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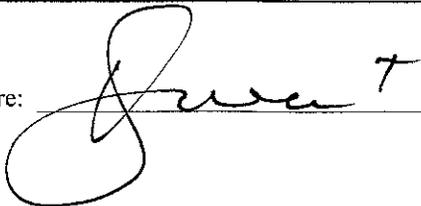
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11-14-12

UNITED STATES DISTRICT COURT

CHAMBERS OF
ROBERT W. SWEET
DISTRICT JUDGE
500 PEARL STREET
NEW YORK, NY 10007

November 14, 2012

Ms. Calais Nelson
Room 222
Alspaugh Dorm
Duke University
Box 92823
Durham, NC 27708

Dear Calais:

Herewith my consent.

It was good to talk with you.

Sincerely,

A handwritten signature in black ink, appearing to read "Sweet". The signature is stylized with a large, looping initial "S" that extends upwards and then curves back down to the right, followed by the name "Sweet" in a cursive script.

Calais Nelson

11/14/21

A Social and Political History of Genomics

Oral History Interview Transcript

Judge Sweet: What can I do ya?

Cali Nelson: First of all, thank you so much for agreeing to do this.

JS: Yeah, no, I'm delighted. What can I do that will be helpful to you.

CN: I'm really interested in gene patenting, specifically the case of Myriad, and you decided the district court case, so I thought it'd be really interesting to interview you. I'm actually a student of Robert Cook-Deegan's and he recommended you. So, did you get the consent form I sent to Margaret.

JS: I did and I will send it back to you.

CN: Ok. Thank you. Then the it will be thirty to forty five minutes depending on how long it takes or how long you have. I've got eight questions that I'd really like to ask you.

JS: Sure. Let me just tell you something that may be helpful to you. Last October I attended the sixty first annual conference of the American Society of Genetics in Montreal and gave a speech, and that speech really sort of described my views about this case and so on and so on. So, I think you might want to get that, and I think they have a printed record and it's there, and if they don't I have a copy of it.

CN: Okay. Thank you very much. that actually would be really interesting, I'd be really interested in that.

JS: Well I think you would find it useful because simply would give a precede of it. I spoke about a description of the issues presented by the case and its significance and the process of how I got involved and the present status of the case, well that was a year ago, and the appropriateness of a process which resolved these issues of law and science, and science in the context of patent litigation. And finally I exhorted them to be alert to the problems in this area and pursue them. Now shoot, what can I do ya?

CN: As an introduction, before you were assigned the case how much did you know about gene patenting or the biotechnology industry?

JS: I had not had a gene patenting case before.

CN: So you basically did not know much about genetics or biotechnology in general either?

JS: I have had an interest in genomics, just a citizen's interest. My wife has been interested in this field and endowed a professorship, the foundation that she was the director of did that and so I have had that kind of an interest. I've always been interested in the work done by Rockefeller University, but I haven't had any specialized knowledge or training or anything like that, it's just a citizen's interest in an obviously very important field.

CN: So when you first saw the case, as soon as you knew that you were going to get it and you saw what it was about what were your initial thoughts, before you even looked at any of the arguments that the lawyers were making?

JS: Well, I got a call from one of my former clerks whose practice is in the area of drug development and represents drug companies and I guess also perhaps people in the genomics area. I got a telephone call from him and he said "you've got the case" and I said what do you mean I've got the case. He said, "this is a big case and it's going to be very significant" and he described it and that's the first I knew of it. I heard that before I'd actually seen the complaint, but once you look at the complaint you see the nature of the parties and you have to realize that it's a significant issue.

CN: You said he called and said "you got the case" and at that point did you know that this was going to become such a huge issue, especially in the national media? That it was just going to blow up, because it's become very significant.

JS: It was obviously a significant issue, that's clear. The degree of interest, one never can predict that. I mean some issues attract more attention than others but it was quite obvious. Particularly as I got into it and saw the history of the Patent Office determinations and so on, it became obvious that it was a very significant case.

