



DEFENDING THE PROPOSITION 65

BOUNTY HUNTER CASE:

A DIFFERENT APPROACH

A WHITE PAPER FROM THE

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PROPOSITION 65 ATTORNEY TEAM



A bounty hunter is an individual who seeks out fugitives ('Hunting') for a monetary reward ('Bounty') for apprehending by law, if such laws exist.

(In lawless areas, bounty hunters still exist, and are, indeed, even more common.)

-Definition from Wikipedia, the free online encyclopedia



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INTRODUCTION: The Offer You Can't Refuse

California's Proposition 65, and particularly its private party enforcement, or "bounty hunter" provisions, have created a massive, expensive, baffling headache for companies doing business in California in the past thirty years. The law requires meaningless warnings of chemical exposures which often pose no real risk. Simultaneously, the law creates a system for relieving defendants - particularly out-of-state companies - of large amounts of money.

Worse, lawyers who "defend" clients in Proposition 65 litigation often don't defend anyone - Proposition 65 has become an enormous money machine for the attorneys representing both sides. Cases almost never make it to court, and the lawyers in the "Proposition 65 bar," who deal with each other every day, routinely settle five-figure and six-figure cases at the expense of businesses all over the country. Welcome to California. Bring your checkbook.

To companies from out of state, the scenario is usually like this: One day, out of nowhere, you get a letter from a law firm you've never heard of. The letter informs you that (a) a product you import, manufacture, provide parts for or sell causes cancer and/or birth defects; (b) you're going to be sued in 60 days; and c) there's a number you can call to discuss settlement. Sound familiar? We thought so. A Proposition 65 bounty hunter has just cornered you. After reviewing your options, consulting with your attorneys, and learning a lot about a law you didn't even know existed, it looks like you don't have much choice. One way or another, if you want to keep doing business in this state, it's going to cost you.



However, as is always the case when considering options, it's helpful to know what they actually are. This white paper addresses two basic topics. The first is Proposition 65 itself - what it is, where it comes from, and how it works. We address this subject from what we think is a unique perspective - the real world. We are interested in what Proposition 65 actually does to real businesses who become entangled in it. We are not interested in legal or political theory. We assume you aren't, either.

The second topic is an overview of the three basic responses defendants can have to a Proposition 65 action - settle, fight, or utilize the *Baxter v. Denton* strategy. We have done all three. In fact, one of our attorneys invented the third. Again, our goal is to present Proposition 65 defendants with a realistic view of what their options are, and the costs and benefits of each.

We will pay particular attention to the *Baxter* case, in which the leader of our Proposition 65 team represented the defendant. *Baxter* invites companies sued under Proposition 65 to seek a court order that makes Proposition 65 irrelevant. While this approach won't work in every case, it is something that should be evaluated by every company sued in a Proposition 65 case. In this white paper, we'll map out the hazardous terrain of Proposition 65, and explain how *Baxter* created a way around it.

HOW PROPOSITION 65 WORKS: Weird (and Expensive) Science

California's Proposition 65, the "Safe Drinking Water and Toxic Enforcement Act of 1986," is a textbook example of unintended consequences. The legislation was originally designed to create a market mechanism for minimizing the presence of toxic chemicals in California, particularly in the water supply. It requires the Governor to create and regularly update a list of chemicals "known to the State of California to cause cancer, reproductive or developmental harm." The Governor delegates this task to the State EPA's Office of Environmental Health Hazard Assessment, or "OEHHA." The list contains more than 900 chemicals, to which OEHHA periodically adds more.

So far, so good. However, the law also encourages and rewards lawsuits by organizations and individuals often known as "bounty hunters" - against businesses, located anywhere, who sell products containing even trace amounts of these chemicals in California. The result has been the development of a legal cottage industry in California, which usually operates at the expense of out-of-state companies.

As applied by the courts and interpreted in regulations, the statutory scheme of Proposition 65 provides for the following:



- OEHHA maintains and updates two lists: one of chemicals "known" to the state to cause cancer, and one of chemicals known to cause developmental or reproductive harm. While some of the listed chemicals are generally accepted as being harmful to humans, many others have reached the list only as a result of animal testing involving extraordinarily sensitive laboratory animals and massive, prolonged exposure to very high doses.



- As one commentator has pointed out, in high enough doses, anything will cause cancer. In many instances, the mechanisms that cause malignancies in animals have no corollary in humans. In others, the lab animals were subjected to doses in the lab that bear no relationship to that which humans would ever encounter.
- Once a chemical is listed, it becomes unlawful for any company with ten or more employees (smaller companies are exempt) to knowingly and intentionally "expose" a person in California to it without first giving "clear and reasonable warning" of the exposure. A violation is actionable even if the company knew nothing of the law and had no idea it was acting illegally. The court may award penalties of up to \$2,500 per day for each violation. Since in the absence of a warning, every exposure is a violation, potential

penalties can easily reach hundreds of thousands or even millions of dollars for companies with significant sales volume.

