Episode Title: Confidential Business Information under TSCA

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A full recording of the podcast is available at https://www.lawbc.com/confidential-business-information-under-tsca/.

Producer: Can you look at Rich and just tell him what you had for breakfast or what --

Lynn L. Bergeson (LLB): I had my usual five cups of coffee.

Richard E. Engler (REE): *Laughing*

Producer: Okay.

LLB: Hello, and welcome to *All Things Chemical*, a podcast produced by Bergeson & Campbell, P.C. (B&C®), a Washington, D.C., law firm focusing on chemical law, business, and litigation matters. I'm Lynn Bergeson.

In each episode, we try hard to bring you intelligent, insightful, and engaging conversation about everything related to pesticidal, industrial, and specialty chemicals, and the law and business issues associated with chemicals. Our incredibly gifted team of lawyers, scientists, and regulatory consultants keeps you abreast of the really changing world about domestic and international chemical regulation and provides thoughtful analysis on the many intriguing and complicated issues surrounding this space.

This week, I'm really excited to sit down with Dr. Richard Engler, B&C's Director of Chemistry. We discuss confidential business information, [also known as] CBI.

CBI is both a term of art under the Toxic Substances Control Act, which we call TSCA, and can be understood broadly to be anything from trade secrets to the secret sauce, the pixie dust of a chemical formulation that makes a chemical both special and the product in which that chemical is contained very profitable. In our conversation, we focus on how this concept of CBI functions under TSCA and how businesses need to handle CBI during EPA's chemical review process.

Rich is the perfect person to discuss the concept of CBI. Rich is a 17-year veteran of the U.S. Environmental Protection Agency (EPA). He participated in thousands of chemical reviews and addressed hundreds and hundreds of CBI issues when he was with EPA and knows the ins and outs of CBI like nobody's business. Our conversation touches upon some of the most important legal and business considerations when dealing with CBI and EPA, for example, how EPA exactly defines CBI, where problems arise, and how to avoid these problems through careful and strategic business preparation. Here is my conversation with Dr. Rich Engler about CBI under TSCA.

Rich, it's wonderful to be here today to talk to you about one of my favorite topics: the ever-elusive CBI: what it is and, more importantly perhaps, what it is not.

REE: Pleasure.

LLB: Let me ask you first: What the heck is confidential business information? We in the legal community fondly refer to it as CBI.

REE: For TSCA purposes, information that is submitted under TSCA may be eligible for protection from release to the public. EPA, in response to something that EPA publishes or in response to a Freedom of Information Act (FOIA) request -- there are certain circumstances where EPA is not only permitted to *not* release but is obligated to protect information if it's claimed as confidential under TSCA. The term in the statute is "confidential business information." As we're using CBI, we're talking about the CBI provisions of TSCA that may have meaning outside of TSCA, but our discussion today will focus on the statute itself.

LLB: When you say, "protect from disclosure," are we talking about corporate espionage here? I mean, disclosure to whom? Who would be asking a company for its CBI?

REE: It might be a competitor that's trying to short-circuit research and development (R&D), trying to understand what their competition is doing, how big the market is, who their customers are, might be seeking to gain advantage. There are a variety of ways -- there are a variety of types of CBI, and CBI can be used in a variety of ways, depending on what the particular information is.

LLB: Help me out here. You were with EPA for 17 years as a chemist. You are a Ph.D. chemist. I'm guessing what we're talking about here relates to maybe chemical formulae or manufacturing processes -- how things are made. The law enables entities to protect that information because it's proprietary and very important.

REE: No, absolutely. It protects manufacturing processes; it protects -- it may protect the specific substance identity, it can protect the production volume -- how much you're making, importing, or manufacturing -- the specific information about a mixture, so if you've got some proprietary formulation, what's in that formulation and what quantities? That can be protected as CBI. Specific customers or suppliers, often the supplier-customer relationship is confidential. Specific uses, very often the specific function and use is something that's confidential. A generic use must be provided if the specific use is claimed as confidential, but there is an opportunity to protect, because sometimes you've got a performance additive that you're putting into something. It might be a lubricant, it might be a metalworking fluid, or a plating bath, and you put that additive in, whatever the necessary concentration is, and it works better. That's your --

LLB: -- That's your edge.

