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THOMAS KILEY

Life Sciences Foundation

Transcript of a Research Interview
Conducted by

Mark Jones

in

San Francisco, California

on

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(With Subsequent Corrections and Additions)

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INTERVIEWEE

Thomas Kiley discusses his involvement as legal counsel for Genentech, including his role in legal matters related to the successful expression of somatostatin in 1977, human insulin in 1979, and the human growth hormone in 1979. Kiley joined Genentech full-time in February 1980. He discusses controversies surrounding agreements and settlements between Genentech and organizations like Eli Lilly, KabiGen, Wellcome Trust and Genetics Institute, and the University of California. He also discusses several noteworthy cases, including Diamond v. Chakrabarty, related to patent protection for microorganisms artificially produced, and the role he played in filling an *amicus curiae* brief in which he argued that Congress rather than the Supreme Court was better suited to weigh the many considerations pertaining to patents.

Kiley also mentions several cases in which he served as an attorney, including his first big case—what he called the "permanent press" case—as well as litigation related to tissue plasminogen activator (tPA) while counsel for Genentech, including Dianne Pennica's role in cloning and expressing it. He discusses Genentech's suit against the Wellcome Trust in the greatest detail, mentioning his involvement in the court case overseas in the United Kingdom as well as the case in the United States. He talks about interactions with prominent scientists, including Sydney Brenner and Paul Berg. Near the end of the interview, Kiley speaks about his involvement with Hybritech and the mouse wars of the 1990s. He concludes by discussing his favorite trademark litigation case in which he was involved between Miss USA and Miss Nude USA.

INTERVIEWER

Mark Jones holds a PhD in history, philosophy, and social studies of science from the University of California, San Diego. He is the former director of research at the Life Sciences Foundation and executive editor of LSF Magazine. He has served in numerous academic posts and is completing the definitive account of the origins of the biotechnology industry, entitled *Translating Life*, for Harvard University Press.

ABOUT THIS TRANSCRIPT

Staff of the Life Sciences Foundation conducted this interview, which became a part of our collections upon the merger of the Chemical Heritage Foundation and the Life Sciences Foundation into the Science History Institute in 2018. The Center for Oral History at the Science History Institute edited and formatted this transcript to match our style guide, but, as noted, Science History Institute staff members did not conduct the interview.

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INTERVIEWEE: **Thomas Kiley**

INTERVIEWER: **Mark Jones**

LOCATION: **San Francisco, California**

DATE: **25 February 2013**

KILEY: I wonder if you've happened to have seen my oral history at the Bancroft Library.

JONES: Sure. With Sally [Smith Hughes].

KILEY: All right.

JONES: Yeah. No, we've got that. So . . .

KILEY: Do you have it online, or have you looked at the hard copy?

JONES: We have the digital copy, but I've read through it.

KILEY: All right.

JONES: Yeah. And we have it actually posted on our website.

KILEY: The reason I ask is because there's some exhibits to it, including a paper I wrote on the tPA litigation, which I don't find here, but I can get you a copy of that.

JONES: Okay. That'd be great. Yeah. Wonderful.

KILEY: Okay. So what I have for you is . . . and you may have seen this already. This is the original Genentech business plan.

JONES: Beautiful. Yeah. We don't have a copy. So that's good to have. Great.

KILEY: This is one of the exhibits to the oral history, which is our amicus brief in Chakrabarty.[1]

JONES: Great.

KILEY: And most of this I can leave with you.

JONES: Okay. So we can make scans of these, and . . .

KILEY: You can have that. You can have the business plan.

JONES: Great.

KILEY: I'd like . . . and you can have this. I would like to have copies of these.

JONES: Yes. Very good. Yeah. We'll take good care of them and return them promptly.

KILEY: Let me just make a couple of notes here. Okay. How would you like to proceed, Mark?

JONES: Well, we've got the oral history with Sally, and it's pretty thorough, so we could . . . what I usually do—as Sally does—is start at the beginning, and get complete biographies, but unless there's something that you think should be added to that about your early years growing up from Pittsburgh and—

KILEY: No, I don't think any of that's required. I guess . . . . I don't think we did quite a good enough job on some of the legal aspects in the oral history, and particularly the relationship of the initial projects at Genentech and their corporate sponsorship, and the sequelae of that, which

[1] Kiley references the United States Supreme Court case Diamond v. Chakrabarty, 447 U.S. 303, dealing with whether living organisms can be patented. See Dennis J. Walsh, Diamond v. Chakrabarty: Oil Eaters: Alive and Patentable, 8 Pepp. L. Rev. Iss. 3 (1981). Accessed at https://digitalcommons.pepperdine.edu/plr/vol8/iss3/4 on 22 February 2026.

involved some significant litigation in later years. And so it would be interesting to describe the genesis of those arrangements and what eventuated. I think it's worth discussing Chakrabarty at some length.

JONES: Yes.

KILEY: And perhaps the first patents, Golde litigation . . .

JONES: The UC litigation, we're interested in hearing about that—

KILEY: And the City of Hope litigation as well.

JONES: Yeah.

KILEY: All right.

JONES: Yeah. No, sounds good. And generally, Sally's book goes up to the IPO, and, you know, you were at Genentech till '88, right?

KILEY: That's right.

JONES: So I guess covering those years in some of this—what you just mentioned—through to . . .

KILEY: Together with some of the litigation that arose from events in the pre-1988 years, but which were tried subsequently.

JONES: Okay. Great.

KILEY: All right.

JONES: Maybe we could . . . do you want to start with somatostatin?

KILEY: Certainly.

JONES: Yeah. So I was just talking to Niels Reimers the other day, and he was commenting on the fact that there's . . . and, you know, he's at a distance from this, but commenting on the fact that no UCSF investigators on the patent for somatostatin.[2]

KILEY: Oh, right. As you will see from Bob [Robert A.] Swanson's business plan, his initial objective—indeed, his only objective at the time—was to use recombinant DNA to express, manufacture, and sell for Genentech's own account human insulin. And when I got involved, he was in course of establishing collaborations with the City of Hope National Medical Center and UC San Francisco to synthesize and express DNA for human insulin.

He was disappointed when Riggs and Itakura at City of Hope insisted on doing somatostatin first because while somatostatin was an intriguing molecule, **<T: 05 min>** it then had no marketplace, and indeed, has no market today. Nevertheless, Riggs and Itakura wanted to do it first because it was a simpler protein—about one-third the size of human insulin—and it was a single-stranded polypeptide, whereas human insulin is a protein with two polypeptides joined by sulfur linkages.

And so ultimately, he agreed. The DNA was synthesized at City of Hope and sent up to the Boyer laboratory at UC San Francisco to be expressed. In the event it could not be expressed—or when expressed, was rapidly degraded—and Riggs conceived that a way to turn defeat into victory would be to make a conjugate of beta galactosidase with the small somatostatin peptide in a way that would permit its subsequent cleavage.

Now Roger [G.] Ditzel at the time was in charge of contracts and licensing at the University of California system, and when the somatostatin project succeeded, he expressed some dismay that no one from the university was named as an inventor. Our arrangement with City of Hope provided that Genentech itself would own any eventuating patents, insofar as City of Hope inventors would be concerned. The University of California arrangement, on the other hand, would leave patents in the hands of the university, which would receive a royalty not only on products covered by UC-deriving patents, but also as a result of a mistake Bob made in negotiating that particular arrangement, royalty for unpatented know-how that arose in that laboratory as well.

JONES: Were you involved in that negotiation? Or were you advising Bob?

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[2] Niels Reimers, interview by Mark Jones in Carmel, California and via phone, 22 February and 30 April 2013 (Philadelphia: Science History Institute, Oral History Transcript # 1031, in process).

KILEY: I was advising Bob from a distance, but I was in trial in another matter, and Bob, to save some money, took it on himself to do that negotiation by himself, or largely by himself. Well, in the event, we expressed somatostatin, and it fell to me to decide what had been invented. And after discussing matters with people involved at both ends of the project, I concluded that the inventions were at least threefold. One was the notion of expressing what I called a homologous—or rather a heterologous protein under homologous control. That is, you use the control elements of the bacterium to express a polypeptide that the bacterium ordinarily doesn't make. And so the first patent application I prepared would have covered the expression in any microbe that is extending from bacteria into yeast as well—of any foreign protein under the control of the microbe's homologous control region.

JONES: Wasn't it . . . this is not covered in the Boyer-Cohen patent?

KILEY: The work that we did would be dominated by the Boyer-Cohen patent, but no, they had not expressed a foreign protein under friendly control as such in the Boyer-Cohen patent.

Now the second invention we conceived was the use of codons that were preferred for microbial expression to produce a mammalian polypeptide. Owing to the degeneracy of the genetic code, you have codon choices, and Keiichi Itakura, who was a DNA synthesist, thought it would be best to use the codons that bacteria were most familiar with.

JONES: Did they try other combinations to see if they **<T: 10 min>** would work? Or did they just go directly to the—

KILEY: They went directly to codons that Keiichi thought would be preferred. Now the third invention we concluded had been made by the expression of a conjugate protein with a linker that could be subsequently cleaved. And so that we found had been invented, conceived by Arthur [D.] Riggs.

