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Article 5

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Oral Argument before the United States Supreme Court in the Matter of Salvador Dolly v. Nugenera, Inc.

AT THE CROSSROADS OF LAW & TECHNOLOGY: FOURTH ANNUAL CONFERENCE, PATENTING THE HUMAN GENOME†

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Edward J. McCaffery
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The Honorable Alex Kozinski, Presiding
The Honorable Ming W. Chin, Presiding
The Honorable Kim M. Wardlaw, Presiding

Ms. Lisa Wang
Ms. Petty Tsay
Mr. Craig Countryman
Mr. Brian Kucsan

MR. MANHEIM: Welcome to the Fourth Annual Conference "At The Crossroads of Law & Technology." My name is Karl Manheim. I'm the Loyola Director of the program, and with me is Ed McCaffrey, the Caltech Director of the program.

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MR. MCCAFFERY: I'm Ed McCaffery, . . . and I just want to say a few words on behalf of Caltech. We have two of our students who made [an] unbelievably long trek from Pasadena in rush hour to be here today. I want to say just a couple of things about the program, then a couple of things about the case.

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† The following is an edited transcript of a panel discussion held November 1, 2002, in conjunction with the Fourth Annual At the Crossroads of Law and Technology Program sponsored by Loyola of Los Angeles Law School. This panel based its discussion on a hypothetical situation. N*uGenEra v. Dolly*, (W.D. Cal. 1999) (No. MHPO19999) is a hypothetical case. For an introduction to the facts of the case, see the Background section of the mock Supreme Court opinion published within this issue.

This program started four years ago, with just sort of an idea, inspired by Henry Yuen, some people at Caltech, and people at Loyola Law School, that lawyers and scientists should get together and study issues of law and technology.

The initial trial, which we had four years ago in November, I believe, was put together in a very short period of time, and we sort of co-opted some Caltech graduate students, paid them a bunch of money and got them to pretend to be lawyers. But it was such a success that we decided to stick with the program and grow. In our second year, we had an appeal of that initial case in cyberspace.

But these Caltech students had no exposure to law, except for a handful of law courses taught by people like me, but the law courses of Caltech have now grown . . . . largely because of this program. You'll see today, if you sort of close your eyes, . . . [that] it will be hard to tell who the Caltech undergraduates are, and who the Loyola law students are. Although the Loyola law students are tremendously impressive representatives of national Moot Court teams, we don't want to put too much pressure on [either of] them . . . .

So the teams are collaborative. There's a Caltech person and a Loyola person on each team . . . .

But now, sort of moving into the case, this is a very simple case. It's a case of a man and his genome, but it raises some of the most complex issues at the intersection of law and technology: the patentability of human life.

There is material in this brochure that we put together, largely Karl's work, that I think will help you get up to speed . . . . Let's all join together and witness these young men and women put on a very impressive display of their knowledge, as we all talk together with some very distinguished judges about these interesting and important questions.

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The matter is turned over to the court clerk.

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COURT CLERK: Everyone please rise. The Honorables Chief Justice and Associate Justices of the Supreme Court of the United States.

Oh ye, oh ye, oh ye. All persons having business before the Honorable Supreme Court of the United States are admonished to draw near and give their attention, for the court is now sitting. God save the United States and this honorable Court.

JUDGE KOZINSKI: Good afternoon. Please be seated. We have argument in the case of *Dolly v NuGenEra*. Counsel ready? Are you sure?

Petitioner?

MS. WANG: May it please the Court. My name is Lisa Wang, and I'm representing petitioner, Mr. Salvador Dolly.

MS. TSAY: May it please the Court, Your Honors. My name is Petty Tsay and I also represent the petitioner, Salvador Dolly.

MR. COUNTRYMAN: May it please the Court. My name is Craig Countryman and I represent NuGenEra, the Respondent.

MR. KUCSAN: May it please the Court. My name is Brian Kuscan, representing Respondent, NuGenEra.

JUDGE KOZINSKI: Very well. Petitioner may proceed.