REE: That's your edge; that's your magic fairy dust that you put into that, and that's the value added for that particular product or that particular substance in that particular product, and that's what's confidential. Information like that can be protected and very often is claimed as confidential in premanufacture notices (PMN).

LLB: It sounds like the law, TSCA, acknowledges that certain categories of information are appropriately deemed confidential and not amenable to disclosure?

REE: Absolutely, I would characterize it as really three bins of information. There's information that cannot be protected, and we can come back and talk about that some more. There's information that I call presumptive CBI, and it's things that are broadly recognized as particularly sensitive, things like manufacturing process, production volume, and supplier-customer relationship. Those are exempt from substantiation. The submitter can claim those as confidential without providing justification to the Agency.

LLB: That's what substantiation means? Is that a formal term of art?

REE: Yes. That's a term of art in the statute where the submitter must answer a number of questions that substantiates their claim that a particular bit of information needs to be protected as CBI. The categories that are exempt from substantiation are recognized in the statute as presumptively sensitive so that you do not have to demonstrate that your production volume is sensitive; you merely assert that it's confidential.

LLB: --Because it's presumed to be sensitive?

REE: Because it's presumed to be sensitive, right. Then there's the information that requires some substantiation, where the submitter has to provide some justification. There are a number of questions that EPA lays out that provide the justification for protecting that information. That's the substantiated category. There's presumptive, substantiated, and then "not able to protect."

LLB: I'm guessing -- because the law, as I understand it, Rich, changed quite a lot from its original enactment -- TSCA was originally signed into law 42 years ago in 1976, and there were confidentiality provisions or CBI provisions embedded in the old law. But that law changed two years ago in 2016. Section 14, which is, I think, the provision that we're talking about, was modified. Was it modified to address a particular problem? Or was it modified just to keep pace with the evolution of technology?

REE: It was modified for a variety of reasons. Certainly from my perspective at EPA -- inside EPA, there was a view that there was overclaiming of CBI, that submitters would basically check every CBI box without much thought to whether the information was actually confidential. It was quite frustrating when I was at EPA, looking at a submission that claims something is CBI and then looking at the submitter's website and seeing that same information on the web.

LLB: Did you actually do that?

REE: Yes.

LLB: Oh my.

REE: That is a circumstance that really cried out for some change. It was really a change in behavior on the submitters' part. There were also circumstances where EPA would need to share information. The old law was very narrow on who could access CBI. You had to be a federal employee or a federal contractor to access CBI. State agencies were not eligible to access CBI, and medical professionals were not eligible to access CBI. There was a view that others might have a reasonable need to access the CBI and could handle it, could protect the CBI. But the authors of the new law recognized that there were circumstances in which others had a legitimate need to access CBI, and so they built a mechanism for states and medical professionals -- emergency responders -- to access CBI in cases where it was necessary and that they could still protect the CBI.

LLB: That makes all the sense in the world, and I recall in many of the hearings in the run-up to TSCA reform in 2016. First responders -- say, for example, there's a spill of a chemical into a waterway. What you're saying is that state public health officials were denied CBI in some instances, information that may well have facilitated a cleanup or an appropriate response.

REE: Absolutely.

LLB: Sounds like that was a welcome change and has on the whole been accepted by all stakeholders? Or are there issues even with how that particular aspect of TSCA reform is being implemented?

REE: It's still being rolled out. EPA has proposed a mechanism where it's going to permit or provide access to CBI, especially in cases of emergency response, where a prompt response is critical. I'm not aware that that has been activated yet, that anyone's attempted to access CBI through that mechanism, but EPA has proposed something. I think it still remains to be seen: Will it provide access timely enough? Will the CBI be properly protected? Because the statute does require agreements on the person that accesses the CBI, and that agreement may be after the fact, after they've had access. But the law does envision an emergency need, and EPA has authority under the statute to provide that information to the emergency responder so that they can use the information in the emergency response. But still the law does require after that disclosure that the recipient still protect it to the extent reasonable.

