3D Fakes: Chemical Fingerprinting in Additive Manufacturing, from Pharmaceuticals to Engines

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Abstract

The rise of 3D printing brings with it manufacturing opportunity and new challenges in intellectual property protection. We address the use of chemical fingerprinting as a strategy to validate genuine product and protect against counterfeits.

The Counterfeiting Challenge \\

The revolution in 3D printing is enabling distributed production at a scale unprecedented in the history of manufacturing. This technology also unleashes an opportunity to counterfeit goods to an equally unprecedented extent (Figure 1). [1] [2] [3]

Figure 1. Counterfeiting is an enormous problem worldwide, costing up to a trillion dollars a year and placing companies and consumers at risk.

We examine the benefits of tagging methods for anti-counterfeiting, with a focus on chemical fingerprinting. Experience fighting counterfeits, including in the pharmaceutical and luxury goods markets, suggests that ease of use fosters greater security: if tagging and testing are easy, more tagging and testing take place. Chemical taggants provide additional advantages, especially if they can be detected with a non-destructive evaluation in the field. If it feels unwise to trust a supplier's certification document, a new test can be performed, optimally in a few seconds by a tester with minimal training: "That guy might be lying, but we can just check for ourselves."

Evil is a major challenge in anti-counterfeiting: it is difficult to adopt the adversary's mindset. An example from the Cold War illustrates the problem, as NSA history notes in an examination of their discovery of bugged typewriters in the U.S. Embassy in Moscow.

"Another lesson that GUNMAN taught us was to expand our thinking. Many of us in the COMSEC area expected the bug to be in crypto or other COMSEC equipment. It ended up being in a typewriter that produced plain text. We had to pay more attention to plain text communication devices if we were to keep U.S. communications secure." [4]

Despite those lessons, it remains difficult to anticipate the scope of wrongdoing. To ensure the safety of electronic parts in the Department of Defense (DoD) supply chain, current published rules for DoD contractors and subcontractors include ongoing adjustments. The Defense Federal Acquisition Regulation Supplement (DFARS) Publication Notice 20160802, "Detection and Avoidance of Counterfeit Electronic Parts – Further Implementation" apparently continues to rely on a fundamental belief in supplier good will and accountability [5].

This supplement amends the DFARS to implement a requirement of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2012, as modified by a section of the National Defense Authorization Act for Fiscal Year 2015, which addresses required sources of electronic parts for defense contractors and subcontractors. The final rule, effective August 2, 2016, requires DoD contractors and subcontractors, except in limited circumstances, to acquire electronic parts from *trusted suppliers* in order to further address the avoidance of counterfeit electronic parts. Apparently the expectation is that no one will lie or cheat in their quest to be a "trusted" supplier in this chain, but the advent of 3D printing makes it much easier to make credible fakes, and suggests a need for a stronger deterrence system.

It is all too easy to get caught up in procedures that seem secure, but mostly succeed in placing a burden on the law-abiding while allowing work-arounds by determined counterfeiters. Viewing glasses were widely counterfeited for the 2017 solar eclipse, in a typical pattern. As demand grew, shortages developed and a market opportunity arose, with eager patrons ready to pay inflated prices. As often happens, the consumers had no way to check quality, creating a bonanza for counterfeiters. At the same time, considerable burden fell on legitimate manufacturers, some of whom were mistakenly blacklisted on Amazon and lost out on a major opportunity or were stuck with completely unsaleable, though high-quality, merchandise. Evidence of burden has shown up in the rollout phase of the current U.S. law for drug safety, with companies complaining that even initial setup costs exceed a million dollars.

Serialization, i.e. numbering and then checking every item at every stage of the supply chain, is the approach FDA mandated for pharmaceuticals in the Drug Supply Chain Security Act of 2013. (Figure 2) Numbering items without checking them, of course, is pointless: a counterfeiter discovers that 34555 is a legitimate code, and proceeds to create many more 34555 items. Thus monitoring is required, with each player at every stage able to confirm that 34555 is legitimate and has not been seen before. However, that monitoring provides no guarantee that the first 34555 is the legitimate one, since there are many tales of speedy counterfeiting, sometimes on the market before the genuine drug. Furthermore, compliance has been cumbersome enough that the deadlines are slipping, with a recent year-long extension:

"FDA does not intend to take action against manufacturers who do not, prior to November 27, 2018, affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce as required by section 582(b)(2)(A) of the FD&C Act." [6]

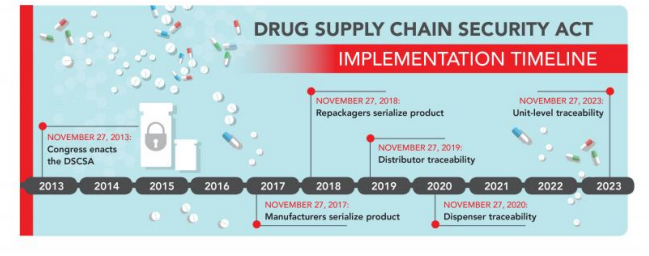

Figure 2. Supply chain security is a complex undertaking, and even seemingly simple measures such as serializing drug packaging can expand into years-long processes plagued by complications and delays.