MS. WANG: May it please the Court again. My name is Lisa Wang, and I'm representing Petitioner, Mr. Salvador Dolly. Your Honors, two issues are before the Court today. One is patentability, which I will address, and the second is constitutionality, which my co-counsel will address.

We respectfully ask that five minutes be reserved at the end for rebuttal.

Your Honors, this case is about a large corporation, NuGenEra, stealing genetic information from an individual, Salvador Dolly . . . .

JUSTICE WARDLAW: Why are you saying that NuGenEra stole the tissue? Wasn't it [sold for] tissue by the company that did the genetic testing on Mr. Dolly?

MS. WANG: Your Honor, NuGenEra did not obtain consent when they sought this tissue and the DNA sample from Mr. Dolly. Mr. Dolly went to AGTC [(Advanced Genetic Testing Company)] to have his DNA tested for conceiving a child. However, NuGenEra did not have [the] consent [of] Mr. Dolly and thus, NuGenEra stole this genetic information . . . .

JUSTICE CHIN: But wasn't the sample to be discarded?

MS. WANG: The sample was to be discarded by AGTC, and AGTC agreed with Mr. Dolly that a sample was to be used for the sole purpose of genetic testing for known diseases.

JUSTICE CHIN: And doesn't the California Supreme Court case of *Moore v Regents of University of California*[1] hold that tissue does not have a continuing property right in excised tissues? I mean, after all, California's a fairly enlightened jurisdiction—

MS. WANG: Yes, Your Honor. *Moore v Regents of University of California* definitely applies here, and my co-counsel will address that in

1. Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990).

the constitutionality part of this argument. I will focus on [the] patentability argument first.

JUSTICE WARDLAW: You know, I think you should answer Justice Chin's question.

MS. WANG: Okay. Thank you. So Justice Chin, in response to your question about the *Moore v University of California* case, that case definitely does apply here. However, we are considering the case of privacy rights, not property rights, because Mr. Dolly's human genome, unlike a piece of property—

JUSTICE WARDLAW: You are welcome to answer it from a technical standpoint if that makes it easier for you.

JUSTICE KOZINSKI: You said in your first sentence, that they stole it. Okay? Now, theft is a crime. You've accused the other side of a crime. I'm not sure it's important so that it necessarily makes any difference at all to your case, but you chose to stake your claim on that. And we're all questioning how you came up with that. Now, if you abandon that claim of theft, we can go on and discuss [other] issues, or you can answer our questions.

MS. WANG: Your Honor—

JUSTICE KOZINSKI: Are we going to discuss this all night.

MS. WANG: Your Honor, the issue of NuGenEra obtaining Dolly's tissue and Dolly's DNA sample without consent is definitely an important one. However, the issue that I will discuss right now is the issue of patentability.

JUSTICE KOZINSKI: So you're withdrawing the claim of theft. Is that what you're saying for purposes of your argument?

MS. WANG: For purposes of my argument.

JUSTICE KOZINSKI: So you want to start again?

MS. WANG: So Mr. Dolly's genome was taken by NuGenEra and NuGenEra filed a premature patent on that genome.

JUSTICE KOZINSKI: Which was approved by the United States Patent and Trademark Office [("USPTO")]?

MS. WANG: Yes. The USPTO did approve it. But it based this approval on incorrect information.

JUSTICE CHIN: Well, isn't that presumed to be valid?

MS. WANG: It is presumed to be valid, and my burden of proof here today in front of you is to show clear and convincing evidence against the patentability of that, of Claim 1 and Claim 2.

JUSTICE KOZINSKI: In fact, you have a double burden, because not only did the USPTO approve the patent, but you then have a district

judge who took evidence and upheld at least one of the claims, upheld in fact, exactly one of the claims.

MS. WANG: Yes, Your Honor.

JUSTICE KOZINSKI: So you not only have the USPTO and its presumption. There's also a district court and its presumption. As we know, district judges get much deference.

