



Legal Issues and Challenges in the Cosmetics Industry

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Companies manufacturing, importing, distributing or selling cosmetics face a number of legal challenges that are unique to that industry. Persons investing in cosmetics companies, or considering entering the U.S. market, should also be aware of these particular challenges. If not completely understood and planned for, these issues can derail what would otherwise be a successful venture. With appropriate legal and regulatory guidance, however, the challenges can be addressed in advance to minimize potential disruption and reduce the risk of incurring costs to address problems after they manifest.

This article presents a brief overview of several areas of law that are either unique to the cosmetics industry, or present risks that are different from other types of consumer products categories. Its purpose is to surface these issues in a way that can help provide guidance as to when to engage specialty counsel and what questions to ask.

INTRODUCTION

Cosmetics are big business under any definition of the word. Most people associate "cosmetics" with makeup and beauty items used primarily by women, such as lipstick, mascara, foundation, concealers, blush, wrinkle creams and maybe perfume.

However, the category of products regulated as "cosmetics" under the U.S. federal Food, Drug, and Cosmetic Act (FD&C Act) – administered by the U.S. Food & Drug Administration (FDA) – is much broader. Under that statute, "cosmetics" are defined in part as:

"articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance" [21 U.S.C. § 321(i)]

In addition to those noted above, this definition includes moisturizers, deodorants, permanent waves, hair colors, most shampoos, most body washes and body bars, most body powders, some mouthwashes and toothpastes, plus any substance intended for use as a component of a cosmetic product.

COSMETIC OR DRUG?

The examples above include qualifiers for some types of products, such as "most shampoos" and "some toothpastes." Why aren't all shampoos and all toothpastes simply cosmetics? The answer is because some of them are also drugs.

Under the FD&C Act, "drugs" are defined in part as:

- "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"
- "articles (other than food) intended to affect the structure or any function of the body of man or other animals"
- "articles recognized in the official United States Pharmacopoeia"

[21 U.S.C. § 321(g)(1)]



Note that the first two prongs of this definition include the phrases "intended for use" and "intended to affect." Why is this important?

Let's start with the example of lipstick. Under the definition of "cosmetic," it can be easily determined that lipstick is an article "intended to be rubbed . . . or otherwise applied to the human body . . . for beautifying, promoting attractiveness, or altering the appearance." Hence, lipstick is plainly a cosmetic.

Now consider how the manufacturer might label its lipstick. If it states that the lipstick "prevents chapping and heals cracked lips," it has turned the product into a drug, because it is now intended to affect the structure or function of the human body. It does not matter if this lipstick is actually effective for these purposes, nor does it matter whether ordinary lipstick that does not make such a claim may help prevent chapped lips by acting as a mechanical barrier. Whether the lipstick with the "prevents chapping and heals cracked lips" label actually works does not matter: by writing this on the label, the manufacturer indicates that it is intended to have these effects, which makes it a drug. And similarly, even if all well-made lipstick helps keep one's lips healthy, it is not a drug because it is not intended to have this effect.

This example illustrates the importance of a product's intended use. How is intended use determined? The first place that the FDA will look is the label, but advertisements and promotional literature will not escape FDA scrutiny. If a manufacturer is promoting its product with claims that cross the line from cosmetic to drug – including statements on a website – they are evidence that the intended use of the product is as a drug.

Thus, what may seem to be minor differences in language on a product's label can have a profound effect on how it is regulated under U.S. law. As one might expect, drugs are regulated far more heavily than cosmetics. With the exception of color additives, ingredients in cosmetics do not require FDA approval. Nor are cosmetics as a whole subject to premarket approval, various registration requirements, certain labeling and disclosure obligations, and other rules that apply to drugs. The point here is not that it's overly burdensome to sell drugs if that's what a company intends to sell, but rather that the laws governing the sale of drugs are overly burdensome if only meant to be selling cosmetics.

A historical example helps illustrate the point. High-end wrinkle creams are among the most expensive cosmetics in the U.S. market, selling for more than \$10 per gram. Careful manufacturers, alert to subtle distinctions in language, have generally stated that such products "reduce the appearance" of wrinkles instead of "reducing wrinkles." The intended use of a product that "reduces the appearance" of wrinkles is as a cosmetic (beautifying, promoting attractiveness, or altering the appearance). By contrast, the intended use of a product that "reduces wrinkles" is as a drug (affecting the structure of the body).