The basic idea went back to a grant application that Riggs and Itakura had filed with NIH [National Institutes of Health], and, in that application, we found evidence for the conception of the notion of expressing a foreign protein under friendly control. And in later years, when this became controversial, the university had Bert Rowland, who had written the original Boyer-Cohen gene splicing patent, go through the documentation that underlay my decision to make Riggs and Itakura jointly and severally inventors of these various applications. And I presume Bert pronounced himself satisfied with my decision, because at that point, the issue went away.

So we had our success. We filed our patent applications. And the somatostatin success prompted Eli Lilly to approach us—or we approached them—with a view toward having them

sponsor the human insulin project, which would be next up. That was a lengthy negotiation, and as reported in my oral history, was concluded only days before we would announce the somatostatin success, or rather the insulin success. Lilly had been funding the work under a term sheet but had not completed the full negotiation with us. We felt it important to announce the insulin success. Lilly was concerned that the FTC would become a third party to the negotiation, because Lilly at that time was operating under a consent decree that settled charges of insulin monopolization that had been brought the Federal Trade Commission.

So we completed our insulin deal, and I mark that, and the human growth hormone deal we did with KabiGen of Sweden, as among the first—if not first—examples of a new symbiosis between the pharmaceutical industry and molecular biology startups. In fact, until that time, the universities would from time to time license their drug-related inventions to big pharma for relatively nominal royalties ordinarily and little more than intellectual property would change hands. The pharmaceutical company would take development under charge. We—

JONES: And in those days, the big pharma companies had chemistry, but they didn't have biological expertise, right?

KILEY: That is true. And indeed, I think one of the things that permitted Genentech and some other companies to grow toward full integration—even though they were surrounded by trees that cast great shade—was the controversiality of gene splicing at the time. And I believe that caused many major pharmaceutical companies to hold back, and that gave Genentech an opportunity to pick some low-hanging fruit.

JONES: So were you involved in or present for the discussions, formulation of the strategy, the licensing strategies?

KILEY: I was. In the three-and-a-half years before I had joined Genentech, I helped in negotiation of the City of Hope arrangement. I—with Bob—negotiated the KabiGen human growth hormone deal, which was the first deal signed by Genentech. **<T: 15 min>** Lilly was being negotiated concurrently, but that arrangement was signed only a week or two following the Kabi deal. I participated in the human insulin negotiation, and later in the Roche alpha interferon negotiation as well. And those were the three deals that positioned the company for its initial public offering in October 1980.

What was interesting about the Lilly and growth hormone deal was this: at the time, the question whether microorganisms engineered to produce such things as human polypeptides would be patentable was open. Indeed, the United States Patent Office in Chakrabarty had rejected claims to an altered microorganism.

JONES: In rulings prior to these deals?

KILEY: More or less contemporaneously with them. And that was on its way to the Court of Appeals. And so we didn't know if we would have patents on the microorganisms, and we had the usual concern that arose from perhaps a bit of paranoia, and that is that if it turned out there was a great deal of money involved, one could not rule out the possibility that the licensee would later attack the validity of the patents to escape its royalty obligation because there is no . . . nothing in law that prevents, and indeed, the law actually encourages parties to act as private attorneys generally and to root out bad patents, even if that means they escape their royalty obligations.

Well, it occurred to us that what we were doing was not so much licensing a patent to Lilly or to Kabi but rather providing them with a factory that would produce a human polypeptide. And why not sell it to them on an installment plan? And since the parties in the agreement acknowledged that it was uncertain whether patents would issue, that they nevertheless wanted access to the microorganism. It was difficult to value the organism in advance, and hence, we would let the market assign a value to it in this way. They would pay a royalty over a period of twenty years, and those royalty payments would be installment payments against the ultimate purchase of the microorganism. And those royalties would be due whether or not patents issued so long as the product they made arose from the microorganism or its progeny or anything advantaged in its creation by their possession of the Genentech microorganism.

And later, Lilly found it remarkable that it had . . . that the agreement could mean that. Indeed, in the agreement, they undertook to make no use of the Genentech microorganism other than for the production of human insulin. Somehow, they went ahead and used the control elements of the Genentech microorganism for the production of human growth hormone and then sued in later years to break the broad patents arising from the City of Hope collaboration, which would have dominated their use of . . . or their manufacture and sale of growth hormone. Genentech countersued for breach of that agreement and breach of trust, and that litigation, it got to be quite a bit deal. And Donald [R.] Dunner, past president of the American Patent Law Association, represented Lilly. And his view was that we had somehow coerced Eli Lilly into signing something that amounted to an abuse of patents, and that our patents were therefore unenforceable, and the agreement—despite **<T: 20 min>** its clear terms—could not possibly mean that they could not use the microorganism for purposes other than insulin.

We had provided in the agreement that Genentech would have the right to terminate the agreement and to return of the microorganism should Lilly produce as little as one gram of GMP material from a microorganism derived from some other source. Don found that to be a patent abuse. Our view was that nobody produces GMP material in the amount of one gram unless they have the intention of producing a heck of a lot more of it down the road. We would need advance notice so that we could recover the microorganism and find another home for it. And so that gram of shall we say foreign recombinant insulin would be the canary in our coal mine. Well, ultimately, I have to conclude that Lilly came to its senses because once I left

Genentech, that litigation was settled with I am told the payment of a very large sum of money by Eli Lilly, and the parties went their respective ways.

JONES: And this did drag on for a number of years?

KILEY: It did indeed.

JONES: And you were directly involved the entire time? Or you had gone off to do other things by the time . . . by 1988?

KILEY: That litigation for the longest time was in the hands of Weil, Gotshal & Manges, and I was almost wholly preoccupied with the tPA litigation in the United Kingdom where on behalf of Boehringer Ingelheim, our licensee, we sued the Wellcome Trust and Genetics Institute for infringing our patents on tissue plasminogen activator and recombinant means of making it. At that time, that was conceived as Genentech's flagship product, anticipating a very large market, and Bob wanted me to spend virtually all my time on that. And so I was less active in the Lilly litigation, although my testimony was taken in the usual course concerning the agreement.

JONES: Well, let me ask about the licensing strategy going back. Where did that originate? Who was . . . and you were there. Bob Swanson's there. Is Tom [Thomas J.] Perkins involved in this? Who else has input to . . . ?

KILEY: Well, certainly Tom was an active participant in devising strategy, but remember that Bob's notion initially was that Genentech would become a make-and-sell company. We would produce human insulin. It turns out that that would require a very large amount of capital, certainly more in terms of full development through the FDA—you know, building a plant, hiring a sales force, more than we thought we could achieve with the venture capital available. And also, human insulin is as close to being a commodity as any pharmaceutical can be imagined. It has to be detailed with a very large sales force. And ultimately, Genentech concluded that the better course would be to turn it over to Lilly, who dominated North American insulin sales at the time—witness the consent decree. And so to validate the company by sponsorship of . . . by a prestigious pharmaceutical company to bootstrap itself with the milestone payments, so as to require less dilutive venture capital, and to go on and make human growth hormone for our own account. Now when we negotiated the human growth hormone arrangement, Bob insisted on retaining the North American market for Genentech's own exploitation. Kabi, of course, **<T: 25 min>** was not well-established in the United States, but they wanted—at a minimum—to have co-exclusive rights in our market.

JONES: To the US?

KILEY: In the United States. And they got those, although some years later, we were able to go back to Sweden and talk them out of those rights. And so Genentech ultimately won exclusive human growth hormone rights in the United States.

JONES: And on what basis did they give it up? How did you persuade them?

KILEY: Honestly, I don't recall. I'm sure there was ample consideration given for it, but I don't recall what that was. I think it's possible that . . . well, I won't speculate. I don't really recall. Of course, the growth hormone situation was complicated by the fact that Lilly had stolen a march on Genentech through its misuse of the Genentech tangible organic materials in that it achieved what we called methionine free human growth hormone. When Genentech first produced human growth hormone, it came accompanied at its N-terminal end with an extra methionine group as an artifact of the way it was made. Lilly had got orphan drug designation for its methionyl free human growth hormone. And so for a period of years, Genentech would be obliged to compete with what Lilly might call the real human growth hormone as against our growth hormone that differed by that one amino group from the natural state.

JONES: And was there a functional difference in the molecule as a result?

KILEY: Evidently not. And of course, that was an additional aspect of, the litigation over the growth hormone. And indeed, Genentech sued the FDA, seeking to overcome the orphan drug designation, and not something that most pharmaceutical companies like to do. And indeed, Kirk Raab says he would never sue the FDA again for any reason.

JONES: The fallout wasn't . . . obviously, the fallout was not damaging over the long term, yeah?

KILEY: That's right. So the . . . an interesting aspect of the growth hormone arrangement with Kabi appeared years later when the twenty years had expired. Under the agreement, they now had title to the microorganism that produced growth hormone in their hands. And their royalty obligation came to an end, whereupon Pharmacia, who by then owned KabiGen, came to the odd conclusion that what our agreement meant was that on expiration of that twenty-year period, and at which time Kabi would then have the right to come into the United States market, Genentech was obliged to leave the market. And I never could understand how they could derive that from the nature of the agreement, and ultimately, the arbitrators agreed with Genentech that that was not what that agreement meant. But that proved to be a complex and

expensive undertaking. The chief arbitrator was retired federal judge Charles [B.] Renfrew—later I think a senior official at the FBI, or Department of Justice, if I'm not mistaken—who coincidentally tried his first patent case when I was a young lawyer, and my firm and another here in San Francisco, [California], combined to sue virtually everybody in America who made pants for infringing the permanent press patent.[3] So at the beginning of my career I see Charlie **<T: 30 min>** Renfrew in eighteen cases consolidated for a single trial with forty lawyers in the courtroom, and late in my career, there he is again, adjudicating this issue between Pharmacia and Genentech, along with two others, one from Canada, and another who I think was a British barrister.