LLB: Right, and that's where I've seen a little bit of pushback, and not surprisingly so, from the regulated communities, like, "Wait a minute. What type of showing must there be by the recipient of CBI? How do you demonstrate that comparable provisions and safeguards are in place to ensure that that information will not subsequently be re-released to parties that don't belong in that process?" I think there's been some pushback on that, but I also know that states certainly need the information, and so where the rubber hits the road might be in demonstrating comparable safeguards are in place to protect it.

REE: Absolutely. EPA takes CBI protection very seriously. The provisions for managing TSCA CBI were the most stringent of all the statutes that I touched information on. It was the most protective of CBI. The employees took TSCA CBI very seriously. There is an expectation -- the law certainly envisions and expects a high level of protection for CBI by recipients outside the federal government. It remains to be seen how that'll be implemented. Will the recipients use the same degree of protective measures storing information in information systems that are not connected to the Internet, that are properly encrypted? That only those with a need to know have access?

EPA does have guidelines on how to protect CBI. There's a CBI protection manual, and that can certainly inform others. Will the other recipients be as protective? It's not clear. Will

EPA monitor the degree of their protection? It's not clear. But when I was at EPA, federal contractors that received CBI would get inspected. Someone from OPPT [EPA's Office of Pollution Prevention and Toxics] would go out and inspect their facilities and make sure that they were properly protecting CBI. Not clear how that's going to happen with 50 states, Tribes, emergency responders, and medical professionals.

LLB: It's kind of a quaint thought to dispatch inspectors to see if facilities are appropriately managed to protect information when now, security breaches are all done online.

REE: One of the things that would be inspected was were the CBI computers connected to the Internet? For a long time, CBI computers were air-gapped. If information had to be transferred, it was transferred through, for instance, a DVD or CD, or floppy disk back in the old days.

LLB: Right. Those good old days.

Rich, circling back to these buckets of information, as I understand your remarks, there are several categories. Some information is presumptively protected: the secret sauce, the stuff that makes the widget work. That's presumptively CBI. Then there are categories of data that might be amenable to CBI protection, but you have to kind of work for it, and you have to make the case. One of the indicia of not making that case is it's already out of the barn, it's on the Internet. Your SDS, or safety data sheet, might already disclose the identity of a chemical substance. But let's talk about that category of information in which you have made the case. Are you entitled to CBI in perpetuity? Is it time-limited? If it isn't time-limited, how long can it be presumed to be safe from disclosure, and what do you need to do to re-up?

REE: Information that requires substantiation, you substantiate when it's submitted to EPA, so that substantiation goes with the CBI claim, goes into the Agency. The Agency is required to review all CBI claims for chemical identity and 25 percent of other claims. You provide the substantiation at the time of submission. EPA may challenge your claim in a follow-up letter, either because you've neglected to substantiate something or they had a question about your substantiation, but once that substantiation is accepted, that information is protected for ten years.

There's a ten-year sunset provision for any information that's substantiated. That clock starts, presumably, from the day of submission. If you want to extend the protection after ten years, you would substantiate yet again. This is still information that's protected. It hasn't been released, hasn't been publicized, hasn't been released for some other reason. You haven't disclosed it under some other regulatory regime. That information remains confidential. You, again, re-substantiate, provide that justification for further protection, and then EPA will allow another ten-year period of protection. There is no limit to the number of ten-year renewals, but after each ten years, some justification will be required again.

LLB: What's interesting here is that when you achieve patent protection, and I know CBI is not the same as a patent protection. Assuming there is a difference, it sounds like you can extend the CBI protection of certain categories of information depending upon your ability to make the case that that horse is not out of any barn in perpetuity, pretty much. It also seems to me that companies have a pretty heavy burden of monitoring the release of information, of keeping CBI in a lockdown mode, and that the cost of doing that is probably growing with these new restrictions that are coming on board, the need to re-up every ten years, the need to make sure that information is amenable to protection. With all of that background, how

many companies are actually really trying to keep information proprietary? Is the pool of data getting smaller and smaller because it is completely inconsistent with shareholders' demand for transparency, for disclosure, and for enhanced communication, particularly when it comes to chemicals?