Another way that a product that seems to be a cosmetic may end up being a drug is by choice of ingredients. Returning to the examples of cosmetics, we noted above that most shampoos and some toothpastes are cosmetics. But the choice of ingredients can make them drugs too, even if no claim is made on the label that they 1) cure or prevent disease, or 2) affect the structure or function of the body. That is because any product containing an ingredient recognized as a drug is itself a drug. For shampoo, the antidandruff ingredients selenium sulfide and zinc pyrithione are each considered drugs. This means that any shampoo containing each of them is automatically a drug, even if it is not labeled as an antidandruff shampoo. For toothpaste, any form of fluoride is considered a drug, and hence all fluoride-containing toothpastes are automatically drugs even if they are labeled as helping to prevent cavities.

Without attempting to provide an exhaustive comparative list, here are some examples that help illustrate the difference between cosmetics and drugs based on the presence of a drug ingredient:



COSMETIC

Underarm deodorant
Whitening mouthwash
All natural toothpaste
Foundation (for face)
Scented body powder
Moisturizing shaving cream
Body wash
Body bar

DRUG

Antiperspirant
Antigingivitis mouthwash
Anticavity toothpaste
Foundation with sunscreen
Itch-relief body powder
Razor-bump preventing shaving cream
Anti-acne body wash
Deodorant body bar

A review of Warning Letters sent by the FDA to cosmetics manufacturers can also help illustrate the type of language that will be viewed as making impermissible "drug" claims. Recent examples include the following statements cited by the FDA as falling into this objectionable category, with the key problems noted below each:

"CREAM: ...soothing cream that protects and alleviates the skin from the itchiness, pain and irritation of skin ailments such as psoriasis, eczema and rashes..."

Problems: psoriasis and eczema (disease claim); itchiness, pain, irritation and rashes (structure/function claim)

"PLUS CREAM: ...blended with Therapeutic Grade Essential Oils beneficial for burns and cuts...break outs from acne to rashes...."

Problem: acne (disease); burns, cuts and rashes (structure/function)

"Eliminate burning, chafing or irritation from skin. . ."

Problem: burning and irritation (structure/function)

"Rebuild Damaged Tissue. . ."

Problem: rebuilding tissue (structure/function)

As can be seen, in order to stay on the "right" side of the line between cosmetics and drugs – and avoid inadvertently transforming a product intended as an ordinary (lightly regulated) cosmetic into a (heavily regulated) drug – the purveyor must carefully attend to both 1) the statements on the label, and 2) the choice of ingredients.

CONSUMER CLASS-ACTION LITIGATION

In general, the FDA does not pay much attention to cosmetics, preferring to devote its resources to more pressing areas, or products that may pose a hazard to public health (as opposed to products that are likely harmless but that simply run afoul of regulatory standards). Unfortunately for manufacturers, however, the FDA is not the only entity that may scrutinize labels or advertising materials for cosmetics.

Plaintiffs' class action lawyers solicit complaints from consumers and themselves scour cosmetics labels and advertisements looking for an opportunity to bring a class action lawsuit. In one telling, consumer class action



suits provide a way to vindicate consumers victimized by deceptive practices in an omnibus, class lawsuit when each consumer's individual claim would be too small to be worth pursuing. In another, class action suits are a way for lawyers to enrich themselves with frivolous lawsuits filed to coerce settlements from innocent companies. The purpose of this review is not to choose sides in the battle over class action litigation, but to point out several areas that have resulted in class action suits against cosmetics companies, with the idea of learning from other's misfortune.

In February 2019, a major cosmetics company with a line of mass-market products sold in supermarkets and drug stores was sued in California in a class action complaint directed to its line of wrinkle products. The claim was that the product labels made claims of prompt action – such as "immediately" hydrates and makes the skin "more radiant" – in combination with claims that stated that continued use for a period of weeks would reduce wrinkles. According to the plaintiff, this showed the manufacturer's intended use of its products was as a drug, despite the fact that it had never been approved by the FDA as such. And while only the FDA has authority to enforce the FD&C Act, the plaintiff alleged that these representations constituted unfair trade practices under California state law. The interaction between federal law and state law is complex, but the general rule is that states are free to impose stricter standards, so compliance with federal law is not necessarily sufficient to comply with state law.

