

## Pharmaceutical Anti-Counterfeiting and Process Patent Protection via Isotopic Characterization

**The Problem.** Counterfeiting of pharmaceutical products and infringement of patented processes are multi-billion dollar problems for the pharmaceutical industry.

**Who is Molecular Isotope Technologies LLC and how can we help you?** The mission of Molecular Isotopes Technology (MIT) LLC is to identify counterfeit products and cases of process patent infringement for pharmaceuticals clients, thereby protecting valuable assets. Nature's Fingerprint accomplishes this by applying the science of stable isotopic analysis, widely used in the petrochemical industry, to pharmaceuticals.

**Background.** Naturally-existing tracers ("stable isotopes") exist in all pharmaceutical materials, recording the identity of individual product batches as well as the processes by which they were made. These natural tracers occur in all matter with highly-distinctive "isotopic fingerprints" that can be used to unequivocally authenticate product in a method known as Product Authentication. Analogously, the isotopic fingerprinting of a multi-step synthetic sequences leading to a specific product is known as Process Authentication. Nature's Fingerprint has patents granted and pending in these areas and now owns the Isotopic Pedigree<sup>®</sup> trademark.

**The "Manufacturer's Fingerprint."** In 2005, MIT LLC characterized isotopically 26 batches of Naproxen in a blind study for the FDA to determine their product fingerprint or source characteristics. The isotopic compositions of the Naproxen samples clustered into six groups, corresponding to six manufacturers from around the world. The Product Fingerprint is the combined result of two variables -- the isotopic composition of the starting material and the isotopic characteristics that result from whatever multi-step process is used to convert starting material to finished goods.

**The Process Fingerprint.** Isotopic characterization of both the starting material and product allows development a fingerprint for the multi-step process. With this information, infringement can be identified, process patents can be defended, and the product's useful life and revenue stream can be extended.

The key concept of Process Fingerprinting is illustrated in Figure 1. Knowing isotopic composition of starting material and product allows calculation of the vector (arrow) that represents the multi-step process fingerprint. The same fingerprint results despite multiple sources of starting material having different isotopic compositions.

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The Process is Same Regardless of the Source of the Reactants,  
though the Product Fingerprint is Different.

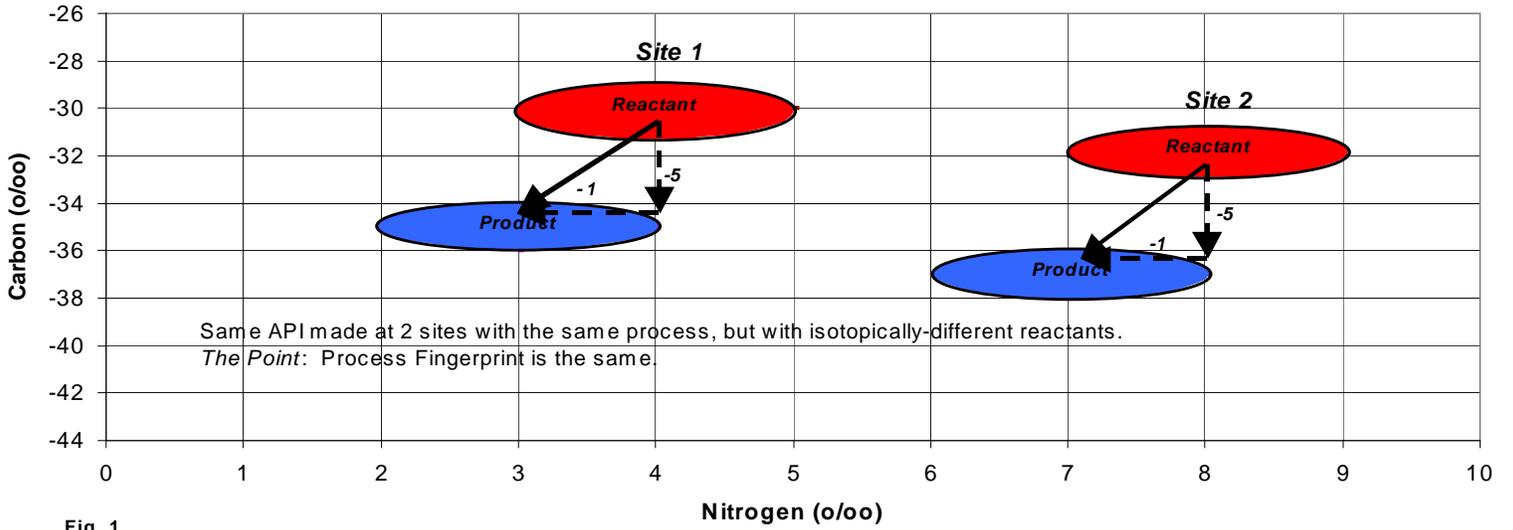


Fig. 1

**Fig. 1.** This plot of paired carbon- and oxygen isotopic compositions of a reactant and product shows that the chemically-same API that was made at two separate manufacturing sites was made with the same process (-5 in  $^{13}\text{C}$  and -1 in  $^{15}\text{N}$ ).