MS. WANG: Well, Your Honor, you're correct in saying that I have a double burden of proof here. The district court correctly ruled that Claim 1, that is the claim to Mr. Dolly's entire genome, does not constitute a valid patent here. And that is correct because in filing Claim 1, NuGenEra is trying to claim ownership to Mr. Dolly's entire human genome. That is the essence of Mr. Dolly, and yes, it is true that the U.S. patent system is set up—

JUSTICE KOZINSKI: You're going for the easy argument. Why don't you address the hard argument, because we don't have a lot of time, and that is the claim that Judge Patel upheld, and so not to the whole genome.

MS. WANG: Yes, Your Honor. Claim 2, claim to the P1-P10 sequences also fail in relation to Claim 1, and I will show that.

JUSTICE KOZINSKI: Correct me, if I'm wrong. He only needs, they only need to win on one claim, right?

MS. WANG: Yes, that is the case. And I will show that Claim 2, the claim to P1-P10 sequences failed to meet statutory requirements for patentability. Claim 1 was upheld for the patentability of the genome. Then, if Claim 2 were a valid claim, if the P1-P10 sequences indeed present utility as a diagnostic tool or for RFLP [(Restriction Fragment Length Polymorphism)] analysis, then why would NuGenEra still hold on to its Claim 1? Because if NuGenEra—

JUSTICE KOZINSKI: Have you ever heard of belt and suspenders?

MS. WANG: Yes, Your Honor.

JUDGE KOZINSKI: Now let me ask you, in your vast experience as an attorney practicing in the patent layer, do you know [a] single patent that has only one claim supporting it?

MS. WANG: No, Your Honor.

JUSTICE KOZINSKI: I think we all know that the reason patent holders seek more than one claim is because, sometimes, some of them get knocked out.

MS. WANG: Yes, Your Honor.

JUSTICE KOZINSKI: But they only need to survive, only one needs to survive.

MS. WANG: Yes, that is the case. However—

JUSTICE KOZINSKI: And you have a district judge who found utility. Was Judge Patel drunk or crazy when she made that decision?

JUSTICE WARDLAW: Well, to be more specific, why isn't the in vitro and animal experiments that NuGenEra performed sufficient to show the substantial and specific credibility of Claim 2?

MS. WANG: Your Honor, that is a very good question—

JUSTICE WARDLAW: It's probably where we should be right now in terms of our discussion. So why aren't those experiments sufficient? Given the case law on patents, that you don't really need to know everything about the patent claim itself, but they've got these experiments, especially the one in mice, that show that the P sequence does confer HIV resistance. They're not sure all the reasons why, but it does seem to work for its asserted use.

MS. WANG: Your Honor, that is an important discovery, discovering that P sequences do confer HIV resistance in mice. However, in order for that claim to be held valid, it has to fulfill the requirements of utility. That is, we need a real world utility, something that we can use P1 through P10 sequences for. However, the NuGenEra claims—

JUSTICE KOZINSKI: Isn't that how we generally establish usefulness of a particular drug or procedure to man? By testing on animals?

MS. WANG: Yes, indeed—

JUSTICE KOZINSKI: Obviously, there's enough validity to it that people are willing to buy your client's blood at much more than they would pay for my blood or your blood.

MS. WANG: This case differs from other cases with gene patents or patents for other biological compounds, because here, in using the P1-P10 sequences, NuGenEra cannot simply implant P1-P10 sequences in another patient and expect other patients to develop HIV resistance for heightened HIV resistance.

Similarly, NuGenEra's claim that P1-P10 sequences demonstrate a good utility for RFLP analysis is unfounded. That is because in district court rulings, the district court rested on the RFLP's well-established utility in forensics cases.

Indeed, RFLP analysis is a very useful procedure. However, we're comparing apples and oranges here. If we're looking at RFLP analysis as applied to this case of diagnosing whether someone else has HIV.

JUSTICE CHIN: When RFLP is used for identification purposes, at least when it first came out, they only tested what? Three or four sites?

MS. WANG: Yes.

JUSTICE CHIN: But in this case, for diagnostic purposes, how many loci do you have to test?

MS. WANG: Your Honor, for forensic cases and when RFLP was first used, you only needed to test a few sites because testing these sites will reveal the identity of the DNA. That is, if I have a baseline—

JUSTICE CHIN: I think that's what I just said. But, my real question is, how many sites do you have to test for the diagnostic purposes that we're talking about in this litigation?