Labels and advertisements using the word "natural" have also drawn class action lawsuits. For example, a suit was filed in December 2018 in New York against a smaller cosmetics manufacturer that referred to a line of products as "high performance naturals," and stated "we believe in high-performance AND natural." The plaintiff asserted that these representations "are false, misleading, and deceptive" because the products "contain multiple ingredients that are synthetic," including citric acid, xylitol, kaolin and glycerin. To give a sense of the level of analysis behind some cases of this sort, the complaint cited another manufacturer's website for the definition of some of the allegedly "unnatural" ingredients.

The term "hypoallergenic" has also presented a target for class action cases. In August 2018, a case was filed against a major cosmetics manufacturer in New York that has a product line based on claims that its products are hypoallergenic. According to the complaint, each and every product contained one or more "Category 1 skin sensitizers," defined as agents that causes "an allergic response in a significant number of people" at a concentration of 0.1 percent or similar. Among the common cosmetic ingredients alleged in the complaint as rendering the "hypoallergenic" claim misleading were cellulose gum, chamomile extract and niacinamide. For reference, niacinamide is a form of a B vitamin commonly used as a dietary supplement: the complaint identifies it not only as a "Category 1 skin sensitizer" and a "Category 2 eye irritant," but as a "mutagen, meaning that it is suspected of mutating human cells in a way that can be transmitted to children conceived after exposure."

In an industry that requires advertising and promotion in order to survive, no amount of legal review can eliminate the risk of class action lawsuits. However, lawyers can help by reviewing copy before it is used, and suggest changes that may reduce the risk without compromising its effectiveness.

PATENTS

In the spectrum of patent "intensity," cosmetics present fewer patent problems than pharmaceuticals but more than most other consumer products. Unlike pharmaceuticals, where most U.S. consumers will happily accept a generic product in order to save money, the acceptability of cosmetics is heavily driven by brand reputation and consciousness. The consumer who will happily select an over-the-counter store-brand pharmaceutical to achieve a modest cost savings over the brand-name product stocked next to it is not so likely to reach for a store-brand shampoo, foundation or lipstick (if even available).



Although patent infringement cases between two large and established cosmetics companies occur from time to time, they are not very common. Litigation is more likely in the case of a smaller company, or one that is entering a new field, that tries to carve out an exclusive space with its patents to prevent encroachment by larger competitors.

That said, a search of patents and applications will return hundreds of items spanning the entire field of cosmetics, including not just formulations, but also devices and implements such as mascara brushes and various applicators.

In most cases, it is neither necessary nor economically viable to conduct a comprehensive search of patents and applications to assess "freedom to operate" for a prospective new product. A more focused approach, however, is often advisable to prevent the situation in which substantial investments are made in bringing to market a product that infringes a competitor's patent when the opportunity existed to avoid the patent by making minor changes that would not have compromised the potential product's appeal.

First, if the proposed product is to be based on a competitor's marketed product, the packages of that product should be inspected to see if the packages include patent numbers, or refer to a website for patent information. Although patent marking is not mandatory, many companies will mark their products with applicable patent numbers because doing so conveys certain advantages (which are beyond the scope of this article).

Second, even if the proposed product is not based on a competitor's marketed product, the similar products existing in the marketplace can also be checked for patent markings. This is another good way to uncover potential risks.

Third, if a relatively small number of companies are known to be the leaders in a certain category, it is often possible to design a search for patents assigned to those companies that will return a reasonable number of items, making their review a manageable task.

Fourth, if the company has applied for its own patent on the prospective product, the prior art cited by the patent office in the course of examination may return earlier patents that are still in force and which could pose an infringement risk.

Searches and evaluations should be conducted by, or under the supervision of, qualified patent counsel. Reviews conducted by a company's nonattorney employees will not be protected by attorney-client privilege in the event of litigation, and will be available to the other side in the course of pretrial discovery. If they write that there are risks or problems, their statements can be used against the company, even if the conclusions are incorrect or the employees making them did not have legal training, to allege that it willfully infringed (giving rise to claims for enhanced damages and attorneys' fees). Moreover, reviews conducted by technical personnel can oftentimes produce results that are technically correct but legally inaccurate, because the interpretation of patents is more of a legal exercise than a technical exercise.

