

Caitlin Drover
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Mr. Bloom
SJ Gov't

Oral History Transcript

Caitlin: This is Caitlin Drover interviewing David Drover for a Palo Alto High School Social Justice Pathway student project. Today is Sunday, April 26, 2015. This interview is recorded on an iPhone 5s. Please tell me your name and where you live.

David: David Drover, Stanford University.

Caitlin: What is your current occupation?

David: I'm an anesthesiologist, and my official title is Professor of Anesthesiology at Stanford University.

Caitlin: Where did you attend school and what did you study?

David: That's a longer story. After graduating from high school, I went to do an undergraduate degree at Dalhousie University in Halifax, Nova Scotia. My major was in chemistry, and I graduated from my chemistry degree in 1985. After my chemistry degree, I went on and did a masters. My masters was actually in clinical pathology; but which actually was clinical chemistry, and I graduated with that degree in 1998 (*correction: 1988*), which overlapped my medical degree, which started in approximately 1997 (*correction: 1986*), and I graduated from my medical degree in 1990. I went on and had additional training with what we call an internship, graduating in 1991, followed by a residency in anesthesiology, which I graduated in 1995. Subsequently, I left Dalhousie after 15 years of education and came to Stanford University where I did a fellowship, or postdoctoral program, in clinical pharmacology.

Caitlin: Can you give some background information about the court case you were involved in?

David: The court case I was involved in had to do with a drug called, well, it's called zolpidem, but most people know it as ambien. Ambien is the most common sleep medication on the market. It's a prescription medication, a controlled medication, for helping people that suffer from insomnia. And so the company I was helping, named Purdue, had actually developed a new formulation of zolpidem, and they had a patent, and we were trying to defend that patent against generic makers who wanted to make the same medication and break the patent.

Caitlin: How did you initially get involved in this court case?

David: That would go back to my earlier work, so in 1995 when I came to Stanford University, my clinical pharmacology fellowship involved a lot of research, and I continue to do research to this day, but my earlier work was actually on zolpidem, so I have done research on zolpidem and I have published a couple of publications, and those publications are quite well known worldwide. And when the lawyers were looking for someone with an expertise on zolpidem, they found me.

Caitlin: What was your role in the case?

David: My role was truly as a clinical pharmacologist. As a clinical pharmacologist I know all about what the drug does and how it works, so we're going to have to break that down into two little parts. When we do clinical pharmacology, we have the part that's called pharmacokinetics, and pharmacokinetics is the part of pharmacology that describes what the body does to the drug. In other words, how does the body chop up the medication and deal with it. And then the other half of clinical pharmacology is called pharmacodynamics, and that is what does the drug actually do to the body. In this sense, to give an example, a sleeping pill puts you to sleep. So that's what the pharmacodynamic response is; it puts you to sleep. So I'm an expert in clinical pharmacology, so I know all about how the drug enters the body, what the body does to the drug, and how the body responds, so I'm really the expert on the medication. And my job was to explain to the court, and when we say that, that's the fancy term in this situation because there was no jury, explain to the judge, how this medication works.

Caitlin: Can you describe what it was like to testify?

David: I thought it was going to be a little more anxiety producing than it was, I mean, it truly is like giving a presentation in front of an audience, except it's sort of directed, instead of having the plan of what you're going to present as your presentation, you actually have to go along with what the other people want to be the presentation. It wasn't as bad as I thought it was going to be, so if you envision, you're up there sitting beside the judge and there's someone down below you recording everything you say, and there was probably in the range of 15-20 lawyers in the courtroom. There was a few spectators but they were really just the court support staff and the secretaries. No one really comes from the public to watch boring cases like this. It was really just focusing on what the questions being asked of me, and I just took my time and answered each question so the judge could understand. You have to really slow it down, you can't sound too complicated because the judge is not trained in clinical pharmacology, so you

have to actually explain to the judge all these answers, just as if he was just any other person that just strolled in off the street.

Caitlin: What were some steps you had to go through before the trial?

David: There's many steps. I tell you, we were 2 years leading up to this trial. There was so much of the early years just going over thousands and thousands of documents. I had filing cabinets full of publications and court documents and briefs. To know all that was going on with the medication. Know all that's going on with the patents that were protecting the medications. You just really have to have all of that in your head because when you're asked a question, it's not as if you get a chance to say, 'I've got to pull out binder #43 and see what it says.' As the expert, I was supposed to know all of that. That was the first year of getting to know stuff really well, and I had to write a number of very long reports. My reports, I wrote 3, and they were all well over 100 pages long. The reports are followed by a deposition. A deposition is when the other lawyers get to close you in a room, swear you in just as if you were in a trial, and ask you as many questions as they see fit. And I had a deposition, and we spent two-7 hour days being peppered with questions. If you can imagine just sitting there across from 5 lawyers that peppered you with questions for 7 hours, 2 days in a row. Absolutely exhausting. Then after that, when all the documents were gathered from the experts, then we went to court. So there was so much preparation leading up to the court time.

Caitlin: What was the ruling?