CN: So you realize at the time, as you were making your decision, that it would be such a shock to the patent bar, who from everything I've read, all thought the case would end up in Myriad's favor?

JS: Well, you know, I think that it was perfectly obvious that there was a vested interest in preserving the patentability of genes. I mean, obviously. It had been the practice for a number of years. I've forgotten how many, five, six, something like that, maybe more. And since the Patent Office made their determination, obviously there is a vested interest involved. But that is something that a judge meets all the time. Not in every case, but there's always an interest that is involved in the status quo and there's an interest on the other side that is trying to change the status quo, and that's what litigation is about. So, did I know? I guess I thought some people might support the decision in the patent bar and some would not. And I guess, I didn't really think about it much to be honest. I don't think that is a significant; I mean it is not an appropriate consideration.

CN: When you were making your decision, did you ever consider the effect that invalidating these patents might have on industries such as biotechnology and pharmaceutical companies, who are very invested in gene patenting?

JS: Well, I think if you read the opinion, I don't mean to say that nastily. I think the opinion indicates that I'm aware of the tension that results from this issue. I think it's there. I tried to make clear that there is a tension here as to how science best proceeds, and I'm aware of that. But that's the larger issue, which underlies all of this. But the narrower issue, is the issue of the, you know, the patentability or the product of nature. Yeah, I think one has to be aware of it.

CN: So, do you agree or disagree [with Judge Moore], because on the appeal she did insinuate that one of the reasons for which she upheld Myriad's patents was the consideration of the enormous amount of time and money that they had put into developing this product? And do you think that such consideration should not have any part in deciding whether gene patents are valid?

JS: I don't think you, I think you should decide the case on the issue of whether or not the breast cancer gene is a product of nature or its not. I don't think you should decide that based on your view as to what is the best way to proceed in the development of knowledge and health benefits and all of that. That's the kind of thing that seems to be probably legislative, but I don't think it is appropriate, considering the narrower issue of patentability.

CN: On the same strain, what would your general opinion of the dissenting appeals decision be?

JS: Since that was in my favor, I like it. But, you know, that's what happens to judges all the time. You get reversed, or in this case of course, affirmed in part and reversed in part. I thought, obviously, the dissent was more closely aligned with my views than the majority.

CN: One part that Judge breaks with you is the difference between cDNA or what Myriad had patented and human DNA. And you thought that they were not separate enough or a product. So, where would you, I'd say, draw the line, in that?

JS: Well, the line I drew in this case is there and I can't, I don't want to, I guess I can't generalize on what the decision was.

CN: Okay. So what do you think the difference between cDNA and such things such as man made proteins that have been upheld, there patentability has been upheld? What do you think the difference between those two are?

JS: Well, I wouldn't wander into a thicket I have not been inside yet. Hypothetically, I don't think, I don't want to venture any opinions as to the effect of the decision on other similar issues if they exist, and of course they do exist, and they will. And I guess it is going to depend to a large degree on how it all works out. We don't know the last word yet.

CN: So, I assume you have read Parke-Davis, then do you not agree with his [Learned Hand} decision in that?

JS: Well I think if you read, I'm sorry I shouldn't say.

CN: It's fine.

JS: My footnote on that case, I think indicates that I thought he was wrong; that Learned Hand, the local deity of the Second Circuit, was wrong.

CN: Do you think he was wrong because he, Parke-Davis, actually shouldn't have addressed the product of nature? Or do you think its wrong just because you believe Adrenalin is not a product of nature, or is a product of nature?

JS: Well, I think, now that I've been away from it for a year, I think he was wrong in his analysis and I tried to spell that out as best I could.

CN: Do you think, in your opinion, many people think that this case is bound for the Supreme Court, and do you think that, and if so what do you predict that their decision might be?

