vital to assess a strategy for dealing with fraud before disseminating the technology or entering a new market. This strategy should start with understanding the specific types of fraud and fraudsters in specific segments or geographies of the market. The strategy should also include ongoing market monitoring for new fraud, and an aggressive litigation plan that focuses on deterring the fraudsters and reducing the fraud opportunities. Part of the assessment should include analysing a company's own standard-business operating procedures and best practices, which may inadvertently contribute to the problem. The questions to ask are: What is the scope and scale of the problem? What are sales revenue losses and litigation exposure? What is the cost of countermeasures (including the confidence in the countermeasure and how success will be measured)? and what is the cost of doing nothing? A company cannot state they do not have a counterfeit problem if they do not look for counterfeits.

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