JONES: Well, the origins of Genentech's human growth hormone are also controversial, and—

KILEY: Indeed.

JONES: There's a lot of different options, speculations about what actually happened. What's your view on that and subsequent litigation?

KILEY: Well, that's a lengthy story. Have in mind that the earliest projects of Genentech involved synthetic DNA, and that proved a great advantage. If you read Stephen Hall's book, *The Invisible Gene*, you'll find that synthetic DNA was outside the literal scope of the NIH's recombinant guidelines.[4] And so, for example, we weren't obliged to do our work in a P3 facility. Our competition for insulin, including workers at UCSF who were under contract to Eli Lilly were using cDNA, and with the technology then available to them, they were unable to produce from complementary DNA the intended product itself free of any fused protein. So we nevertheless realized that cDNA would be of value in subsequent projects, and we recruited Axel Ullrich and Peter Seeburg from the University of California to join the company.

JONES: They had been looking around—right?—to go . . . they had gone over to talk to Cetus? Do you recall that?

KILEY: I'm not aware of that. I do know that Bob Swanson, before he formed Genentech, approached Cetus, and asked Cetus if they wouldn't hire him to put them in the recombinant DNA business, and as said in my oral history, they gave him a little pat on the head and told him that they didn't think this would be ripe for commercialization for ten years, and off he went to Kleiner Perkins. So we brought Peter and Axel in, and when it was learned that they would be going to Genentech, their coworkers at the university became somewhat paranoid, locked them

[3] Renfrew served as the eighteenth United States deputy attorney general under President Jimmy Carter.
[4] Stephen S. Hall, *Invisible Frontiers: The Race to Synthesize a Human Gene* (New York: The Atlantic Monthly Press, 1987). Accessed at https://archive.org/details/invisiblefrontie0000hall/mode/2up on 22 February 2026.

out of their laboratory, and it nevertheless developed that when they arrived at Genentech, they brought with them certain tangible biological materials, including sources for messenger RNA for human growth hormone. I learned of this and looked into it. They were somewhat naïve—and I would say apprehensive—about joining industry at a time when that was regarded as distinctly unfashionable, concerned that going commercial might adversely affect their scientific reputations. And now they were being accused of all sort and manner of wrongdoing by their colleagues at the university.

They were strident in their claims that they needed this material to finish their academic work for purpose of publication, that no use of it would be made for commercial purposes at Genentech, and that practice and custom in academe supported their right to take those materials with them, as their colleague John Shine had done when he went off to Australia. **<T: 35 min>** This became a matter of discussion between myself and Roger Ditzel, who was somewhat exercised over it, because he was getting a lot of pressure from Baxter and Rutter and Goodman, the laboratories from whom Peter and Axel had come. And I sought to settle it in the immediate advent of our initial public offering because it was clear that the worst thing that could happen to us would be litigation over this when we were in registration for an IPO.

Bert Rowland appeared for the university during one of the settlement discussions and mentioned that he had heard that Genentech was planning an initial public offering. I had no particular interest in affirming that, because I thought it would give them more leverage in the negotiation. And I told him the truth, and the truth was that I didn't think the company was sufficiently mature to go public. Bert, who was not a trial lawyer, didn't ask the follow-up questions, and Moses Lasky, a famous lawyer who was present for Genentech in that discussion, later said that well, I hadn't told a lie—perhaps just a little white lie. Well, we settled the trade secret aspect of that controversy by undertaking to pay the university three hundred thousand dollars. And in our prospectus, we were able to set that against three hundred thousand dollars that we had been paid by Biogen—more or less contemporaneously—to settle a rather silly claim that Bob Swanson had leveled against Biogen to the effect that when they . . .

JONES: Well, it was INCO had been in Genentech, right? Dan Adams and Ray Schaefer.

KILEY: That's correct. So Bob's view was that Genentech's business strategy, its business plan, had been carried by INCO to Biogen, and at one point, as said in my history, they offered him a board seat to mollify him and when he attended the Biogen board meeting, they made him sit in the hallway while they discussed what they were going to do about this, and ultimately, they bought him off. But the nice thing was we settled the trade secret aspect of the human growth hormone controversy with the university and were able to set it off against—set off that payment against—to settle this other thing, and the one seemed to cancel the other out. What we were unable to do was settle the question whether we would infringe any patents that arose from university work in the growth hormone area because Lilly, having funded that work, had an option to acquire exclusive rights to those, and that couldn't be settled. Of course, at the time of our public offering, that . . . those patents had not issued in any form. Having settled that, I

guess . . . we expressed somatostatin in 1977, got human insulin in 1978, and human growth hormone in 1979. I did not join the company full-time until February of 1980. As it happened, Peter Seeburg, who was assigned the task of doing growth hormone, proved unable to do it at Genentech for various reasons. And unknown to me, Dave [David V.] Goeddel took the project over. Because I wasn't aware that Dave Goeddel was stepping up, he may not have been aware of my injunction that none of this material be used for commercial purposes or the Genentech growth hormone project. I was trying a case in Fresno, [California], at the time for another client, and **<T: 40 min>** David—it was claimed—went ahead and used some material from the University of California in his successful production of human growth hormone.

JONES: Has he denied . . . did he deny that?

KILEY: He not only denies it, but the laboratory notebooks appear to refute the university claims, and those have been . . . were published by Genentech on its website for all to see. Later, there was litigation over that, and . . . let me see. Either the . . . either it didn't get to trial, or there was a hung jury, and it was to be retried, or it was settled before trial. I don't really recall because this was after my departure. But the matter was settled by Genentech later when it was being run by Kirk Raab, with, amongst other things, Genentech's undertaking to build a fifty million dollar building on the University of California's Mission campus. Presumably, we got a tax deduction for doing so. I don't know what other terms of that settlement there may have been. But a good settlement is—or a bad settlement is—often seen as better than a good lawsuit, and that's where the matter ended. Unhappily, it ended with Peter Seeburg recanting his deposition testimony, and subsequently, I believe he received upwards of twenty million dollars as his share of the settlement judgment, a matter that has left a bad taste in the mouths of some at Genentech.

Now let me return to the City of Hope. I told you that the agreement with City of Hope provided that we would pay royalty when we used the DNA that we paid them to make, and that would encompass somatostatin, it would encompass human insulin, and once again, while I was off at trial in 1979, David Goeddel, to save some time, had the university—or had City of Hope—supply DNA for the front end of the construct that, with cDNA in its back end, led to the direct expression of human growth hormone. And so the royalty obligation attached to our human growth hormone sales as well. That's fair enough. Many years later, City of Hope, under I think new administration, as the expiration of the Riggs and Itakura patents approached, with the foreseen extinction of their royalty stream, took another look at that agreement and concluded that it didn't mean what it said, but rather, it meant that Genentech undertook to pay a royalty on anything embraced by these very broad patents, irrespective whether the DNA came from the City of Hope or no. Again, something that I found rather remarkable, since the . . . to me, the clear words of the contract are to the contrary.

Now they also remarkably claimed that Genentech had fraudulently concealed the existence of license agreements for subjects other than growth hormone, insulin, and, in particular, despite the fact that any reader of the business press would know that Genentech had

gone on to produce other things, like tissue plasminogen activator, the interferons, nerve growth factor, etc., etc. **<T: 45 min>** So the City of Hope sued Genentech for breach of contract in the California Superior Court, and the matter went to trial before a jury of lay people. Bob Swanson had, in the meantime, died. The attorney who represented the City of Hope had either—in the negotiation—had either passed away or had become enfeebled. And I was the only person surviving to testify. No, strike that. It is possible that the attorney who represented the city in that negotiation was able to testify. I can't recall. He, of course, was being paid five hundred dollars an hour for his expert consultation through the whole litigation, and the jury was entitled to take that into account.

The ultimate denouement was that the jury found it convenient to hold against Genentech, a rich corporation, on behalf of the City of Hope, a charitable institution engaged in curing cancer, and that outcome is not surprising, aside from the fact that it's completely at odds with what the agreement says. But under California law, the jury is left to interpret the agreement. And persons involved in the negotiation of the agreement are not permitted to say what their intent had been in producing the words in the agreement. So you have laypeople basically engaged in legal construction of an agreement, and there it is. While I think the award was justified—or unjustified, rather—at the end of the day, considering that Genentech began with an infusion of two tranches of venture capital—a hundred thousand dollars followed by two hundred thousand—once the City of Hope agreement was negotiated and that when Roche took the last piece of Genentech and acquired full ownership, the imputed value of the company was a hundred billion dollars, the payment to City of Hope really in the overall scheme of things was not terribly wounding.

JONES: I'm curious. You were . . . the other night at the dinner, I think you were seated at the table with Bill [William J.] Rutter. Do you guys avoid any mention of litigation in the good old days?