REE: There is a tension between transparency and CBI, and companies need to decide when they're asserting CBI in a TSCA submission. The first question that's asked when you substantiate, when you go to substantiate a CBI claim, is: "What would be the substantial commercial harm to the company if the information were disclosed?" If a company, before they check a CBI box, if they think about if this particular information would become public, what would be the substantial commercial harm? If the answer is "ehh," then it's probably not a box you should check.

LLB: From whose perspective? I mean, what is substantial for these purposes, and you can make the case that it will harm a company if a competitor knows a little extra about something of the manufacturing process or the chemical composition. I mean, the burden presumably is definitely on the person asserting the CBI.

REE: No question.

LLB: EPA ultimately is the arbiter of the rules. But is it a difficult showing? I mean, I'm trying to get our listeners to understand, "Geez, do I have to bring in experts to make the case?"

REE: I don't think so. For the conversations that we've been having with EPA on these issues, on substantiation issues, EPA is asking very reasonable questions and expecting a reasonable amount of substantiation. Mostly I think that if submitters are thoughtful, they have a legitimate claim, and can make a reasonable argument about: what would be the substantial commercial harm? How much R&D was expended? Part of that is the effort that the company takes to protect CBI is also an indicator of how important it is to protect it.

Think about soda formulation. That little bit of information in a vault somewhere is extraordinarily valuable to Coke, and it's very well protected. The way that Coke protects that formula is an indicator of the substantial commercial harm that would be done if that formula were to be released. When a submitter is deciding whether or not to check a particular box, framing the thought as: What would happen if my competitor knew this? What would be the harm to the company? And if it's like, pretty much everybody knows this particular aspect, but we just don't want to publicize it, that's probably not going to clear the bar for substantial commercial harm. But if it's a chemical substance that you've just spent a couple of million dollars developing and you've discovered something that no one else knows and you have not disclosed that, then you've got a pretty good argument that there would be substantial commercial harm.

Then, thinking about the presumptive categories, the standard business practices: How much do you make? What are the markets that you sell into? How do those markets break down? Those things are generally recognized, again, those are the presumptive CBI categories.

LLB: That sounds a whole lot like a trade secret.

REE: Yes, it's like general business secrets. These things are routinely protected by businesses. They're widely recognized as important confidential information for running a business.

LLB: To your point regarding R&D, a lot of these data are very expensive. Are you saying that R&D data, health and safety effects data, for example, are able to be submitted under a FOIA, and the government would be forced to disclose those data?

REE: The Lautenberg amendments to TSCA do specify that health and safety data are NOT eligible for protection as CBI. A study report would have to be submitted with a PMN or perhaps a Section 8(e) submission.

LLB: These are required submissions to EPA?

REE: Right, and the health and safety information in the report is not eligible for protection. There may be information in the report, such as a confidential chemical identity, that could be protected. The report that would be released under a FOIA request, or published to EPA's website, if it was part of a docket, for instance, to support a significant new use rule, that would be the redacted version that only protects that small bit of CBI -- the chemical identity or whatever other information would be CBI.

LLB: But I'm guessing that small bit would be sufficient to render a document that is returned from the Agency under a FOIA request -- that redaction may render the serviceability of those data less, right? Health and safety data are really, really important, and they're also really, really expensive.

REE: Right. If a health and safety study were submitted and the CBI chemical identity, for instance, were redacted, and the competitor submitted a FOIA request and got a copy of that health and safety study, that health and safety study could not be submitted to another regulatory body to support a registration in Europe or in Asia because the chemical identity is redacted. The competitor couldn't point to it and say, "This study supports this information, and we want this other regulator to consider that and to support a registration." The other regulatory bodies wouldn't accept it because there's too much -- enough is not disclosed that it renders the value of the study less for that registration. But it does provide some visibility to the public. If the public is reviewing, for instance, the generic name of the substance and perhaps that it's in a particular product and they could associate that with the particular health and safety information, so that there is some trust, some transparency to support public right to know, in terms of health and safety. But there is some protection for the company that's generated the data and generated the CBI.