For most companies, a “warning” until recently has meant a posted sign or label, typically stating following:

“WARNING: This product contains a chemical known to the State of California to cause cancer”

or

“WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.”

These are known as “safe harbor warnings,” and were established by regulation in 2008. However, the regulations are changing dramatically effective August, 2018. The “safe harbor” warnings will become much more difficult, and any company selling products in California should consult with counsel to make sure its warnings will be in compliance with the new safe harbor regulations.

- It matters not at all that a company being prosecuted pursuant to Proposition 65 may never have done business in California. If Manufacturer X in Wisconsin sells a product containing a listed chemical to Distributor Y in Arizona, who sells the product to Sub-distributor Z in Oregon, who sells it to a retailer in Los Angeles who sells it to a consumer from San Diego, X can be found liable under Proposition 65 for failing to give a “clear and reasonable warning” to California consumers that the state thinks the chemical may cause cancer. Furthermore, so can Y, Z and the retailer.
- Although the California Attorney General undertakes some enforcement, nearly all Proposition 65 enforcement actions are filed by bounty hunters. These are individuals or environmental organizations who often file enforcement actions against dozens or even hundreds of companies - many of them from outside California - each year. The bounty hunter need not have been personally exposed to the chemical, need not have suffered any damage, and need not have any connection whatsoever with the product, the chemical, or the company.

Then why sue? Because California law provides that a public interest plaintiff’s lawyer - including a Proposition 65 lawyer - can recover, among other things, attorney’s fees. A Proposition 65 plaintiff’s firm can rack up big legal bills, which are paid by the defendant. Because of this, the bounty hunters rarely have anything much to do with the suit itself. Although their names are on hundreds of cases, the real heavy lifting is done by law firms specializing in this litigation. Bounty hunters receive only 25% of the penalties recovered (75% of the penalties go to the State); however, attorneys’ fees can rapidly mount to six-figure amounts. If you



file dozens of basically identical lawsuits every year, you become very efficient. Nice work if you can get it.

DEFENSE, SETTLEMENT AND THE BAXTER DEFENSE:

If you are a Proposition 65 defendant, you have basically three options. You can settle. You can fight, which almost nobody ever does. Or you can use the Baxter defense. We're going to review each option. Again, keep in mind that we're writing this from the perspective of the real world.

Defense and Settlement

Just as a special segment of the bar prosecutes Proposition 65 enforcement matters on behalf bounty hunters, there is also a specialized Proposition 65 defense bar. This is a small group of attorneys, some of whom have represented industry in enforcement actions since the proposition was enacted. The Scali Law Firm is part of it. While the defense model has evolved over the thirty-year history of Proposition 65, there have been three consistent themes:

- First, while Proposition 65 is a difficult statute for companies to deal with, it is not without its defenses. A company may be able to defend an alleged carcinogen by showing that the exposure poses no significant risk of cancer to humans at the levels in question. In the case of an alleged developmental or reproductive toxicant, the company can defend by showing no observable effect assuming exposure at one thousand (1000) times the level in question. There are statute of limitations defenses, defenses based on the number of employees the company had at the time of exposure, and sometimes issues as to whether the chemicals are sufficiently encapsulated that there is no real exposure.
- That being said, Proposition 65 cases almost never make it to trial. Because of the expense, the time and the headache, for all intents and purposes defense and settlement can be considered the same thing.
- Therefore, after a certain amount of saber-rattling, chest-pounding and heavy breathing, Proposition 65 plaintiffs nearly always settle these cases for a combination of (a) injunctions ordering warnings in the future; (b) penalty payments; (c) attorney fee payments; and sometimes (d) reformulation. The possibility of being liable for attorneys' fees gives defendants a powerful incentive to settle these cases quickly, before the costs really start to add up.

In 2017, the average Proposition 65 settlement totaled \$37,564. Not surprisingly, an average of 75.5% of settlements went toward bounty hunter attorneys' fees.

Baxter Healthcare v. Denton: A Different Approach

Baxter Healthcare Corporation is one of the world’s largest manufacturers of intravenous bags and tubing -- essential and ubiquitous life-saving tools of modern healthcare. For more than forty years, the plastics from which these devices were constructed were made more flexible and pliable by adding 2 di-ethylhexyl pthalate (DEHP) to their formula. IV bags and tubing are regulated by the Food and Drug Administration as prescription medical devices, meaning that their labeling is subject to FDA approval.

Laboratory testing has clearly proven that although DEHP causes liver cancer in laboratory mice and some rats, it is not carcinogenic to larger animals.