MS. WANG: For diagnostic purposes, you just test the entire genome, and that would include—

JUSTICE CHIN: And is that why the trial court said as to Claim 1, it's much too expensive and too time consuming?

MS. WANG: That is the exact same argument.

JUSTICE CHIN: Do the new technologies in PCR or SGR have any applicability for diagnostic purposes?

MS. WANG: Those techniques are promising, but no, they do not apply applicable techniques here.

JUSTICE CHIN: There was some hint in something that I heard. It may have been on a video about going into a drugstore and giving a drop of blood and getting back a printout of your entire genome. What's the status of that?

MS. WANG: That is something that people suspect will happen many, many years down the road. It will probably provide a lot of uses. However, granting a patent—

JUSTICE CHIN: Is there such a thing as a gene chip that's useful yet?

MS. WANG: A gene chip is still under development. There is not something that's a marketable product, and we cannot grant a patent to more and more patents in the future. We're bringing a patent for real specific utility that's present today. And today, NuGenEra failed to show that it can use . . . Claim 1 or Claim 2 to diagnose a patient or for RFLP analysis or to confer [partial] HIV resistance to another patient.

JUSTICE KOZINSKI: That is an argument, and I think it's a good argument, but it was rejected by the Patent Office. It was rejected by the district judge. Let's say we really have a lot of sympathy for you and your client, and really want it to go your way. How would we be able to say that their mice experiments, the very fact that your client has a market for his blood; all that is in the record does not support utility? I mean, we'd be like ostriches, wouldn't we?

MS. WANG: Your Honor, it is equally important to [look at] USPTO's ruling and . . . the district court's ruling in regard to this case. However, here, we need to re-examine this case because the district court—

JUSTICE KOZINSKI: Is it really your position that this was not proven to be useful? I mean, you're standing there. Why are we litigating this? Why even the highest court in the country disputing this? If it's really truly not useful, who's paying the lawyers? And why?

MS. WANG: HIV resistance is definitely something that's useful. AIDS is an epidemic that's killing millions.

JUSTICE KOZINSKI: But if this is not useful in fighting that, why is everybody so interested?

MS. WANG: Your Honor.

JUSTICE KOZINSKI: Isn't the very fact that you're standing there proof enough to support the district court's finding?

MS. WANG: Your Honor, Mr. Dolly's genome definitely possesses a lot of significance. It's a gold mine to be explored. However, NuGenEra's patent is—

JUSTICE KOZINSKI: Is that a confession, a confession of error?

MS. WANG: Mr. Dolly's genome is definitely of significant value. However, NuGenEra has merely found a haystack out there, and NuGenEra's trying to apply a patent to prevent—

JUSTICE KOZINSKI: Well, how do we know that it's his blood rather than somebody else's blood that has this marvelous effect?

MS. WANG: His blood is the only blood found to confer HIV resistance.

JUSTICE KOZINSKI: How do we know that?

MS. WANG: That is the only discovery that was patented.

JUSTICE KOZINSKI: But it wasn't just done. Who did that?

MS. WANG: NuGenEra.

JUSTICE KOZINSKI: There we go. So without NuGenEra's work, your client's blood would be just like everybody else's.

MS. WANG: Yes, that is the case, Your Honor. However—

JUSTICE KOZINSKI: I think you've just given up your case, haven't you?

MS. WANG: Your Honor, NuGenEra definitely did the work in sequencing Mr. Dolly's DNA. However, NuGenEra's claims, although show partial HIV resistance, fail to meet patentability requirements, and that is what this Court has upheld, the patentability requirements when testing each patent.

JUSTICE WARDLAW: So suppose that you prevail, and we find

that the patent is invalid. Is Mr. Dolly going to go out and try to patent his blood?

MS. WANG: Your Honor—

JUSTICE CHIN: Based on the P sequence?

MS. WANG: That will be Mr. Dolly's personal decision, and Mr. Dolly has a decision, has a constitutional right to do whatever he wishes with his body, as upheld with *Roe v Wade*.[2]

JUSTICE KOZINSKI: He's looking for an abortion?