Chemical Tagging

Chemical markings, then, offer several advantages. They are covert, so that counterfeiters are not alerted to their presence. One can argue that overt marks, such as holograms, reassure consumers about brand integrity, but by now that argument is misplaced: holograms are broadly counterfeited. [7]

Chemical tags lighten the monitoring burden, because any player in the supply chain can re-validate independently. No one needs to trust that the upstream supplier handed over reliable paperwork, since they can just retest. This independence is an advantage in any situation, but it grows in importance in a complex international supply chain, or when special circumstances intervene, such as supplies for military special forces, or logistics monitoring for a product like medical cannabis or opioids.

Chemical taggants fall into three general categories, crafted, intense, and formulation-based (as-is or intentional).

Crafted. Taggants can be crafted micro- or nano-particles, preferably with many options so they can tag different items or batches differently. [8] However, crafting taggants adds manufacturing cost and may limit users to a single supplier. Other potential concerns with the crafted taggant approach include the need for additional testing and approvals in regulated industries. If crafting is too easy, counterfeiters can do it too; if it is extremely difficult, it is likely to be expensive, and fall into the mistaken trap that anti-counterfeiting that is complicated and costly is a smart deterrent. Instead, complex and expensive solutions are likely to be applied less comprehensively and tested less often, adding cost but not sufficiently enhancing security.

Intense. Taggants can offer an intense signal, generally at a particular wavelength, so that a detector can find them. These intense taggants include up-converting fluorophores and rare earth oxides, often sourced from China. They are available to counterfeiters, however, on the same marketplaces, and there are already cases in which the anti-counterfeiting taggants have themselves been counterfeited, as a Google search for *anti-counterfeit upconverting fluorophore alibaba.com* will quickly illustrate. Beyond the security limitations, intense taggants suffer from other disadvantages as well. Companies that offer them are likely to have only a very limited repertoire of solutions, with a limited number of suppliers. If there is a problem, whether of copying or of supply disruption, it can be a major struggle to deploy backup options. So while the use of an intense taggant can appear advantageous, it does not scale well to serious manufacturing environments.

Formulation-based. Chemical analysis makes it possible to differentiate via composition, to a high degree of precision. It is tempting to use a detector (like a Raman spectrometer) and try to distinguish real from fake without any deliberate tagging at all. Pharmaceutical anti-counterfeiting in some parts of Africa has been detected using handheld Raman or near-infrared (NIR) spectrometers, without intentional tagging, because the counterfeits are quite different from the genuine product. [9] When the counterfeits are better, however, the as-is technique fails, and intentional tagging is required.

Intentional tagging is a hybrid approach, leveraging an analytical technique, spectroscopy, that has long been used for forensic laboratory studies. The rise, in the last decade, of high-quality, portable, low-cost (and now even smartphone) spectrometers transforms the technology into a fast, easy-to-use, field check. Without intentional tagging, spectroscopy is insufficient to distinguish similar formulations. Searching for taggant alone is not particularly secure, and counterfeiters have already defeated many such schemes. Some are covert and require an ultraviolet light for validation… and counterfeiters use UV lights to detect such taggants and then replicate them on fake products. The intentional tagging hybrid takes advantage of spectroscopy's full chemical profile, matching not just D in an ABCDE matrix, but instead requiring a whole match of ABCDE. Figure 3 illustrates the use of NIR spectroscopy to distinguish 3D printed polymers. In field use, the spectrometer shows a Yes/No, Match/No Match interface to the tester, but the graph is presented here to show what is going on behind the scenes. The spectral graph compares two visually-identical beige samples, with ULTEM thermoplastic resin in green and polyphenylsulfone (PPSF) in maroon. Significant differences appear, especially around 1350 and 2000 nm.

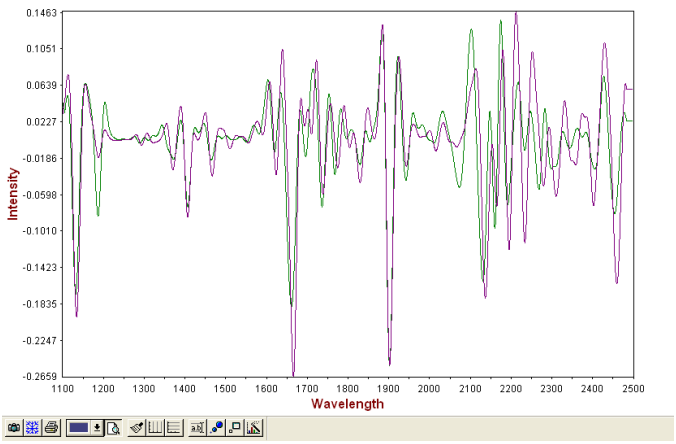

Figure 3 shows different peaks for the two beige samples: they may look the same to the eye, but not to the spectrometer.