KILEY: Oh, not at all. I think that . . . you know, you can't be in the litigation business if you have a thin skin. And you don't win them all. And as far as Rutter is concerned, his side won that one, and more power to them. And no, Bill and I get along very well. We've had some other dealings over the years. On the other hand, there was a scientist at that table who still seems in a state of high dudgeon over the fact that no one at the university was named as an inventor in the original patents arising from the somatostatin collaboration. What is his name?

JONES: It must have been Gelfand.

KILEY: Gelfand. David [H.] Gelfand.

JONES: Yeah. He was at . . . he was there at the time, I think, at UC.

KILEY: Yeah. Right. And, you know, all I can say is that we have an obligation to choose the correct inventors. If you intentionally choose the wrong inventors, the patents can be invalid. [Herbert W.] Boyer and [Stanley N.] Cohen plainly made a remarkable invention, but it doesn't follow that everything that uses their **<T: 50 min>** invention becomes patentable to them as well.[5] Elsewise, there would be no patents in molecular biology beyond the Boyer-Cohen patent.

JONES: Yeah. Well, I get the part—the codon part—and the three parts, the three inventions: the use of particular codons, what was the other, the . . .

KILEY: Yes.

JONES: And . . .

KILEY: The expression of a foreign protein under friendly control.

JONES: Yeah. That was the first one you mentioned. And Boyer and Cohen had done that, yeah?

KILEY: I think if you go back, you'll find that they took a chunk of *X. laevis*, the African clawed frog, and they put it into a plasmid, and put the plasmid into a bug, and they may have expressed it.

JONES: Oh, you know what? It was RNA. It wasn't . . .

KILEY: But what they expressed was not the . . . . I think the control region may have gone in with the structural protein.

JONES: Oh, okay.

[5] Herbert W. Boyer, interview by Arnold Thackray, Sally Smith-Hughes, and Mark Jones in Boston, Massachusetts, and San Francisco, California, 28 March 2000, 24 April 2013, and 21 May 2013 (Philadelphia: Science History Institute, Oral History Transcript # 0193, in process).

KILEY: Or the . . . or . . . in fact, you know, this was considered by the patent office, and we overcame that as prior art, so . . .

JONES: Well, this could . . . that claim could be pretty broad, then?

KILEY: It was quite broad. The problem with a very broad claim is that if you assert it against the whole industry, you know, you could wind up spending a lot of money in litigation. And frankly, litigation is not a good way to profit. You make your profit by making and selling products. And all you really need are patents more or less coincident in breadth with the products that you're going to sell, and then people leave you alone. Indeed, imagine if Niels Reimers had strongly asserted the Boyer-Cohen patent, seeking very substantial royalties against the industry at large. He would have spent the entire life of the patent litigating that, and instead, he wisely chose to take a . . . if you will, to wet his beak and have many, many licensees, you know, with a small royalty, a royalty too small to fight over.

JONES: Well, there's the one hand, generating revenues is a goal for the university, but also disseminating the technology broadly. And . . .

KILEY: Correct.

JONES: Non-exclusively.

KILEY: Correct.

JONES: But—

KILEY: But the fact of the matter is that there was . . . there's really little point in Genentech trying to shut down the pharmaceutical industry when its purpose in life is to make a reasonable number of products and focus on protecting those, right? And so ultimately, Genentech decided that it was simply going to create a foundation, and for a very nominal royalty make those patent claims available to every . . . to all comers. And that's what we did.

JONES: Didn't Bob Swanson try . . . he tried to get an exclusive license for recombinant DNA? Is that right?

KILEY: Yes. Bob and I went down to the Stanford University and explained not to Niels—but to one of his subordinates—that we were going to make a company to make human insulin and a few others things, which is basically all we had in mind. And these happened to be polypeptides, and they were going to be mammalian polypeptides, and could we have an exclusive license for that limited purpose? And I think we had this young man half talked into it before Niels got wind of it and, sort of, put the kibosh on that. I think that was, I fear, hubris on our part at the time. But Mark, you . . . then one didn't know what to do with gene splicing other than make a handful of therapeutic polypeptides that were in short supply: insulin, growth hormone, albumen . . .

JONES: TPA.

KILEY: Well, I don't think we were cognizant of tPA at the time.

JONES: Factor VIII?

KILEY: Factor VIII.

JONES: Interferons, those—

KILEY: Yeah. But frankly, we scratched our head over how to expand that list in the patent description because there just weren't that many of them. Who knew that the tools **<T: 55 min>** arising at that time would lead to such a cornucopia of products of different kinds? Let me come back to the third arrangement that Genentech put in place before its IPO, and that would be the alpha interferon collaboration with Hoffmann-La Roche. That discussion also took place over many, many months, and I believe it is right that, again, we got Roche to finance the work as it was ongoing during the negotiation. And for a long time, we didn't seem to be getting anywhere. The subject was to be alpha interferon and so-called fibroblast interferon, or beta interferon. And this, again, was before I joined the company full-time. I happened to go over to Switzerland on behalf of another client to negotiate a deal over a cancer drug, and I got that negotiation—

JONES: A biological, or is it a big pharma company?

KILEY: It was said it was a negotiation with Roche over a modified form of Adriamycin that was said to be non-cardiotoxic. It would have been a heck of a drug. It was on behalf of a Spanish investigator. And I went over and got that deal done in one day. And then I went on to

Copenhagen, [Denmark], to visit my sister, who was teaching there. And when I got home, I found that Irv Lerner, who was president of Roche US, had learned of this, and he called Genentech, got Bob Swanson's secretary—Bob wasn't in town, I wasn't in town. He said, "You tell him that I'm coming to California, and we're going to finish this deal, and I'm not leaving until it's done, and I want the peripatetic Mr. Kiley there." So there it was. They flew out, and we . . . he had dinner with Tom Perkins. Then he went off and he left his number two man, Elliot Anderson—I think his name was—here and said, "Don't come home until you have the deal done." So in a very trying day, we got the deal done, and two or three days later, Biogen announced the expression of alpha interferon, which was fortunate timing for us. In the event, again, they didn't have the same facility Genentech had acquired by that time in combining synthetic DNA and cDNA to produce the desired protein directly and without any encumbering extra protein that could only with great difficulty be cleaved away. So—

JONES: They were first, but you had a better technology to . . . ?

KILEY: That's correct. They produced a fusion protein—one of the alpha interferons—and Dave Goeddel went on to produce a whole family of them and demonstrated that there was a family of them and produced them directly. And so we got patent coverage that was cross-blocking with theirs, and ultimately, that got sorted out, and both parties came—or the clients in both parties—came away with licenses to the alpha interferons.

JONES: Right. Any royalties involved in that, or royalty-free?

KILEY: I don't know the answer to that. I would be . . . . I'd be speculating. I'm sure—

JONES: Did that happen later, or did it happen during your . . . ?

KILEY: Yeah, I think it happened following my departure. Because I don't think any of those interferon products came to market prior to 1988 when I left the company.

JONES: I think Biogen might have had . . . . I think it might have been eighty . . . . I'll have to check, but I think they might have had one in '86. I'm not sure about that.

KILEY: Then that would have led to a discussion and the ultimate deal. And again, by that time, I was up to my hips in the tissue plasminogen activator litigation. **<T: 60 min>** So we succeeded in satisfying—I suppose to some extent—our client Roche. You will have read about the Golde litigation against Roche, which arose, again, just in the advent of our IPO. I'd settled

what I could of the human growth hormone controversy with the university. Now we . . . [David W.] Golde's sitting in my office and advises me that Sid [Sidney] Pestka at Roche had broken his word by passing on . . . let's see. What had happened? No, someone at NCI [National Cancer Institute] had broken his word by passing on the source of interferon messenger RNA to Pestka at Roche, who in turn had passed it to us, and we in turn had used it to make alpha interferon, and under personal property law principles, our clone now belonged to the University of California, just as, you know, Indians steal my timber and build a barn, now I own their barn. All right? Well, that was awkward. And I called Elliot Anderson at Roche and said that Sid Pestka evidently has poisoned our well, and he needed to indemnify us against any money damages. And he basically said, "Well, why should we do that?" I said, "For our goodwill." And so he did.

JONES: And . . . ?

KILEY: And then I turned to my former partners at Lyon & Lyon, and I said, "I'd like to know if it is your opinion that if we cure cancer with interferon, no court will enter an injunction against our continuing to use the means to cure cancer." And they said, "Yes, we can give you an opinion to that effect." So now if you look at the prospectus for our initial public offering, you will find in a footnote the fact that indemnified against money damages, counsel opines there is no prospect of an injunction; ergo, no harm can come to us from this litigation, which then proceeded . . . I can't recall if they . . . if he sued, or if there was just a rumbling of a suit that didn't eventuate. It may be that there was no lawsuit. But it was ironic that subsequently Golde was sued by a patient from whom he'd obtained tangible biological material, leading on to Moore versus California, or Moore versus Regents of the University of California.

JONES: Right. Now Golde at that time was a consultant to Genentech. Is that . . . ?

KILEY: He was. He was a consultant to us, and—

JONES: Did that relationship come to an end at that point? Or he's, kind of, holding you up for ransom?