No discussion of patents would be complete without considering whether, and when, a company should apply for its own patents to protect a new product. There are two competing principles at play.

First, people without familiarity with the patent process may erroneously assume that a new product could not be protected by a patent because it is not too different from previous products. To the contrary, the patent system thrives on small improvements to existing products, and recognizes that innovation and progress typically proceeds in small steps.

Second, some people succumb to a condition recognized by any experienced patent lawyer as "patent mania," believing that everything they do is patentable and that applying for patents is the surest path to success.

Unless dissuaded, this results in a waste of money and a distraction from actually designing and producing better products, as resources that would be more productively employed elsewhere are poured into the patent process. A sad example from history is Adolphe Sax, inventor of the saxophone, who was driven into bankruptcy by pursuing patent infringement cases.

How best to navigate between these extremes?

The place to start is to consider whether a patent on a new product – assuming that a patent could be obtained – would actually convey any commercial advantage. For example, a patent might be issued to a specific combination of ingredients, with what patent lawyers call a "picture claim." But if competitors could make a product that was just as good, but which would not infringe because it had small changes to the amount or identity of one of the ingredients, the patent would serve no commercial purpose beyond the potential marketing advantage of advertising it as a "patented formulation."

If you conclude that having a patent – assuming that one can be obtained – would be likely to give the company a meaningful commercial advantage, it is advisable to consult with qualified patent counsel on how best to proceed. Commonly, a relatively inexpensive search of the prior art, often called a knock-out search, will provide sufficient information to determine if filing a patent application is warranted.

TRADE SECRETS

Trade secrets have an outsized role in the cosmetics industry because the details and specifics of formulations often cannot be determined from the label's listing of ingredients. Accordingly, cosmetic formulations are commonly considered by their manufacturers to be trade secrets.

A key aspect of maintaining information as a trade secret is taking steps to guard against disclosure. For example, employees should be required to sign confidentiality and nondisclosure agreements at the start of employment, and should receive periodic training about the importance of maintaining confidentiality. Trade secret information should be shared within the company on a need-to-know basis, and should not be disclosed outside the company (for example, to a consultant, contract manufacturer or testing laboratory) absent a suitable nondisclosure agreement. Employees leaving the company should receive, as part of an exit interview, a documented reminder that their obligations to refrain from using or disclosing the company's trade secrets survive the termination of their employment, and be asked to sign an acknowledgement of their understanding. These steps serve the dual purpose of reducing the risk of an improper disclosure, and providing the basis to claim trade secret protection if it becomes necessary to pursue enforcement.

Companies should also be sensitive to reducing the risk of being on the receiving end of a trade secret claim from the former employer of a new hire. As part of the onboarding process, new hires should commit (in writing) to refrain from using or disclosing any confidential information of prior employers. Consideration should also be given to the potential overlap between a new hire's responsibilities and his or her function at the prior employer. When possible, it can be helpful to limit the degree of overlap to both protect against the inadvertent use of a prior employer's trade secret, and to demonstrate in the unfortunate event of a lawsuit, that the company did not hire the person with the idea of obtaining his or her prior employer's trade secrets.

TRADE DRESS

Trade dress refers to the appearance of a product – typically, in the case of cosmetics, the packaging – that serves as an indicator of the product's source. It is similar to a trademark, but more about the overall visual appearance of a product and not a particular name or logo. Trade dress often consists of a combination of elements, such as color, typeface, package shape and the arrangement of design features. While everyone



understands the obligation to refrain from copying a competitor's trademarks, the need to avoid infringing a competitor's trade dress is not as universally appreciated.

Although it is possible to inadvertently infringe a competitor's trade dress, the more common situation is one in which a designer or marketing person use a competitor's product as the starting point for their design. There is nothing inherently wrong with this, as long as care is taken to make sure that the final product is sufficiently distinctive. Problems arise, however, when decisions are not adequately vetted. For example, if the employee responsible for clearing the proposed design of a product is not informed that a competing product was in the design process, he or she will not know to check it for potential trade dress problems, and may catch the problem only if he or she happens to know of that model product.

Companies working on product design should also consider their own trade dress. The use of a similar design scheme in a consistent manner across a range of products can create trade dress rights that could be asserted against a future competitor that attempts to ride on the company's good will and brand reputation by using a similar scheme on its own products.