MS. WANG: We're not—

JUSTICE KOZINSKI: I didn't see that claim.

MS. WANG: As my co-counsel will later attest, *Roe v Wade* is not going to be . . . used in that exact sense. We are trying to examine whether Mr. Dolly can be prevented from doing one thing with his body—using his blood for whatever purpose he wishes. This Court should find the 271 patent to be invalid, first of all because patentability criteria are not met for either Claim 1 and Claim 2.

Claim 1 was not met, as the district court found, because it failed to demonstrate any type of utility, be it well-established utility or substantial specific product utility.

And likewise, here in Claim 2, Claim 2 is merely another fishing expedition with a slightly reduced haystack of DNA. NuGenEra does not know how this partial HIV resistance [has] came about. NuGenEra also does not know exactly which one of the P sequences confer HIV resistance. In Claim 2, it [is] said that partial HIV resistance is due to any combination of P1 through P10 sequences. In order for P1 to P10 sequences to be patentable material, we need to demonstrate that that criteria is not fulfilled.

JUSTICE KOZINSKI: Thank you very much. [Now] we'll hear from co-counsel.

MS. TSAY: May it please the Court, my name is Petty Tsay, and I represent petitioner Salvador Dolly. Your Honors, constitutionally protected rights are the bedrock of society, and it is the duty of this Court to safeguard those rights. Allowing a large corporation such as NuGenEra to patent Dolly's genome and P sequences would deprive the individual—

JUSTICE KOZINSKI: Would it make a difference if they were a mom-and-pop shop?

MS. TSAY: Yes, it still would, Your Honor.

JUSTICE KOZINSKI: Okay. So it's not really important that it's a giant corporation?

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2. Roe v. Wade, 410 U.S. 113 (1973).

MS. TSAY: No, it is not, Your Honor.

JUSTICE KOZINSKI: You're not staking your claim on that fact?

MS. TSAY: It does give an additional resource.

JUSTICE CHIN: Did you hear my question to your co-counsel about the *Moore* case?

MS. TSAY: I did, Your Honor.

JUSTICE CHIN: What is your response?

MS. TSAY: This case is distinguishable from *Moore* for several reasons. First of all, *Moore,* dealt with spleen cells, which are not unique to an individual. Here, there is . . . unique . . . genetic information, conferred by DNA, unique to Salvador Dolly.

JUSTICE CHIN: But this was blood that was to be discarded, correct?

MS. TSAY: No, Your Honor.

JUSTICE CHIN: What's the difference?

MS. TSAY: It was not, Your Honor. It was not blood to be discarded. It was blood managed for AGTC to test to see if Mr. Dolly and his wife—

JUSTICE CHIN: But the blood that was sold was the blood that was left over to be discarded.

JUSTICE KOZINSKI: He didn't have an agreement to have it given back to him, right? Stick it back in the vein or anything like that? Or have it mailed home, or anything? There was no agreement like that, right?

MS. TSAY: No, Your Honor, he did not.

JUSTICE KOZINSKI: I mean, he did not retain any rights in it? He didn't have any expectation that it would come back to him or anything of that sort?

MS. TSAY: Actually, Your Honor, with all due respect, he did. The consent form specifically said, and I quote, "[a]ll the—

JUSTICE KOZINSKI: Oh, come on. You've had blood drawn. How often have you gotten it back? I mean, let's face it. I mean, nobody expects to get it back. The stuff that you send to the lab, it gets tested and thrown away. Thank God. You know, you don't want to see that stuff again.

MS. TSAY: That is correct, Your Honor.

JUSTICE KOZINSKI: So, is this really any different? I mean, just to follow up on Justice Chin's question, is this any different than somebody going through my trash after I've put it out on the street for the pick-up truck to take in the morning?

Let's say I've thrown out my empty beer cans and then somebody

[comes] along and gathers them for aluminum for recycling. Is that theft?

MS. TSAY: No, Your Honor. That is not—

JUSTICE KOZINSKI: How is this different?