KILEY: I don't recall. I would speculate that we would be disinclined to terminate a relationship with David at the time when he's . . . this institution might be thinking about suing us. I mean, why pour gasoline on the fire?

JONES: And Roche must have had . . . even then had high hopes for Genentech? So yeah, okay, we'll indemnify this, and . . . ?

KILEY: It was unusual for them to agree, you know, to do that. I think that . . . well, I think it was a noble thing for them to do. I've always believed that Sid Pestka didn't want to share the glory for cloning and expressing what was then regarded as the . . . on I think the cover of *Time* magazine, the IF cure for cancer. And so he held onto this valuable source of RNA through month upon month of **<T: 65 min>** unavailing effort before we finally talked him into sending it to us, so we could put it to good use. And . . .

JONES: The idea was that he had his . . . from his perspective, he's claiming he had an agreement with Golde not to pass it on then?

KILEY: No, I think that the agreement was between Golde and someone at the National Cancer Institute from whom Pestka had gotten the material.

JONES: Okay. Right. Right. Yeah.

KILEY: Let me see what I'm missing here.

JONES: There's Chakrabarty, your role in Chakrabarty.

KILEY: Yeah.

JONES: Was there . . . is there more to the interferon?

KILEY: No, I think what we have yet to discuss is the tPA litigation.

JONES: You want to do that?

KILEY: And Chakrabarty. Let's talk about Chakrabarty.

JONES: Okay.

KILEY: So, as you know, patenting in this area was controversial from the outset. Witness the kerfuffle over the Boyer-Cohen patent and universities patenting and so on. And I think that Niels Reimers ably defended the legitimacy of patents in the life sciences, whether deriving from the university or no. And, in particular, the Bayh-Dole Act, which encouraged universities through patent licensing to make products available for private investment in their development.[6]

JONES: When that legislation was made, did that register at all in companies like Genentech that something had changed? Or it was only later that . . . in negotiating with universities, that it became apparent that, you know, there was a different—

KILEY: No, I think that it registered early on. The difference it made was that prior to Bayh-Dole, universities were reluctant to grant exclusive licenses. But in the drug industry, if you don't have exclusivity, you can't justify the deep investment required to conduct clinical trials and seek FDA approval. And so Bayh-Dole was very, very important. But to the scientific community . . . and remember that in the seventies that the molecular biology community was almost entirely in university settings. There weren't many molecular biologists that had gone commercial, and Boyer was roundly criticized for having done so.

So Chakrabarty came to the patent office, not with a recombinant organism, but with, if you will, an organism that had plasmids from other organisms, so that it was one-stop shopping for oil digestion. And I think that the controversy over recombinant DNA may have fueled the patent office concern about granting patents of this kind. Certainly, Jeremy Rifkin for the so-called People's Business Commission was making a fuss over recombinant DNA generally. And so, Chakrabarty's rejected, and the argument was that if Congress had wanted patents to issue on new forms of life, it would have said so when it enacted the Plant Patent Act. And when it enacted the Plant Patent Act, it confined itself to plants that were propagated vegetatively and nothing else. So that was an argument to **<T: 70 min>** the effect that Congress excluded patents on other new life forms.

And the whole Chakrabarty thing got bogged down in a sort of a Jesuitical disquisition involving legislative history—very boring stuff. And I thought this would . . . could be important to Genentech, and so I asked Bob if I could brief it in the Court of Customs and Patent Appeals, which was the appellate court over the Patent Office. It's now the Federal Circuit Court of Appeals. And Bob reluctantly agreed, so long as I didn't charge him for it. And indeed, in those days, he didn't have a lot of money. So I wound up . . . . I went ahead and did that, and I also wound up chairman of a subcommittee of the American Bar Association's patent section on patenting microorganisms. And so I got the ABA to pass some resolutions supporting that. And along with other amici—that is, *amicus curiae*, or friend of the court, briefs—the

[6] The Bayh-Dole Act of 1980 granted patent rights to institutions that received funding from the federal government rather than to the government.

CCPA affirmed the availability of patents on microorganisms, and the government sought certiorari, and the court agreed to hear the case.

JONES: Did you have a sense at that time how important this was going to be? Because if you look now, it's . . . you know, entire industries have grown up, multiple industries are based on—

KILEY: Well, not really because I had to deal with the possibility, and indeed, given the murkiness of the argument over legislative history, the probability that the Patent Office would win in the Supreme Court, and then what would we do? Well, the answer would be that we would patent our plasmids, which, as I said, perhaps in the brief, are the carburetors that help the microbial engine cough into life. And if we had patents on the plasmids, which are absolutely dead bench chemicals, that's all we needed, and so we could protect ourselves in any event. But the fact is that had the court four or five months before our initial public offering come out with a decision banning patents on new life forms, I think the consequences would have been problematic for the attraction of capital to industries based on these microorganisms. Well, I wasn't a member of the Supreme Court Bar at the time, and I had to become a member for a purpose of filing a friend of the court brief there as well. And—

JONES: Is that an exclusive club?

KILEY: No, it's pretty easy to get into, as long as you've been practicing for five years or more and/or in good standing in the bar. But you have to get your application in in time for them to pass on it so that you can file your brief in a timely way. And I think I made it by forty-eight hours. I had neglected to do that, and it was a near thing. In any event, I was sitting in the library one day trying to figure my way through this legislative history, and I happened to notice something that Judge [Phillip Benjamin] Baldwin of the CCPA had said in his dissenting opinion to the effect that the court was being asked to greatly expand the scope of patents. And I said, "What if we just turned that on its head and say the court is being asked to greatly contract the scope of patents? So we're not widening the ambit of the patent system, but rather, we're shrinking it, and then we're doing it a, kind of, a meat axe way. You know, all patents on all life forms for all purposes shall be excluded from the Patent Act."

And it occurred that the patent laws are a broad mandate for innovation of every kind because how can politicians who are **<T: 75 min>** making patent law before innovation contemplate what form innovation will take? So instead, they want to let a thousand flowers bloom. And what the government was asking the court to do was shrink the patent system, shrink its mandate for innovation of every kind. And if you look at what Congress did when patents on atomic energy were controversial, Congress said, "No patents on atomic weaponry, but patents permitted for every other kind of atomic or nuclear innovation."

JONES: Did . . . was that part of your argument? Did you—

KILEY: Yeah. It's in the brief. So we said to the court, "The court is fundamentally unsuited to weigh the competing social and economic considerations involved in so large a question, and if the broad scope of patent protection is to be curtailed in any way, it should be left to Congress, who's better suited to weigh the many considerations involved. Witness their surgical approach to patents on atomic weapons as against the meat axe approached urged the People's Business Commission here." And what an argument like that does is it gets the court off the hook, you know. The court can say, "Yeah, yeah, let Congress do this. We don't have to do this. We're not well-suited to do it." And that's what they did, five to four. And if you look at the decision, and then you look at our brief, you'll find that basically our brief became the majority decision. And that happens sometimes. You know, they . . . my partner said when you write a brief that the court adopts in that way, you become the sixth justice. [laughter] The coolest thing that anybody ever said.

Okay, so then this decision comes out, and we win, and it's big news. And that was very welcome in the advent of our public offering. It was . . . it also came at a time—to look at its larger consequences—when American industry was hollowing . . . heavy industry was hollowing out. You know, Japan was the country that could say no. We were still suffering the economic malaise arising from the Arab oil embargo and the Carter administration. We still had a whole generation of federal district judges that had come out of the Department of Justice where they were young trustbusters, and they hated patent . . . the so-called patent monopoly. And so until Chakrabarty, the courts were generally unreceptive to patents, and in fact, I think it was Justice [Felix] Frankfurter who said, "The only patent that's valid is one this court hasn't got its hands on yet." Well, now you have the Supreme Court saying, "You can patent anything made by the hands of man." You know, that indeed, the patent laws are a vast charter for innovation. And it came at a time when knowledge-based industries were on the rise, and filling the vacuum left by our loss of heavy industry to other countries. And I think that subsequent decisions of the courts have been more favorable to patents as a result. At least we've eliminated that philosophic bias against the so-called monopoly.

JONES: And do you think that that economic logic had any kind of influence on that particular decision? I mean, that is the result. It's a fortunate result.

KILEY: Well, I'd have to go back and look at the decision again, but I think the decision does speak with some fluency about the incentive of the patent system, and the economic benefits that flow from it. Certainly, you'll find plenty of that in our brief. The only thing that bothers me about that brief, which otherwise I think is a perfect brief, is that I was at a . . . . I finished the last draft, and I handed it to a paralegal, and said, "Get this printed, proof it, and send it to the court, because I've got to go **<T: 80 min>** try a case in Boston, [Massachusetts]." So I'm in Boston with my partners trying a case against ITT [Corporation], and the brief goes to the Supreme Court, and there's, kind of, an epigram right at the beginning of the brief with a

misspelled word right in the middle of it. You know? It's just like a fly in the soup. And every time I look at it, it pisses me off. I'll show it to you. Oh my. Here's a note I didn't even know. So this is a copy of the brief that I sent to my partner and mentor January 28, 1980. "I'm leaving the firm to join Genentech February 1. So to Jim, with fond regard, here with my last gasp."

JONES: And who was your mentor?

