Protecting Formulas

Strategies for addressing formula disclosure requests for flavors and fragrances and recent challenges

In the flavor and fragrance industry, intellectual property (IP)—and formulas in particular—are key. Without limited disclosure, companies would have little in the way of uniqueness or value. Still, the industry is always keen on cooperating with customers and regulators while remaining as transparent as possible in the interests of public health and safety. Wherever the questions and requests come from, there are strategies available to IP owners for avoiding or minimizing disclosures, responses that can be narrowly focused to address only the specific information the requester is seeking.

Limited Formula Disclosures

In January 2007, the IP task force of the Regulatory Affairs Committee of the US Flavor and Extract Manufacturers Association (FEMA) released a white paper called "Strategies for Limited Flavor Formula Disclosures." The document stated that, "Trade secret laws protect any formula, pattern, device, or compilation of information that provides a business advantage for the owner." And because IP law tends to be a largely civil matter, it is the responsibility of the IP owner to defend it and remedy any misappropriations.

The FEMA white paper detailed a number of formula disclosure scenarios, including the voluntary disclosure by the IP owner and disclosure due to a governmental or legal requirement. The US Federal Food, Drug and Cosmetic Act (21 USC §§ 301 ET SEQ.) allows for the collective declaration of spices, flavors and exempt colors without listing individual ingredients. There are of course some flavor exemptions to this law for certain materials used in flavors, such as monosodium glutamate, which must be disclosed. In addition, there are a number of regulations that may call for additional information, including the Safe Drinking Water and Toxic Substances Control Act of 1986, the 7th Amendment to the Cosmetics Directive and the California Safe Cosmetics Act.

Meanwhile, pharmaceuticals have their own rules, requiring that inactive ingredients such as flavors be disclosed to registration authorities. This sometimes includes disclosure of the full flavor formula. FEMA encourages IP owners to obtain copies of any statute or regulation that requires/authorizes such action.

Finally, certain flavor materials such as benzaldehyde, which is a US Drug Enforcement Agency listed chemical because it can function as an illegal drug precursor, must be registered and require some amount of reporting and recordkeeping, at times including limited formula disclosure for customers or regulatory authorities.

Responding to Disclosure Requests

According to John Cox, FEMA's assistant general counsel, "The first step in responding to a request for disclosure is to establish the authority of the person requesting the information. Who is the person requesting the disclosure and what is their position with the requesting organization? Is it someone that might be in a legitimate position to ask for some formula information?" Taking the time to confirm the legitimacy of the individual (such as regulatory professionals at customer companies), and his or her request in light of legal and other requirements, can prevent unnecessary formula disclosures.

Cox continues, "There's been an increase in recent years in legitimate requests prompted by allergen labeling requirements, drug precursor regulations and additional regulatory requirements over certain classes of products like pharmaceuticals."

But not all formula disclosure requests are created equal. "The most common inappropriate request comes

FEMA's place in IP protection

"FEMA's role [in IP protection] has been to provide guidance on what the law is," says John Cox, FEMA's assistant general counsel. FEMA aids the industry by highlighting which scenarios might legitimately require formula disclosure. To that end, FEMA's Regulatory Affairs Committee also published, in January 2007, a white paper outlining strategies for limited flavor formula disclosures.

Meanwhile, FEMA is also on the lookout for emerging legislation to determine just how much IP disclosure is being proposed. Cox cites as an example the US FDA's 2002 Bioterrorism Act. "In the early stages of the legislative development immediately after 9/11," he says, "the bill would have required complete formula disclosure. FEMA and others in the food industry pushed for modification of that." The effort was successful, resulting in a rule that requires disclosure of qualitative formula information to certain FDA officials under certain circumstances.

For more information, visit *www.femaflavor.org*.

from regulatory authorities to the importer of the finished consumer good," says Cox. "And then the manufacturer/importer of the finished consumer good will in turn ask its flavor supplier for formula information." So what can a flavor company do when faced with a customer's illegitimate request? "Be firm, but polite," says Cox. "That's about all you can do." In the meantime, FEMA is working to eliminate these types of inappropriate requests at the source to relieve flavor suppliers of undue commercial pressure.

The dangers of complying with illegitimate requests: The problems created by companies that comply with illegitimate formula disclosure requests affect not just the organization directly involved, but also the larger trade community. To begin with, says Cox, "the IP of that company is lost." Secondly, he notes, compliance with illegitimate disclosure requests "creates an expectation in the future that other companies … will have to comply with the same erroneous requirement. We hear that all the time. When officials are challenged, they say, 'but the other flavor companies have complied.'"

As stated before, because the law that protects IP is civil in nature, it's up to the owner of the IP to protect it. And in doing so, the owner must be consistently vigilant, lest it weakens its own case. "If IP is stolen," says Cox, "and the owner of the property seeks judicial remedies, it's possible that the person accused of harming the owner of the IP by disclosing it will highlight other instances where the formula has been given up to make the point that they [the owner] weren't really treating it as IP. If it's a trade secret, you have to treat it like one—always."