MS. TSAY: This case is different and distinguishable from *Moore* because the consent is different from *Moore.*

JUSTICE WARDLAW: How is the consent limited? Is it limited by the words in the consent or by the circumstances under which it was given?

MS. TSAY: It is limited by the words in the consent, Your Honor. The consent specifically said, and I quote: "[a]ll information will be confidential and will not be disclosed by AGTC's staff except to my personal physician." That is what Salvador Dolly signed. In this case, information was disclosed to someone other than his personal physician; it was disclosed to NuGenEra.

JUSTICE WARDLAW: So why aren't you suing AGTC? They violated the consent, not NuGenEra.

MS. TSAY: That is a separate issue, Your Honor, and AGTC could be sued; however—

JUSTICE WARDLAW: You're asking us to find that the patent, even though we may find it valid, should not be enforced. Is that a reason not to enforce? Does it meet the standards for inequitable conduct under the patent laws?

MS. TSAY: No, Your Honor. There's two issues here. There's a privacy issue and a property issue, and in regard to the property issue, the fact that there was no informed consent does impact the property right that Mr. Dolly has to his DNA. It's distinguishable from *Moore* partly because of the consent, but also because this is property that is unique to Mr. Dolly.

JUSTICE CHIN: But Counsel, wouldn't granting your client a property right in Claim 2 implicate the concern that the *Moore* court had in making available to scientists every possible avenue to advance the science?

MS. TSAY: No, Your Honor. It would not. *Moore* specifically said that it was not conferring property rights to individuals in all situations, that the facts in *Moore* were specific to *Moore. Moore* is also different because in that case, Mr. Moore was suing the University of California Regents for his spleen cells. Here, it is different. NuGenEra sued Salvador Dolly for infringing the patent, [when in fact] the genome and the P sequences are correctly Mr. Salvador Dolly's property. They are Mr. Salvador Dolly's property because they are unique information specific to him—things that he owns, valid to him personally. Not only does [this] give him—

JUSTICE KOZINSKI: But he let go of it. If it was that valuable to

him, he could have written into his agreement with the lab, "[that] every drop of blood that you don't use in testing, I want to have returned to me." There was no clause like that I missed, was there?

MS. TSAY: No, Your Honor. There was no clause like that. However—

JUSTICE KOZINSKI: Okay. It was assumed, was it not, as it is assumed every time blood is drawn in this country, which must be millions of times every year, that whatever portion of the blood is not actually used in testing would be discarded?

JUSTICE WARDLAW: I don't think we're going to assume that anymore.

JUSTICE KOZINSKI: It depends on how we—

MS. TSAY: Your Honor, just as Mr. Salvador Dolly was shocked by the fact that in his consent form, he thought—

JUSTICE KOZINSKI: Now, wait a minute! Are you telling me he expected to get it back? He expected the blood they didn't use for testing to come back?

MS. TSAY: No, Your Honor.

JUSTICE KOZINSKI: He may not have expected that they would use it for something else, but did [he] expect them to get rid of it?

MS. TSAY: He did expect that they get rid of it, Your Honor.

JUSTICE KOZINSKI: Okay. So, once he gives it up with an expectation that it be gotten rid of, he no longer has a property interest under *Moore*. Or, under just common sense, he no longer has any property interest in the blood. If somebody comes along and picks it up, it's just like the aluminum cans I left in my trashcan, isn't it?

MS. TSAY: No Your Honor, it's different, because you may have the expectation for the physical blood itself. Mr. Dolly had an expectation of a property interest in the information contained in the blood. That information is his entire history, his genetic makeup. It tells who his—

JUSTICE KOZINSKI: I'm sorry, is that your property interest or your privacy interest?

MS. TSAY: He has a property interest in that, but he also has a privacy interest, Your Honor.

JUSTICE KOZINSKI: Okay. I just want to keep them straight. I thought we were talking property.

MS. TSAY: Yes, we were talking property, but he also has a privacy interest.

JUSTICE KOZINSKI: I understand, but are you walking away from your private property claim? Is that really what's going on here?

MS. TSAY: No, I'm not walking away from the property claim, Your Honor.

JUSTICE KOZINSKI: Okay. So let's stick with that.