KILEY: A guy by the name of Jim [James W.] Geriak, who's still practicing, remarkably.

JONES: He did a lot to help you?

KILEY: Oh, yeah. He was . . . . I was . . . all my lawsuits I was involved in, he was the lead partner. In fact, he was involved in the permanent press case. He was involved in—

JONES: Was that your first big thing? The permanent press case?

KILEY: Yeah. I would say so.

JONES: And did you make . . . you made a major contribution to that that . . . ?

KILEY: No. No, I was the fifth lawyer on our five-lawyer—what do you call it?—something pool, total pool, whatever. Pecking order. My task . . . this was before paralegals, and one of my tasks was to digest I think eighty thousand pages of depositions. So I was the last guy who touched the facts, so they brought me along, because I knew where, you know, who said what. And I got to sit there in the courtroom here in the city; I was in LA [Los Angeles, California] then. I got to sit in the courthouse for two months watching these great lawyers, you know, swing at each other. Our chief counsel was a guy from Brobeck, Phleger & Harrison named Moses Lasky, who had probably argued thirty cases in the Supreme Court. And he was amazing. It's like the third word. Goddamnit.

JONES: Oh, yeah. There it is for history, for posterity.

KILEY: Moses Lasky. Am I . . . are we out of time now?

JONES: It's up to you.

KILEY: Okay. I've got a few more minutes.

JONES: Okay.

KILEY: Moses Lasky—

JONES: Another thing I would like to ask you about is if you could walk through Hybritech—involvement in that.

KILEY: Sure, sure. Moses Lasky opened to the court, "Judge Renfrew . . ." We had sued Levi, Haggar, Lee, Burlington Mills, Deering Milliken—everybody in the textile business. He said . . . and our client was Koratron, which was a permanent press subsidiary of Koret of California—dressmakers. He said, "If it please the court, Koratron invented permanent press, and in doing so, lifted from the backs of American women the slave burden of ironing. It was called by *Time* magazine, 'The greatest invention in apparel science since the fig leaf.' And hundreds of companies around the world paid tribute to the grant of this patent by the United States Patent and Trademark Office by paying royalties. Over time, a number of these miscreants chose to dishonor their obligation, and others never signed up. And through the genius of the panel on voting district litigation, Koratron has gone about the country and gathered up eighteen of these companies and brought them here to San Francisco, huffing and puffing, to the judgment seat." [laughter] And I just sat back and thought, "This is going to be great." And it was. How did we . . . oh, Jim Geriak. That's how it came up.

JONES: Yeah.

KILEY: Okay. Let's see. We didn't talk about tPA, that litigation.

JONES: Right. Yeah.

KILEY: There's plenty about that in the . . .

JONES: In Sally's . . . ?

KILEY: Yeah, and what can I tell you about that that . . . . I also wrote a paper about it called "A Tale of Two Trials."[7]

JONES: Oh, okay. Great.

KILEY: Which . . . give me your mailing address or LSF?

JONES: Here?

KILEY: Yeah.

JONES: It's 1 Embarcadero Center, 27th Floor, **<T: 85 min>** c/o Burrill and Company.

KILEY: Okay. Burrill. All right. And Mark, what's your last name again?

JONES: Jones.

KILEY: Boy, that's a tough one.

JONES: Yeah.

KILEY: I'll send you that.

JONES: Thanks.

KILEY: Well, you know, we thought that was going to be the making of Genentech, that product. And very important to us. And Diane Pennica had brought word of tPA back from Lausanne, Switzerland, where she was attending a symposium and heard Désiré Collen talk

[7] See Appendix G of Thomas D. Kiley, "*Genentech Legal Counsel and Vice President, 1976-1988, and Entrepreneur*," an oral history conducted in 2000 and 2001 by Sally Smith Hughes, Regional Oral History Office, The Bancroft Library, University of California, Berkeley, 2002. Accessed at https://digicoll.lib.berkeley.edu/record/218103 on 22 February 2026.

about his having isolated a modest quantity of the protein, raised it in tissue culture flasks, and he had enough to dissolve a thrombolytic . . . a leg clot in a patient.

JONES: What was the year? This is after you were already at Genentech? It's 1980?

KILEY: Oh, I was. Yes. So it'd be probably on the order of 1983 or so. And so Jim Gower and I went to Leuven, Belgium, and negotiated with the university an exclusive license under Désiré Collen's patent, which covered the purified protein itself, a composition of matter—tissue plasminogen activator—and obtained from him material that we could use to attempt to clone the polypeptide, which he provided. And ultimately, a team, led again by David Goeddel, with a key contribution by, among others, Diane Pennica, succeeded in cloning and expressing tPA. We had an arrangement with Chemie Grünenthal to make urokinase for them, another plasminogen activator. And indeed, they had . . . and we were able to differentiate tPA from that. And so we were unencumbered from their standpoint.

JONES: Did you . . . was that ever a . . . it wasn't a product, was it? Had you cloned that enzyme?

KILEY: We did clone that for Chemie Grünenthal.

JONES: And sold it to them, or did they produce it?

KILEY: It was an exclusive arrangement. Yes.

JONES: So they sold the recombinant enzyme. Yeah?

KILEY: I don't recall. [crosstalk] At the time, there was another of these therapeutic polypeptides that was gathered at great expense, in this case, believe it or not, from the collected urine of nuns. All right? And obviously, that was as limiting as getting growth hormone from tumor pituitaries, and so we negotiated that arrangement, actually while floating down the Snake River with Bob Burns and I and the CEO of Chemie Grünenthal.

JONES: Hmm. Fishing?

KILEY: Well, he'd brought his family. They were on vacation, so they were just touring. And they invited Bob Swanson and I and Bob Burns, then VP, sales and marketing, to accompany them, and we did the deal there. We also got sued by . . . who was it? Rhone-Poulenc, I think, had gotten a patent on urokinase, I think it was, and . . . which was a plasminogen activator. And so they got a patent claim for plasminogen activator as a composition of matter, a word that embraced tPA. And they sued, and I think ultimately that suit went away for lack of merit. Kirk Raab may have settled it for some nominal consideration. It's reminiscent of another suit that was brought against us when Roche, our partner for one purpose, was trying to pressure us to turn tPA over to them. And we said, "Thanks, but no, we're going to make that and sell it ourselves." And then out of the blue they sued us on a silly patent that had issued to the Hormone Research Institute, based on C.H. [Choh Hao] Li's having synthesized human growth hormone, which I think has **<T: 90 min>** on the order of 137 amino acids, and gotten the Patent Office to give him a claim on so-called synthetic growth hormone, which, again, in terms encompassed recombinant DNA, from an English language standpoint.

And I've always thought that was sort of retaliation for our not, you know, turning over tPA. In fact, I was later told that he had ranted on his return to Nutley, New Jersey, to his people in the . . . his law department, "What good are you? You tell me I am blocked by Genentech's tPA patents, but we have the C.H. Li patent, and you can't do anything about it." So they sued us, and it turned out C.H. Li had edited a book, one chapter of which reported the synthesis of human growth hormone. And when you start thinking about the blocking groups that have to be taken off and kept on in the right order and so on, you wind up with, after 137 or 97 amino acids, this intractable mixture of something like a million different polypeptides. And that's what, you know, he had. And they hadn't bothered to tell the patent office about that publication. And so that lawsuit went away.

Back to tPA. So I think it was Baxter that had funded Genetics Institute to do a tPA project, and Cold Spring Harbor was collaborating with the Wellcome Institute. And the Wellcome Institute came up with a tissue plasminogen activator in which a cDNA copying error made it a single amino acid different from our own. And Genetics Institute had a more differentiable plasminogen activator by reasons of various strategies that they had brought to bear to enhance folding and production. And Boehringer Ingelheim, our partner in Europe, wanted us to bring a suit to shut them down in Europe where BI had rights. We weren't terribly enthusiastic about spending a lot of money to—

JONES: They had rights from Genentech?

KILEY: That's right. We weren't terribly enthusiastic about spending a lot of money to protect someone else's market, and indeed, we weren't obliged to do so. We had the first right to defend the patent, failing which they would have the right to defend the patent. But for the sake of the relationship, we agreed to take on the lawsuit.

JONES: Would it have any bearing in the US? In terms of market rights? Or, you know, if you get a fav—

KILEY: Well, I'll discuss that later.

JONES: Yeah. Okay.

KILEY: So we sued GI, and we sued—

JONES: Baxter?

KILEY: No, we sued the Wellcome Trust.

JONES: Wellcome.

KILEY: A revered British institution. And it was the first patent case to come before the court under the new British Patents Act that had yet to be interpreted by any court, and it was also the first biotech case they'd ever seen. And it went to a fellow who was a so-called patents judge, the only sitting patents judge in England at the time, and one who was approaching retirement, such that this would be his last case. I . . . we had to defend the question whether it was obvious to have cloned and expressed tissue plasminogen activator when the desirability of doing so was known. And my thought was that the way to demonstrate its non-obviousness was to show that it was the most difficult cloning project ever undertaken. And so I took a remarkable group of Genentech scientists up to Lake Tahoe for a very long weekend, when we read every cloning paper that had been published up until that time. Dan Capon, **<T: 95 min>** Dave Goeddel, Art [Arthur D.] Levinson, Peter Seeburg, Axel Ullrich—you know, there were a lot of brains in that room. And then we rank ordered all these papers in terms of difficult . . . relative difficulty. Was there amino acid sequence available? Was there an abundant source of protein? Was there an abundant source of messenger RNA? Was there a good assay? Etc., etc. And by all these measures, one could demonstrate almost quantitatively that this was the toughest project ever.