David: The ruling was not favorable on our side. I was trying to convince the judge and our side was trying to convince the judge that, well, the medication, the new formulation, was unique. And it had a valid patent, and I'll tell you what this, you have to understand what the change was. The company wanted to actually have a very fast acting sleep medication that didn't last too long. It's for those people who wake up in the middle of the night. You don't want to wait around another hour to fall back to sleep, so it was formulated to actually make you fall asleep really quickly. But the of course, if you wake up in the middle of the night you have to make sure you can still get out of bed in the morning to go to work, so it had to wear off really quickly. So that was the patent that this medication was really specific for those 2 things. To go back and answer your question, it sounded easy, but it's a little more complicated than that because there's 3 main things you actually have to worry about when you deal with a patent. We won on 2 things, and we lost on the 3rd. Unfortunately, when it comes down to patents, you have to win all 3 to win. It's not good enough to win, it's like, '2 out of 3 is not bad?' Wrong. You actually have to win 3 out of 3 to actually have a valid patent. The 3 things we had to win on were indefiniteness, validity, and obviousness. And we won on the indefiniteness but we lost on the obviousness.

Caitlin: Can you explain what you mean by each of those things?

David: So, indefinite, if a patent is indefinite, that means it wasn't specific enough. And I'll try to give an example. The lawyers always liked to try to give me examples and they tried to usually, they used cars as examples. So I have just invented a new car! And when I wrote up my patents, so you can't just go out and copy my car. If it was indefinite, I could say, 'I just invented a new car, and I'm not telling you what color it is and I can't tell you how many wheels it has because I'm not sure.' Well you're not being very definite. You have your car, but if you haven't told me anything special about the car, you can't even tell me what color your car is, or how many wheels your car has, so that doesn't sound very definite. So you have to actually be, when you make a patent, you have to actually be really clear what you invented. You have to tell the world that this is a true invention, just like an iPhone. This is an iPhone. You have to tell them it is. In this situation, the judge said, 'Yep, you did a really good job making the patent. You passed that test.' So the next thing was validity. Well, it's no use making a patent and making it very clear, but if it's not valid, it's not worth doing. It's like you're saying... let's do the car example again. I have a patent for a blue car with 4 wheels. Well it's very clear, it's very clearly a car with 4 wheels and blue. There's no indefiniteness about that, but it's not really valid, because it's just average. That doesn't tell us enough, so it may not be valid. But worse than that is it fails on the obviousness side of things. So all of a sudden if I said I made a patent for a blue car with 4 wheels, you're going to say, 'Well that's pretty obvious.' And you're right, it is. You have to make sure you say it very specifically, and that it's unique, and that it's obvious. So you have to pass those tests. We passed 2 of those tests, but the judge, even though this here medication was different from the usual sleeping medication that people take when they go to bed, if you take it when you go to bed, you usually don't care that you fall asleep right away, because maybe you still have your teeth to brush and do whatever, so the judge didn't see that is what really that fancy to fall asleep really quickly in the middle of the night, and he thought, 'Well, it's pretty obvious that if you fall asleep fast then you'd wake up fast too,' he says, 'these things, if any smart guy had really thought about it, you could invent this pretty obviously.' So we lost on the obvious side of things, so even though we've spent 2 years, millions of dollars, and many hours of paperwork and testifying, we lost the case. Just on that one little clause of being obvious.

Caitlin: If you could have done anything differently, what would it be?

David: Tough question. It really is. You always want to be more prepared. We discussed it as the lawyers in the group afterwards. You always hate to lose. It's like being a basketball player, and you played well all season long, you won all your games, and then you lose in the playoffs. I don't think the other side did a better job. I thought the other side, the lawyers on the other side, were slimy and nitpicky and they didn't know what they were doing. The quality of the lawyers, they just didn't know their stuff. Whereas I said, we practiced for 2 years and we

really knew our stuff. The usual answer to ‘what could I have done to make it different’ would have been to practice more, but the truth is we discussed this since we lost the case and there was nothing we could have done. We knew the material better than anyone, we had the best presentation of the court; the court just decided that when the inventors invented this medication over a decade ago, that they did something that was obvious. We could not have done a better job. You’d say, ‘oh, we’d do it all again, if we did it all again, appeal and go back to court, could we do anything differently?’ No, unfortunately not.

Caitlin: Would you be willing to be involved in another court case such as this one?

David: Yes. It’s what I do for a living on the side, even though I’m an anesthesiologist, this is what I do for my entertainment, and it’s just part of my income. It’s just a job in the end, but a job that distracts me from my regular job. It’s educating, it’s very educating. It’s funny you do these things not just to make a living, it’s like, ‘ok, I already have a job to make a living.’ When you actually do something like this, from my point of view as a consultant, this is unique and I learned so much. Because when people ask you questions you have to know the answers, and then you teach yourself new things you didn’t know before. All of a sudden, it’s a unique experience and it makes me better at my first job by practicing at this second job.

Caitlin: Is there anything else you’d like to add?

David: No... it’s a good experience. I’ll do it again, probably again sometime.

Caitlin: Ok, thank you for your time.