To reinforce formula protections, Cox says, protection of trade secrets must be impressed upon the flavor industry's regulatory professionals—an area in which high turnover can lead to a lack of familiarity with the issue's importance.

Yet even if a request's legitimacy is verified, there are a number of response scenarios available to IP owners short of full formula disclosure:

- ***Safety assurance:*** Formula holders can confirm to customers that all ingredients have been approved by key bodies such as FEMA's Expert Panel (FEXPAN) or the Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives (JECFA).
- ***Nondisclosure agreements:*** Though details vary, nondisclosure agreements can be used to legally bind companies or governmental organizations to keep information they receive from IP holders confidential.
- ***Qualitative disclosure (limited disclosure):*** This type of disclosure concerns only the revelation of the *identities* of certain ingredients in a formula.

Experiencing issues protecting your formulas? Have any novel strategies for handling formula disclosure requests? We want to hear from you. Contact us at jallured@allured.com.

"Supply Chain is IP"

New challenges involving ingredient country of origin

John Cox, Law Offices of John H. Cox, PLLC

In the July/August 2007 issue of *The Atlantic*, the article "China Makes, the World Takes" introduces readers to a lively Irishman named Liam Casey. Casey has lived in Shenzhen, China, for the past 10 years where he runs PCH China Solutions, which makes products for overseas companies. Casey lives at the Sheraton Four Points hotel in Shenzhen where buyers from high wage countries come to arrange the manufacture of low cost Chinese products. The article is informative and entertaining.

The author, James Fallows, describes an atmosphere in which buyers and sellers are obsessive about keeping secrets. Why are they so concerned about where things are made? Well, one reason is that some very large public companies don't want their customers to know—for social and political reasons—that their products are made in China. But there is another reason why supply chain information is so closely guarded, because as Liam Casey puts it, "supply chain *is* IP."

I read this article as concerns about Chinese food and cosmetic imports mounted. Following the melamine contamination in pet food in the United States and deadly diethylene glycol in toothpaste in Panama, flavor suppliers began receiving questions about their ingredients: "Are any of the ingredients in your flavor from China?" What can or should you say to such a question? This presents unprecedented challenges.

The law on country of origin: Let's start with what's required under country of origin and FDA bioterrorism regulations. When a US-based flavor manufacturer makes a flavor, the country of origin of that product becomes the United States regardless of where the ingredients originate. FDA regulations do require the flavor manufacturer to maintain some records on where the ingredients come from, but these must only go back to the last supplier who had the ingredient before the flavor manufacturer received it. These records must be turned over to the government under limited circumstances, but the law doesn't require that this supplier information ever be provided to customers.

So the law doesn't require that a flavor manufacturer tell a consumer product manufacturer where it sourced its ingredients. Furthermore, this information—names and locations of suppliers—should be considered the IP of the flavor manufacturing operation. What if the response was limited to just whether or not the ingredients are from China? This doesn't reveal much about the supply chain; after all, China is a pretty big place. But does anyone really think that the inquiry will end there if the answer is "yes?"

Responding to the customer: How can flavor suppliers politely duck detailed answers to these questions? Do the answers to these questions make products safer? Of course not, but they're being asked just the same and suppliers need to know how to respond.

Given the extraordinary circumstances of the current China situation, flavor suppliers must be sensitive to the confidence that large consumer products companies have about the integrity of their products. Given this, what is reasonable for them to ask?

(If any consumer product companies are reading this, I have a suggestion: don't ask anything of your suppliers that you wouldn't want to hear from *your* customers.)

Each individual company must decide how to respond to these questions. Let's assume that your company has decided that, given the pressure and uniqueness of the current import safety situation, you're going to answer your customers' questions about ingredient country of origin. If the answer is yes, that some of the ingredients in your flavor come from China, then what? The next step could be an assurance of some sort, but what are you prepared to assure? If the ingredient is a protein source then you might want to assure your customer that the ingredient has been screened for melamine. The FDA has posted the analytical method for melamine screening on their Web site (*www.fda.gov*). But what else should you look for?

On May 4 of this year, the FDA issued a letter to manufacturers reminding them of their legal responsibility to ensure that all ingredients used in their products are safe for human consumption. What is the best way to do this? By buying from known suppliers and doing adequate quality assurance testing. Exactly what this means is currently up to each individual supplier.

New requirements on the horizon: It's possible that new laws will change the situation. Legislation is pending that would require US certification of foreign countries and foreign food suppliers before their products could be imported into the country. It's hard to imagine how such a system would work with today's enormous supply chain, but perhaps it would put customer minds more at ease? I'm not so sure. In fact, such a certification program could be problematic if countries such as China refuse to comply. The legislation under consideration would then require the FDA to refuse imports from that particular country. Then what?