And then I went to England, and I hired a guy by the name of George [R.] Stark at the Imperial Cancer Institute, who was a member of the Royal Academy—he was an American—and persuaded him using this information that this was the toughest project ever, so that I would have a vehicle with credentials to deliver that message to the court. Instead of a committee of ten guys, you know, you put it in through one guy. And then I wanted another expert, and I approached Sydney Brenner, and over a wine-soaked dinner at Claridge's in London, I persuaded him to stand up as our expert witness. And—

JONES: Didn't he have ties with people at GI? I can't remember. It seems like some . . . may have been—

KILEY: Subsequently, he may have done. In any event, geez, about six weeks before the trial, Sydney called me up and said, "My boss at the Medical Research Council has told me, 'Sydney,' he said, 'If Wellcome loses, it will have vast political ramifications. I insist that you will not appear.'" And I said, "Holy smokes, Sydney, you know, this leaves a big hole in my case. I need you to get me Berg." So Sydney called up Paul Berg, and Paul agreed to meet with me, and talked Berg into being our . . . an expert witness.[8] Berg was always at that time . . . for a long time had been known as "Pure Paul," you know, the last guy to soil his hands with industry.

JONES: Yeah. Although he had by that time.

KILEY: But by that time, he had got interested in DNA Sciences, was it?

JONES: DNAX. Yeah.

KILEY: DNAX. He found . . . was cofounder of that. And he was interested in learning about patents and in supporting patents for the life sciences, and so he agreed to do that. And bless him, he appeared as . . . in London, and then he appeared in Japan where we sued Toyobo for infringing the tPA patent.

JONES: Where . . . who were they working with? They didn't do it by themselves, did they? Do we need to cut this off?

KILEY: No. We're good. They may have been working with Genetics Institute. In fact, they were. And indeed, we sued them successfully. And it was the first biotechnology patent case in Japan, and as a result, the court officers went and seized the infringing goods. And it was . . . made a big splash in Japan, because there, litigation is not quite the blood sport it is in, say, America. Instead, I learned that you don't have a trial. You have trials. And each time you go for a trial, you put on a little more testimony, and the judge butts heads a little bit more trying to get you to make peace. You know, if you can't make peace, he sets another trial. And you bring

[8] Paul Berg, interview by Deanna Day and Jacqueline Boytim at Beckman Center for Molecular and Genetic Medicine, Stanford University School of Medicine, Stanford, California, 16 February 2016 (Philadelphia: Science History Institute, Oral History Transcript # 0950, in process).

one more testimony, and he butts heads again and tries to get you to settle, because, you know, it's unseemly to have these things in public. But when Berg . . . we sent Berg there for his trial, you know, the court said . . . our lawyer, who was this very cool guy that had been captured in Manchuria by the Russians, and sent to the gulag at the end of the Second World War, lived in the gulag for five or six years, finally made his way to Japan, became a trial lawyer, you know? And he . . . this was a guy with teeth. And he was not one of these, "You guys have to make peace." He was a real warrior. Anyway, he called me and said, "The court wants to set the trial of Dr. Berg." And so I said, "Well, he's very, very busy, you know, but he can't come." He says, "The court will accommodate his schedule in any way necessary." So Berg gets there, and he tells me . . . he's supposed to go to the courtroom. He gets a block-and-a-half from the courtroom, and the sidewalks of the road leading to the courtroom **<T: 100 min>** are lined, because the courthouse has emptied because a Nobel laureate is coming. And they're lining the sidewalks and applauding him. [laughter]

KILEY: So anyway—

JONES: He must have enjoyed that.

KILEY: We won. We won that. There's nothing like a Nobel laureate in your pocket in that. And then he came to Delaware and testified when we sued Burroughs Wellcome. So, as you know, we lost big in England despite having decimated their witnesses. The judge came out with this almost incomprehensible decision that basically said, "Well, it's the job of . . . the ordinary workman in molecular biology is a PhD. It is the job of PhDs to be inventive. Therefore, the ordinarily skilled person is inventive. Therefore, they can make inventions—obviously." You know, that was basically it. And he was not about to rule against the Wellcome Trust on behalf of some jumped-up colonial company like ours. And so then we had to come back and take that whole record and put before the United States Patent Office in order to satisfy our duty of candor.

JONES: Oh, the European—

KILEY: Yeah. All the testimony against us, all the evidence against us, the court opinion against us, and say, "Nevertheless, under our laws, we're entitled to a patent." And if you don't do that, you're defrauding the Patent Office, and any patent you get is unenforceable. You have to make a clean breast. And we did that and got the US patent. And on the day it issued, we sued the Wellcome Trust's arm in America—Burroughs Wellcome—in Delaware and got that jury to uphold our patent. Wellcome countersued, claiming that we had stripped their tissue culture organization of its talent and brought their confidential know-how here to help us industrialize tPA. And so in that Delaware suit, it was we're suing them for patent infringement; they're suing us for unfair competition. And we won both to the jury.

JONES: Who had . . . did people come from Burroughs Wellcome?

KILEY: Oh, yeah.

JONES: Yeah?

KILEY: Yeah. So that went through full trial. We won to the jury. And then Wellcome left the field worldwide, because having been deprived of the largest market, they couldn't justify, you know, doing all the clinical work. So the good guys won that one. Hybritech. I didn't play a big role in Hybritech.

JONES: You did review the original intellectual proper . . . well, you tell me. I don't know.

KILEY: Yeah, so Brook Byers, knowing of my involvement with Genentech, when he was the founding CEO of Hybritech, came to me for patent work, and I can't remember what my role was in the founding technology, which was the tandem bioassay, other than sorting out an issue that had arisen whether that invention belonged to the Veterans Administration because Ivor Royston had a joint appointment with UC San Diego and the Veterans Administration. And the question was who owned the patent rights, and where had the invention been conceived, reduced to practice, so on and so forth. So I helped Brook sort that out, and then about . . . and dealt with Howard Birndorf at the time, who was just Ivor's young lab assistant. And then I got busy with Genentech and left my firm to join Genentech before much more was required of me at Hybritech. And I turned over representation of Hybritech to a partner of mine whose name is William Larry Respess, who went on to become VP, general counsel, at Hybritech. But it was remarkable to be involved in any way, really, in both monoclonal antibodies and recombinant DNA at a time when, **<T: 105 min>** you know, this . . . it was all just starting to come together. Right place, right time.

JONES: You also got involved a little later in the Mouse Wars, yeah?[9]

KILEY: Yeah.

[9] The term "mouse wars" refers to disputes in the 1990s regarding intellectual property rights of transgenic mouse models. See Marla Cone, "The Mouse Wars Turn Furious," *Los Angeles Times*, May 9, 1993. Accessed at https://www.latimes.com/archives/la-xpm-1993-05-09-mn-33371-story.html on 22 February 2026.

JONES: I'm going down . . . on Wednesday, I'm going to talk to Jonathan MacQuitty.[10] So can you tell me about that?

KILEY: Certainly. I was the director of GenPharm, and we had hired a fellow from Genetics Institute named . . . or no, not from Genetics Institute. What the hell was his name? Bob something. He had actually been involved at . . . when he was at GI, he was involved in their tPA work, and now he was a key scientist at GenPharm. Let's see. What's the origins of this? So I met Jonathan MacQuitty. Jonathan MacQuitty was at Genentech. He went into Genencor, when we formed that. I was on the board of Genencor and helped negotiate its formation. And then Jon and a few other people came out of Genencor and formed GenPharm. And I was working with a variety of venture capitalists at the time and so went on the board of GenPharm. And—

JONES: You were working as . . . ?

KILEY: I had left Genentech by that time.

JONES: Yeah. And you were making investments, or what was your role at . . . in venture capital? Advising?

KILEY: So in the life sciences, the two things that are important to biotech start-ups, aside from very good science, is patents and business development or corporate partnering. And basically, those are the two things I did at Genentech. And so it became common for venture capitalists to ask me to look at companies they were thinking of investing in, and then if they did invest, ask me to go on their board of directors as an independent director. And, you know, in these thinly staffed companies, they tend to be working boards, and commonly, I would do patent strategy, advise some corporate partnering, things of that nature. And that's what I was doing for GenPharm.

JONES: And did you enjoy doing that?

KILEY: Sure.

JONES: Yeah? A lot of variety?

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[10] Jonathan MacQuitty, interview by Mark Jones at Abingworth Ventures, Menlo Park, California, 20 December 2012 and 27 February 2013 (Philadelphia: Science History Institute, Oral History Transcript # 1059, in process).

KILEY: You know, I'd been on I think twenty—more than two dozen boards since I left Genentech, and so, you know, every intellectual property lawyer is a technology voyeur. And part of the satisfaction is you move from technology to technology and get to see a lot of things, and deal with a lot of interesting, creative people, and that's what I'm doing when I'm helping these startup companies. And at the same time, I, unlike the days when I was jumping through hoops for guys in black dresses, now I'm in control of my own calendar, more or less. And that's a privilege. So anyway, I was on the board of that company, and Steve [Stephen A.] Sherwin's company . . . ?