LLB: To your point, Rich, about getting information through FOIA requests, I'm aware of many different opportunities for entities to be forced to develop data and to submit data to government agencies in Europe, in Asia, Australia, all over the place. So, number one, that puts an enhanced burden on the private sector to curate these data responsibly and very accurately. But it also raises the question of whether information released in Europe, for example, under the European equivalent of TSCA, which is the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) law, whether those data if disclosed in that jurisdiction would nullify a claim that you've managed that information in this country and didn't disclose it -- if that argument were to be successful with EPA? It's been released in Europe to the European government authorities there, but never been released here. Would that disqualify an opportunity to claim CBI if it were disclosed in Europe?

REE: If information were submitted to the European Chemicals Agency (ECHA), and that information was not claimed as CBI and therefore eligible for release under REACH, EPA would probably take the view that that information had been disclosed and therefore is ineligible for protection under TSCA. The first criterion for protection under TSCA is that

the information must be confidential. If the information is not confidential, substantiation doesn't apply, presumptive CBI doesn't apply. None of the other rules apply. If it's not confidential, it's not eligible to be CBI. We have to remember, that's the first test. If it's been released -- if it's been disclosed in a patent, which is something that we can come back to and talk about, if it's been disclosed to another regulatory agency or disclosed for some other reason in the United States -- it's not eligible for protection. If it's been submitted to ECHA but is being protected, then you could still claim it as CBI and seek to protect it in the United States.

LLB: I'm hoping our listeners are beginning to appreciate the complexity of this space, aligning various regulatory requirements across the world to be mindful of what data are amenable to protection, how do you go about asserting those protections, whether you do so consistently and accurately, and then managing these data in a way that takes a broad view, so that you are able comfortably to assert CBI and that you haven't waived it in Europe or Asia or whatever, is a tall order.

REE: Absolutely, and it's also important to recognize that when you generate data, you may be triggering reporting obligations in a variety of jurisdictions. We had clients who were developing data for REACH registrations, and we were reviewing those data to ensure that the data were not reportable under TSCA Section 8(e), the substantial risk notice provisions of TSCA. That's important as well as you generate data, recognizing what particular reporting obligations are triggered by those new data.

LLB: I'd like to switch gears here, recognizing that in the recent past, we've seen state initiatives mushrooming around the country -- California, not surprisingly, comes to mind, and more recently even this year, New York -- where state agencies are compelling product manufacturers to be more transparent with regard to product composition and what chemical ingredients are included in products, particularly in the cleaning area. California came up with a law last year, New York issued its New York cleansing product law this year. I am assuming, but please confirm, Rich, if CBI protections under TSCA are recognized under these state initiatives. Otherwise, why do we have federal protection when states could let that horse out of the barn simply by virtue of state law?

REE: That's a very interesting topic, and we're still seeing people figuring this out, figuring out the space. The product formulators, those brands, retailers, and the various trade associations are trying to figure out where is that balance between the communication -- between the transparency and the openness -- and the legitimate need to protect specific CBI.

And both California and New York do recognize that there are cases where there's legitimate CBI that is associated with a particular formulation, whether it's the presence of an ingredient. Certainly the specific composition is not part of the communication requirements, but both states also specifically reference generic names under TSCA. When you claim a chemical identity as confidential, there must be a structurally descriptive generic name.

LLB: Okay.

REE: Some part of the name is masked, but some part of the name is disclosed. That generic name that's listed on the confidential portion of the TSCA Inventory, that is the name that both states require to be listed on a product label or product communication, on a website, for instance. If there was a particular novel surfactant in a hard surface cleaner, some spray cleaner, and the chemical manufacturer had asserted CBI for the substance identity and

substantiated that claim, introduced that product to the market, and that product was formulated into the cleaner, the formulator must disclose that there is a confidential ingredient, but they would disclose that with a generic name, as opposed to the specific substance identity. The TSCA CBI provisions are flowing through into the state initiatives.