Nonetheless, because it is carcinogenic to at least some animals, DEHP is on the Proposition 65 list of chemicals “known to the State of California to cause cancer.” (It was later added to the “reproductive toxin” list, but that’s a different discussion.)

Baxter and other manufacturers of similar devices began receiving Proposition 65 notices and lawsuits seeking injunctions, penalties and attorneys’ fees for exposing patients to DEHP without “clear and reasonable warning”. After being sued both by a bounty hunter and the Attorney General, Baxter initially joined an ad hoc industry group. However, it soon became clear that the industry group’s approach would be to

seek a group settlement, which would probably include a patient warning of a cancer risk.

Based on all available science, there was no human cancer risk. Unwilling to give warnings to patients which (a) were untrue; (b) were likely to disturb, mislead, and potentially harm them; and (c) would be inappropriate interference with physician - patient communications, Baxter decided to defend itself rather than settling.

The first step was to withdraw from the ad hoc industry group. The next step was based on a premise as old as war and athletic competition: the best defense is a good offense. Baxter sued the State of California, seeking a declaration under Proposition 65 that it had no obligation to warn because DEHP poses no significant risk of cancer to humans at the levels of exposure in question, a technical defense permitted by the statute. In fact, Baxter argued, DEHP posed no significant risk of cancer to humans at any level, because the mechanism that caused cancer in laboratory animals didn’t exist in humans.

In a two-week trial against California’s Attorney General’s office, Baxter presented an array of internationally renowned cancer researchers, epidemiologists, clinicians and other scientists who demonstrated the scientific consensus: DEHP simply was not, and could not be, a human carcinogen. The State presented evidence that DEHP carcinogenicity was still an open question. More significantly for other companies in other cases, the State argued that Baxter had no right to come to court seeking declaratory relief at all, instead of simply defending the suit. Indeed, said the

State, only bounty hunters and the Attorney General had the right to pick and choose which products and which exposures would be the subject of Proposition 65 litigation and where and when suits would be filed.

The trial court disagreed. It held that the preponderance of the evidence showed that DEHP posed no significant risk of cancer to humans. Accordingly, Baxter had no obligation to warn patients, or anyone else, that they were being exposed to carcinogens.

Furthermore, the court held that a company need not wait until it was prosecuted by the State or a bounty hunter; instead, the company was well within its rights to sue the State at any time for a declaration that its product, or chemicals in its product, posed no significant risk of cancer in humans. Such a declaration would be binding on the state and on bounty hunters suing on behalf of citizens of the state.

The trial court's ruling was affirmed on appeal, in a published opinion. And it is binding on all trial courts in the state. To summarize the key holding in *Baxter*, the defendants used the mechanism of declaratory judgment to do an end run around a Proposition 65 suit by getting another court to hold that a chemical toxicity warning would, in fact, be untrue. Goodbye, bounty hunter lawsuit.

The trial court's opinion is available for viewing at <http://tiny.cc/odu52>. The opinion of the Court of Appeal affirming it is available at <http://tiny.cc/5fydq>. The official citation to the case is *Baxter Healthcare Corporation v. Joan Denton, etc.* (2004) 120 Cal.App.4th 333.

CONCLUSION: An Unwanted Education

Most decisions about legal strategy are, in the end, economic decisions. This is true for Proposition 65 defendants, too, particularly those from out of state. The goal, almost always, is to get out of the suit with the minimum expenditure of time, resources and money. Often, that means simply settling on the best terms you can get. However, it often pays to think a little harder about what those terms might cost you in the long run. Often, these costs are unique to the defendant, and are difficult to quantify, but quite real. For example, depending on your product, your market, your customers and your plans, a prominent warning label on your packaging or website might be a marketing disaster, and justify a full-throttle defense.

And thanks to *Baxter v. Denton*, a company that is at risk of, or has been sued in, an enforcement action, need not always passively write a check and submit to a commercially damaging warning requirement. Baxter has created an alternative.

In the world of equities investing, the word “capitulation” has a unique meaning. It refers to sellers who are convinced that they should get out of a market as fast as possible, and without much regard for price, because disaster is looming. Capitulating sellers are more than happy to give up any gains they've made, or even take losses. They just want out, and fast.

The entire mechanism of Proposition 65 is often manipulated to produce a similar effect, particularly for out-of-state defendants. The risks look huge, the game looks rigged, and disaster looks quite possible. But unlike the market, which offers only “stay in” or “get out” as options, an experienced, tough legal team can do a lot to even your odds in court. Before concluding that capitulation is the only route, a company should, at minimum, evaluate the potential for going on the offensive - defending the case, which at the very least will strengthen your settlement position, or applying the *Baxter* approach. Under California law, the best defense really may be a vigorous scientific offense.

MORE INFORMATION

To learn more about recent developments in the Proposition 65 world, visit our team leader’s blog, <http://tiny.cc/CalBizLit-Prop65>.

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