JONES: Yeah, it was Cell Genesys.

KILEY: Cell Genesys.

JONES: And then—

KILEY: Right.

JONES: They had . . .

KILEY: Spun off Abgenix. Yeah. Well, Cell Genesys got public, and we were in registration for a public offering. We were both pursuing, and both had achieved the human monoclonal antibody producing mouse. And they sued us for trade secret theft and derailed our public offering. And indeed, we weren't able to raise any capital during the pendency of that suit and underwent several reductions in force and persisted in our defense. The claim was that we had hired some people—one or more people—from Cell Genesys who was said to have brought with him information we used to achieve the human monoclonal antibody mouse. We didn't think that was right, and we thought the purpose of the suit had been to derail the public offering and deny us access to capital. I hired one of Moses Lasky's one-time partners, a **<T: 110 min>** fellow by the name of Tim Cohler, who, among other things, is an expert in antitrust law. And he conducted arduous discovery, looking for internal documents that would suggest the motivation for the suit.

JONES: How does that work? Can you get access to . . . if you . . . would you have to specify . . . ?

KILEY: Well, sure. In litigation, you have discovery, so you take depositions, you propound interrogatories that must be answered in writing, you can subpoena documents, and so on. And—

JONES: And do you have to know what the document is specifically that . . . ?

KILEY: Well, you can't, you know, as they say, conduct a fishing expedition. You have to have something, but the other side is obliged to identify all documents relevant to the issues involved in the litigation. And of course, one of the things that makes litigation expensive is that people fight over this stuff. And so we went to court, and because they weren't being responsive we thought, and the court would order them to produce, and they didn't produce. The court would order them again. The court finally threatened them with contempt unless they produced. And darned if they didn't turn up a document that said more or less we will bring an action and prevent their public offering.

Now at that time, they were trying to do a merger of some kind, and they were being funded by Japan Tobacco. And Tim Cohler put together an—I don't know—a thirty-page antitrust complaint—may have been sixty pages—in draft form, and handed it to them and said, "Unless we settle this lawsuit, we're going to file this." And now the prospect of litigation was awkward for them. And so I remember the Japan Tobacco people came over, and the Abgenix people came, and I negotiated the settlement, and I remember . . . you may have seen this, this publication of somebody with rats crawling on them, you know?

JONES: No, I haven't seen that.

KILEY: I may have a copy of it somewhere.

JONES: I'll try to find it.

KILEY: So it may be a picture of Jon MacQuitty with a mouse crawling on him, you know. And I'm there, and these Japanese guys are there, and oh, you know, the . . . and I say, "And you put out this publication with our president with rats on him." These guys were . . . . well, anyway, they gave us forty-two million dollars and dismissed the complaint, and the parties went their separate ways. And then we were able to sell ourselves to Medarex. And so at the end, all came out well, although I think Abgenix proved to be an even greater financial success than . . . well, let's put it this way. I think that Genetics Institute got more out of its Abgenix ownership than GenPharm got out of its sell to Medarex. But it depends. It may be that the Abgenix people simply did a better job of exploiting the technology than the Medarex guys did.

JONES: I think it went to Amgen, right? Didn't . . . ?

KILEY: Pardon me?

JONES: Abgenix ended up at Amgen.

KILEY: I don't recall. But somebody bought them.

JONES: Well, there's a lot more that's here. Maybe we . . . some other time we could—

KILEY: Sure, you know, I enjoy talking about this stuff, because it was so much fun, you know?

JONES: Yeah?

KILEY: And, you know, my dad, when I said, "I'm going to be a lawyer," he said, "Well, two conditions. Number one, you pay for it yourself, and number two, don't ever become a patent lawyer. It's dry as dust, you know." And it's been anything but. It's been really a lot of fun.

JONES: Well, things changed around the mid-seventies and 1980s, maybe. Maybe it used to be . . .

KILEY: Yeah. Yeah. Although I . . . you know, I mean, trademark litigation, my favorite case was Miss USA versus Miss Nude USA. You know? The claim was the titles were confusingly similar, okay? And we represented . . . . I got to represent Miss Nude USA. And I went down and made my first appearance in Federal District Court, Central District, California—LA. Judge Andy Hauk, who was called by the *American Lawyer* magazine, "The worst sitting federal district judge in the United States." He was a wild man. And I go in, and it's like we . . . there was a temporary **<T: 115 min>** restraining order against any use of our title when we got into the case. The hearing and the preliminary injunction is twelve days away. Their application for the TRO [temporary restraining order] was supported only by a single affidavit, the president of Miss Universe, who owned the Miss USA pageant. I said, "Well, we have to take this man's deposition." So we subpoenaed him. And the other side moved to quash the subpoena because he was too busy.

And so I went down there to argue that, made my first appearance. I go into Andy's chambers, and he's ripping chunks out of the pleading file and throwing them in the air like confetti, shouting at his law clerk, "Bunch of goddamned nudist freaks out there in San Bernardino. Who the hell do they think they are, stealing the Miss U . . . who are you?" You know? "Well, Andy . . . you know, we finally got the guy's testimony, and we got the hearing and the preliminary injunction." Andy said . . . he looked at some weird precedent, and he said, "Okay, you can use the title, but you have to put a dash or a hyphen after the word "nude." And in your radio ads, you have to pronounce the hyphen." Come on. So we took an interlocutory appeal to the Ninth Circuit Court of Appeals from the preliminary injunction—that aspect of it. And it got heard in short order, and . . . because we weren't going to take the hyphen lying down, right? You know? I mean, it fell to me, pending trial and under penalty of contempt, to ensure that no contestant lost her hyphen. It's crazy.

That's why I went to the annual pageants, okay? So I sat in the press tent with my clothes on, get in front of the Ninth Circuit Court of Appeals, and the lawyer on the other side's making a fuss over the question of whether "nude" is a noun or an adjective. And I got to stand up and say, "If it pleases the court, I don't think that it's any more legal significance than the question whether 'nude' connotes either a dangling participle or a split infinitive." Well, actually, I've embellished that. That was my partner. But, you know, it was—

JONES: That was a lot of fun—that case, huh?

KILEY: Oh, yeah. You couldn't, you know, go ten minutes without tripping over a pun of some kind . . . you know, "we're going to lay bare the deficiencies in the plaintiff's case, which stripped to its essentials is that . . ."

JONES: Yeah. It's kind of silly, though. I mean, confusing nude and clothed? It's hard to imagine.

KILEY: Yeah. Well, in trademark, the likelihood of confusion is what you have to prove. But there was a stinger in that case that I was a little concerned about, and that's something called disparagement—trade disparagement. And the classic case is the Planned Parenthood poster of a pregnant Girl Scout with the legend, "Be Prepared," okay? It was promoting contraception. And the Girl Scouts of America sued Planned Parenthood and said, "You're showing a pregnant Girl Scout. You're disparaging our members, you know, as girls of low virtue." And the court said yeah. So here, that's why this lawyer was so interested in this noun/adjective thing because is it Miss Nude from America? Or is it Miss America in the Nude? Okay? And that's what he was going for. And they could have got us on that.

JONES: Well, it's still a bit of a stretch, but—

KILEY: Well, yeah, I know, but a jury—

JONES: Yeah. Yeah.

KILEY: You know, I would love to have taken that case to a jury, and, depending upon whether they thought we were creeps, or they thought Miss USA was being overbearing, you know, it would have gone one way or the other. See, Miss Universe had this, kind of, locked and loaded lawsuit, and they would file against Miss Black USA, Miss Gay USA, you know, Miss Anything USA. They were very protective of the trademark. And then people would fold up and go away. But the owner of the Treehouse Fun Ranch, which was the Social Family Nudist Resort, wasn't going to take this lying down. And his name was William Flesher, believe it or not. And so anyway, the day came when **<T: 120 min>** I had to call Big Bill and say, "Bill, I have good news and bad news for you. The bad news is I'm leaving my firm to join a company called Genentech. The trial's a month away. The good news is that any one of my partners would be happy to try this case for you, but they're going to charge you for it." Now Bill was a guy who was going to take this all the way to the Supreme Court, but when he heard that, he said, "That's it. She's Miss Nude International." Because I'd been doing the case for fun, you know.

JONES: Yeah. That's a great story.

KILEY: Oh, yes. I've got a picture of me and Miss Nude USA in my office at home. She's wearing a bunch of roses, and that's it.

JONES: Yeah. Well, we're writing a book on the history of biotech. That would be . . . too bad that that photo might not be appropriate for it, but it would be interesting.

KILEY: Matter of fact, my daughter is putting together one of these slideshows for my seventh birthday party, and I tried to get that into it, but for some reason she thought it would be tacky. Okay, Mark. Well, it's been a lot of fun.

JONES: Great.

KILEY: Let me get out of your hair.

JONES: We'll return these. We'll get them back to you promptly. Thanks for those. And—

KILEY: No tearing hurry. There may be some duplication here. And I will get you that talk about tPA, which I think is one of the more interesting things.

JONES: Great. Thanks.

KILEY: Okay. Thank you. [. . .]

[END OF AUDIO, FILE 1.1]

[END OF INTERVIEW]