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As part of their ongoing effort to combat misinformation about COVID-19, federal agencies have issued warning letters to more than 150 companies. While companies know that a warning letter is serious and requires immediate attention, perhaps the greater challenge is what often follows: the so-called “piggyback” class action lawsuit.[1] And recently, plaintiffs’ attorneys have gone one step further: they have been filing “piggyback” class actions not against the company that received the warning letter but against competitors that make similar products.

Because warning letters are publicly available and posted prominently on various agency websites, consumers can view the warning letter and then file a “piggyback” class action against the recipient of the warning letter. Indeed, oftentimes these “piggyback” class actions merely recast the government agency’s allegations as claims for violations of various state consumer protection statutes. For example, in November 2013, the U.S. Food and Drug Administration (FDA) sent a genetic testing company a warning letter ordering it to stop selling and marketing one of its genome tests because the company had failed to show that the test actually worked. Five days later, the company was hit with a proposed class action for allegedly violating several California consumer protection laws.[2] Dozens of other companies – from hotel chains to cereal manufacturers – have also been hit with piggyback class actions based on warning letters.
But things have changed recently. Consumers have targeted companies that never received a warning letter. These proposed class actions are based largely—sometimes entirely—on the allegations in a warning letter directed to another company. In these cases, the plaintiffs’ theory is that, because the products are similar, the substance of the warning letter “applies equally” to the similar products.

This trend has continued in the COVID-19 era. On January 17, 2020, a week before the first reported case of COVID-19 in the United States, the FDA sent a leading hand sanitizer manufacturer a warning letter telling the company to stop advertising its product as one that can prevent an array of diseases, including Ebola, MRSA, and the flu. The FDA explicitly challenged the product’s claim that it “kills 99.99% of most common germs” because the claim allegedly lacked adequate scientific support. On the heels of FDA’s warning letter, at least six class actions were filed against the manufacturer.[3] Although the claims differ slightly, all of the lawsuits are premised on the same basic theory articulated in the FDA warning letter—which all of the complaints cite.

Then came the copycat piggyback lawsuits. The manufacturer of a competing hand sanitizer was sued in February and March 2020.[4] In one of the complaints, the plaintiff alleged that because both products have the same active ingredient, the FDA’s allegations about labeling apply to both products. Separately, a plaintiff sued a large retailer in a class action making similar claims about its generic hand sanitizer.[5] In that case, the plaintiff argued that the retailer’s labeling was also misleading because it had the same active ingredient as the brand name and implied that its product was as effective as the brand name.

So what should companies do? Here are proactive steps to protect against these lawsuits.

Review labels and advertisements. To protect against “piggyback” class actions, companies should ensure that they have reliable scientific evidence to support their products’ stated claims and alleged benefits, particularly if a competing product that makes similar claims has received a warning letter. Additionally, if a company compares its product to competing products, companies should check to see whether those competing products have ever been the subject of a warning letter.

Monitor guidance from relevant governmental agencies. Companies should also actively monitor guidance from relevant federal or state agencies. During the COVID-19 pandemic, agencies have issued and amended guidance more often than they typically do. For example, in March 2020 the FDA issued guidance temporarily relaxing regulatory requirements for production of certain hand sanitizer products. The FDA then revised that guidance on March 28, and again on April 15, 2020. Companies should stay abreast of the most recent guidance to ensure that they are complying with laws and regulations.

Monitor warning letters and enforcement actions against competitors. Of course, a company that receives a warning letter should seek legal advice to determine how to respond. But even if a company does not itself receive a warning letter, companies might learn about federal agencies’ warning letters and enforcement actions against other companies, particularly competitors or companies that make similar products.
Where the products are similar, enterprising plaintiffs' attorneys could repurpose a warning or enforcement action against one company's product into the basis for a class action against its competitors. If a competitor has received a warning letter or been the target of an agency enforcement action, legal counsel may help assess their situation compared to the company's.

Conclusion

It is a challenging time for companies in so many ways. These lawsuits might be the beginning of a trend of class actions filed both against companies whose products appear on the radar of governmental agencies during the COVID-19 pandemic and against companies that make similar products. The plaintiffs' bar is closely monitoring agency warning letters. Companies should take that into consideration.

[1] John E. Villafranco and Daniel S. Blynn, The Case of the Piggyback Class Action, Nutritional Outlook (Sept. 2012) (defining a piggyback lawsuit as “a class action lawsuit filed by a private litigant against an advertiser or manufacturer after a federal agency...has already taken regulatory action against the same company on behalf of the public.”)


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