Use of near-infrared spectroscopy provides additional advantages: in its 70+ year history, it has never been reverse engineered. NIR peaks show chemical bonds, not specific chemicals. Furthermore, the peaks interact, so a reverse lookup fails. If a counterfeiter – even a trained chemist – sees a NIR peak at, say, 1650 nm and tries to look it up in a table, s/he is not going to find Taggant D listed, because Taggant D, which may have a characteristic peak at 1642 nm, has been influenced by the presence of A, B, C and E, to shift the peak.

For the pharmaceutical market, InfraTrac has applied intentional formulation-based tagging for in-dose anti-counterfeiting, manipulating the excipient (inactive ingredient) ratios slightly in order to create detectable spectral fingerprints in drug doses. Formulation-based tagging can be mixed into a whole batch, e.g. for drugs or for a tagged injection molded bottle or cap. It can also be layered in, for those applications and others. The rise of precision medicine brings opportunities in 3D printing to the pharmaceutical industry, as it becomes both more important and easier to craft custom doses tailored to an individual's size, genetics, and metabolism. These 3D-printed precision medications are expected to follow the model of compounding pharmacies, so that a local provider can create a precise, authorized, tailored dose to an individual patient. However, compounding pharmacies not long ago were shown to have provided an opportunity to rogue, sloppy, even criminal sellers, and the rise of 3D printing only expands the challenge. Thus authentication and validation are critical additions to the planning process, and fingerprinting is a strong choice to support supply chain safety in this evolving marketplace.

The same formulation-based fingerprinting technique is being applied to additive manufacturing (AM), including for packaging, aircraft and automotive parts, and even athletic shoes. [10]

Formulation-based tagging uses commodity chemicals, so that it is simpler to follow good supply chain practice and include dual sourcing. Commodity chemical taggants are more likely to be available from trusted sources, more likely to be available at scale, and more affordable. Formulation-based fingerprinting is compatible with regulated industries, since it is not hard to choose safe, compatible taggant materials. The taggant mix is hidden, in the case of 3D printing in an invisible under-the-skin spot, like a square of peanut butter and jelly hidden inside the "sandwich" of 3D printing.

More Materials

Formulation-based tagging can be used in 3D printing applications beyond polymers and pharmaceuticals. Successful tests in metals tagging show that spectroscopic taggants can be used in industrial 3D printing, so far for titanium alloy Ti6Al4V, using x-ray fluorescence spectroscopy as the detection method [11]. While many metals print processes use a powder bed and are, for the moment, limited to a single material, directed energy deposition (DED) metals printing allows deposition of taggant material via a second print head. Printed circuit boards can be created with 3D printing, layering the connective wiring atop a polymer base, and formulation-based tagging can easily be embedded into the polymer, as demonstrated by previous experiments using jettable nanocomposites from Chemcubed [10].

Standards and Quality

Standards for additive manufacturing are being developed, e.g. as consolidated in the emerging America Makes & ANSI AMSC Standardization Roadmap for Additive Manufacturing [12]. It would be a mistake to view counterfeits as outside the standardization and testing process, as failures. Instead, the standardization process should include validation procedures that can catch and reject fakes, even "good" ones, as non-conforming. Cybersecurity has been recognized as a standards concern, but must apply beyond the file and into the physical objects created from those files. Depot outsourcing models are being developed where a spare part can be ordered and delivered by a third party consortium, and it must be recognized that the counterfeiting threat there does not end with the file: if a resulting engine part is substandard, it may jeopardize life and limb. In the case of a medical device, a substandard part may contain nooks and crevices that harbor bacteria and become unintentionally lethal.

Formulation-based tagging and validation aligns well with standards for materials characterization, including particle size, distribution, morphology, and microstructure, with spectroscopy serving as a useful tool to check for conforming – or non-conforming – elements.

Emerging qualification and certification options such as PointSemantics' strain imaging can also play a role, processing a digital video map of surface dots to show strain in use.

Spectroscopy is useful in AM quality control as well, as a form of non-destructive evaluation, and can be used to monitor particle size and moisture during printing, [13] and even to authenticate print media (by detecting genuine media, just as inkjet printers detect genuine ink). [14] It also aligns well with the data fusion recommendations in the America Makes/ANSI AMSC Roadmap, and can be easily combined with other metrics. Fast, non-destructive field-friendly testing fits into a broader risk management program, with high-accuracy screening available to increase the sampling rate and target the more expensive tests to the real problems. In this way formulation-based tagging and spectroscopic detection can contribute to the entire quality process, not only because when a counterfeit sneaks in, quality is utterly compromised.

Author Biography

Dr. Sharon Flank, InfraTrac CEO, is an anti-counterfeiting expert. InfraTrac develops product protection solutions based on spectroscopy, and received a Challenge Grant from America Makes to extend IP protection for additive manufacturing. She worked with defense contractor CSRA to spin out companies acquired by AOL (Navisoft), Chicago Tribune (Picture Network International) and then Kodak (eMotion), and CA (Assentor). Dr. Flank holds ten patents. She received her A.B. from Cornell and her Ph.D. from Harvard.

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