JS: I haven't, you know it would be a nice thing if I could predict, but I don't have the wisdom or the capacity or anything. I don't know. Will they grant certiorari? I don't know. I mean I know what I would do, I know what I would do if I were on the Supreme Court, but I'm not. So, I don't know what they are going to do. A: I don't know whether they will think back, if you look at what has happened in the course of the appeal, it does not, it seems to me that the Supreme Court said, "you ought to consider Prometheus", and the circuit court said,

"Prometheus doesn't change our views". So how is the Supreme Court going to react to that, I don't know.

CN: So, do you think, to you does Prometheus apply to this case?

JS: Well I wouldn't, look the Supreme Court wanted them to look at it. I decided it, but it is one of the elements that should be considered. Do I think that the federal circuit was correct in their opinion? Frankly, the second opinion, do I think they were right in the first opinion? I would have preferred it if they confirmed me all the way across the board, that is what I would have liked. But at the same time they did affirm me in part, so that was good. But, its not, I have no ability or it would be presumptuous of me to comment really on their opinions.

CN: Now, do think that even once the Myriad case is over, do see gene patenting as an issue that's going to live on, even after the Myriad case is decided?

JS: Well, I think if it stays where it is now that is, and the Supreme Court does not change it, I would expect, I would think, that it might well remain an issue.

CN: Do you think that it's an issue that in time might have to be decided by Congress, with maybe new patent laws rather than?

JS: No, no and I'm sure you've done your research in this. There have been bills and they've never, Congress has not acted. It's a very difficult issue and you can imagine what the pressures would be if Congress were to get involved. Frankly I think, I think underlying this issue is how is it best resolved, and the remarks that I made in the conference indicate that I am in, I believe in the judicial process, and I think that it's right that these issues be worked out through the courts. So that, for myself I would think that might be more effective than having Congress step in, because I think the issues are there. There's a basis for decision and I think that that's a good way for the knowledge and the process to go forward. But if Congress were to legislate, of course that would be something else again.

CN: Just as a matter of opinion, do you believe that companies shouldn't be able to patent any sort of gene found in nature and not just human genes, or do think they should be able to patent maybe the genes of other organisms?

JS: I really haven't struggled with that problem and so I just, it's a hypothetical case I think I would deal with when I got it, if I got it. I don't think I, you know an offhand opinion from me is worth just what it is, an offhand opinion and not worth much. So, I guess it's best not to render one.

CN: Well, that's all the questions I have prepared, so if you have anything else you'd like to say, that would be great, but if not.

JS: Okay, well good luck to you and I hope your uh, what is this gonna be? A paper, how does it fit into your program?

CN: Right now, I'm taking a class on the, it's basically on the policy and history behind the human genome project, and we've moved in recently, we've looked at genome patenting a lot. So, Bob Cook-Deegan is my professor, and so we're doing this, this is actually an assignment for the class, but if, it will also go into I guess the database of oral interviews that they have at the Institute for Genome Sciences and Policy.

JS: Well, you know, I think the fundamental issue which lies underneath all this is how does knowledge that is vital to the success of society, help society, what is the best way for that to proceed? And that's an underlying issue, it seems to me. Now, it's not an issue which is the determining issue in the Myriad case, because that's not something that a judge, that's not an appropriate consideration. The consideration is, is this patent, is this process or change, is it patentable or isn't it. And so it's much narrower, but the underlying issue, I think, is there. And it's a question of how does knowledge proceed best. And of course there are those who believe that the free distribution of knowledge involving these kinds of things is beneficial, and those that say the best way to do it is to have investment and not just pure science but driven by the economics. Well, who knows what the answer to that is. But maybe you'll come up with it.

CN: Well, thank you,

JS: Okay, nice to talk to you.

CN: Thank you very much, once again. It was a pleasure.

JS: We'll send the thing. Good luck to you.

CN: I will email Margaret the transcript so you can look it over. If you have any remarks on it.

JS: No, there's no need, there's no need.

CN: Are you sure?

JS: Yes, well you can, that's fine.

CN: Thank you very much, once again.

JS: All right, nice to talk to you.

CN: You too. Have a nice day.