LLB: That's comforting, particularly for branded companies. Let me ask one final question relating to what are the consequences for not getting it right. Let's say, for example, you're a new company. You have invested a good deal of time, and effort, and intellectual know-how into perfecting your product, and you just really don't want to disclose very much, and you haven't been terribly aligned with the requirements. The goal is to protect as much as possible for as long as possible. Can you do that? Is that a legitimate business strategy, or are there consequences if you assert CBI when there's no good basis to do so?

REE: We're very early in the implementation of the CBI provisions and EPA's process for CBI review. What we're seeing is, when EPA reviews the information that was submitted and claimed as CBI and has questions about substantiation, EPA sends a formal letter back, saying, essentially, "Please explain yourself. Please explain why this information must be protected. Please expand upon your substantiation. It's not clear to us that there will be substantial commercial harm or that you are taking proper steps to protect it."

I don't know what will happen when a submitter, in response to that letter, says something that's still not enough for EPA. We have not seen that yet, and I don't know how EPA will respond. EPA seems to have the authority to simply not accept that CBI claim and disclose the information. It can make that determination that it's not a legitimate CBI claim, and then just not accept that claim, and whatever information would be submitted would then be eligible to be released. But I don't know what's going to happen. That's still speculative about how that might play out.

LLB: I'm guessing the entity that asserts the claim has an administrative process that it could exhaust if it chose to enjoin EPA from releasing information that, "We may disagree," but at the end of the day there has to be a process for arbitrating claims as to whether or not they are in or out of the protected zone.

REE: Sure, if EPA decides that a particular piece of information is not eligible for protection, and they make that determination, the submitter can file an appeal, and that does prevent disclosure until the appeals process is exhausted.

LLB: Right. Since the law was amended in 2016, from my perch as a lawyer, I've seen a substantial uptick in client requests for assistance in both identifying what can properly be claimed as confidential and in formulating compelling substantiations. I'm guessing you're doing an awful lot of that, and you see that as a growing area of the law.

REE: Absolutely. We've seen quite a bit of uptick, both in work that we're developing to submit, so PMNs or other notices that we're developing to submit to EPA, where we spend a lot more time looking through a particular submission and checking to make sure that everything that is confidential is protected and then checking also to make sure the things that are not confidential are *not* claimed as protected. We often get into the discussion with the client about "How would we substantiate this?" When a client indicates that a particular piece of information needs to be confidential, we'll evaluate that and have that discussion -- "What is it about that?" -- and help formulate that substantiation statement that will be submitted to EPA in such a way that it's much more likely that EPA will accept it.

We're also assisting -- because clients are now starting to receive these substantiation requests for information that has been submitted -- is under review by EPA, and EPA has issued a letter saying, "Please explain your substantiation claims in this particular submission." Then we'll go back through that submission and look at all the claims. In some cases, we'll withdraw claims, and in other cases, we will beef up the substantiation. Something else that it's very important that clients recognize is the need to be sure that anything that is confidential is protected throughout the submission. EPA might take the view that if you claim it as CBI in one place and disclose it somewhere else, that you've not been sufficiently cautious, and it's not actually that sensitive. It's very important to make sure that your submissions are well QC'd [quality controlled] so that the confidential claims are consistent throughout.

LLB: I hope, Rich, our listeners have a newfound respect for the complexity of this area. This is an area fraught with all kinds of opportunities. Once those data are out, you've waived any claim to CBI, and that could well be commercially very damaging. This has been a wonderful opportunity to discuss this with you, and I greatly enjoyed the opportunity to do so.

REE: Always a pleasure. Thank you very much.

LLB: Thanks to my colleague, Dr. Richard Engler, Director of Chemistry here at B&C, for sharing his wealth of knowledge and practical advice with us. I hope our listeners learned about navigating this tricky, yet critically important, area of processing and protecting CBI during chemical reviews at EPA. If you wish to learn more, check us out at our website at www.lawbc.com and our blog at www.tscablog.com.

All Things Chemical is produced by Jackson Bierfeldt of Bierfeldt Audio LLC.