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- ***Quantitative disclosure:*** Revealing the quantity/amount/concentration of certain elements of a formula.
- ***Bulk flavor regulations:*** When shipping a flavor, according to 21 CFR § 101.22(g), the label may either declare all ingredients or make a blanket declaration that all of the ingredients contained in the formula are US Food and Drug Administration (FDA)-approved. If any materials fall outside of this approval or are nonflavor, they must be declared separately on the label.
- ***Declaration of composition:*** This may be used in conjunction with labels for bulk flavors. Declarations of composition can certify the following without citing the entire formula: 1) the formula meets legal requirements for the country in which it will be used, 2) a declaration of some but not all individual ingredients, 3) the functions of components (i.e., flavor carrier, anticaking agent), 4) percent range for listed ingredients, 5) statements noting that certain possibly undesirable elements—genetically modified organisms, ingredients of animal origin, alcohol, etc.—are not contained in the formula.
- ***Chemical family/class disclosure:*** According to the FEMA formula disclosure white paper, "A limited disclosure might include a description of the chemical families contained in the formula as well as a percentage range for each particular family." A similar approach could be taken employing chemical classes and a percent range.
- ***"Does not contain" statements:*** See point 5 under "Declaration of composition."

Current Challenges to IP

This year, FEMA has fielded a number of complaints about South Korean authorities requesting formula disclosure of flavors at import. Yet Korean FDA rules only require the names of all ingredients contained in the flavor to appear on the import application, not the percentages. "We [FEMA] brought those complaints to the attention of the United States Trade Representative's office," says Cox. "The Trade Representative's office, with our assistance, wrote a letter through the US embassy in Seoul to the Korean officials." The response so far from the Korean officials remains unsatisfactory, claiming if not literal full formula disclosure, then something very much like it. "The response of the Korean officials … calls for more disclosure than [is] required under Korean law." FEMA and US officials are still developing a response to the issue. "The Korean officials have some troubling ideas about what information should be required at the border," notes Cox. "We have misunderstandings down at the import level and we have misunderstandings higher up at the Korean FDA." Complicating the issue is that there is no organized body comparable to FEMA operating within Korea.

FDA drug master file requests: In the course of the FDA's New Drug Application process, excipient* suppliers are required to submit full flavor formula disclosure to the drug master file. Flavors are considered pharmaceutical excipients. Through this system, flavor companies can provide proprietary information to the FDA with the assurance that it will be seen only by drug reviewers. "This protects the flavor formula from disclosure to either the pharmaceutical manufacturer who is the customer or to other people at FDA that don't have a need to see the formula," explains Cox.

Yet when procedures within the FDA aren't followed, troubles arise. Says Cox, "We've learned recently that at certain stages in the drug application process some of the FDA reviewers have not been using the drug master file and have instead been asking the pharmaceutical manufacturers to provide flavor formula information. This is a problem because it means the flavor supplier is being asked to disclose proprietary information, and because a request from [a] pharmaceutical customer or from the FDA can be so intimidating." Because the FDA's pharmaceutical reviews take place on extremely strict timelines, the pressure for pharmaceutical companies to comply with FDA demands is great. "This [then] creates

*Typically inert substances that form, at least in part, a vehicle for a drug.

inappropriate pressure on the flavor supplier," says Cox. "At this point it seems to be a case of FDA officials not being rigorous about following their own procedures for using the drug master files." FEMA's work on this issue continues.

The growing Chinese problem: An avalanche of recent health and safety scares involving Chinese-manufactured products has of course affected the flavor industry, which is now facing increased scrutiny. "There are requests coming from US-based manufacturers for information about ingredients from China," says Cox. "It's a sensitive and challenging area. Flavor suppliers traditionally don't provide information to their customers about their [own] suppliers. The recent controversy regarding adulterated Chinese wheat gluten has challenged this. There is the possibility of additional regulation." (For more information on current supply chain issues, see **Supply Chain is IP**.)

The strain comes in the wake of the 2005 Sudan Red episode in which chili powder was adulterated with coloring that was not approved for use in food. Following that scare, new European requirements were put in place demanding certification that a certain test had been conducted on all chili powder being imported to the EU. Cox says it's possible the flavor industry could see some variation of this. "You see new revelations about Chinese ingredients every day," he says. "There is additional scrutiny, obviously, from government officials in the US and from the importers of these ingredients."

New California rules: The California Safe Cosmetics Act, which came into effect at the start of this year, significantly impacts fragrances and, to a lesser extent, flavors. "The law requires the manufacturer of the product sold in California, meaning the customer company, to disclose to the state a list of all cosmetic products that contain any ingredients that are found on one of several government lists of ingredients that might cause cancer or reproductive toxicity," says Cox. The Act defines cosmetics as any "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles." (This definition specifically excludes soap.) Among the products included in this definition are toothpastes and lipsticks, both of which employ flavor.

At press time, the state had yet to organize the Act's implementation by publishing guidelines on how flavor and fragrance companies are to report. Yet, in light of the new law, customer companies are beginning to ask flavor and fragrance providers if the products they're distributing include any materials on the government's lists. "This requires some level of formula disclosure," says Cox. "Perhaps not complete formula disclosure, but certainly some."