MS. TSAY: Okay.

JUSTICE KOZINSKI: He has a property interest in the information contained?

MS. TSAY: Yes, Your Honor. He has a property interest in the blood that contains that information. The two are inextricable. You cannot separate them because it's not like—

JUSTICE KOZINSKI: And where does he get this property interest? We know it's not in the agreement, right?

MS. TSAY: That is correct.

JUSTICE KOZINSKI: No. It's not in the state law; because *Moore* tells us it's not. So where does he get it?

MS. TSAY: You can derive his property interest from *Moore*, [but] this is very different from *Moore*. In *Moore*, the court said that there are circumstances in which property rights could be allowed. This is one of those circumstances, and you can derive that from *Moore* because in *Moore*, they distinguished between spleen cells, for example, and things that are unique to an individual. In *Moore*, they tried to claim a right of publicity, but they said that that didn't stand because spleen cells are the same in all individuals.

This is different here. This is unique information, specific to Mr. Dolly, which not only gives his entire genetic history but stands for who he is as a person. To not allow that to be his property would really go against what this Court is supposed to be standing for, which is to assure the interest of human beings in what they possess—

JUSTICE KOZINSKI: Do I have, when I walk on the street and somebody takes my photograph, a constitutional right, [a] constitutional interest in that, in my face not being shown to anybody?

MS. TSAY: Yes, sir.

JUSTICE KOZINSKI: I mean, I walk around the street [and] show my face. How is that different? Mr. Dolly, if he was that concerned about his genome, as we all know we should have been, could have said, "don't disclose that information and return the stuff to me, return the blood." I mean, he didn't do that.

MS. TSAY: No, you're right. You're correct, Your Honor. He didn't do that. However, he didn't say that NuGenEra could take his blood and do what they did, which gets me into my privacy argument.

JUSTICE WARDLAW: It's my understanding under *Roth*[3] that in order to determine what your property right interest is based on, with reference to state law, we need to find a California state law property right to uphold your property claim, and that's why we're discussing *Moore*, and that's why it's so important that the California Supreme Court left open in *Moore* the notion that there are some aspects of your genomes that you may have a property interest in.

But that's not a federal constitutional right we're talking about. It's not even a California constitutional right we're talking about, right?

MS. TSAY: Right—

JUSTICE WARDLAW: So you misspoke when you were talking about [a] constitutional property right?

MS. TSAY: No. That really gets into the privacy rights, which I'd like to—

JUSTICE WARDLAW: Okay, that's hinged on the constitution?

MS. TSAY: You're correct, Your Honor. But there are property rights because this case is distinguishable from *Moore*. However, I'd like to move into the privacy rights, because Mr. Dolly does also have a privacy interest in his DNA, for two reasons.

First of all, this is impinging on his right to privacy because by publishing his identity through the sequencing of the DNA and calling this the Dolly genome, NuGenEra is making public Mr. Dolly's private information, which violates his constitutional right to privacy.

Second of all—

JUSTICE KOZINSKI: But, you know, as you started out telling us, they're a giant corporation. They're not the government, and how can a giant corporation be violating his constitutional rights? Don't you need some state action?

MS. TSAY: Yes, Your Honor, and as Judge Patel noted in the district court opinion and found authority in *Shelley v Kraemer*,[4] the district court validating the patent would be the state actor in this case by —

JUSTICE KOZINSKI: But that was not a finding of fact. That was a ruling of law. As to that, we owe her no deference at all.

MS. TSAY: Yes, Your Honor. However, in *Shelley v Kraemer*—

JUSTICE KOZINSKI: I mean, as much respect as we have for Judge Patel, wasn't she just plain wrong here?

MS. TSAY: Your Honor, in enforcing the patent, the court would be

3. Bd. of Regents of State Colls. v. Roth, 408 U.S. 564 (1972).

4. Shelley v. Kraemer, 334 U.S. 1 (1948).

the state actor. In *Shelley v Kraemer*, this court found that the action of state courts and of judicial officers would be the state actor in this case. I see that my time is up, Your Honor—

JUSTICE WARDLAW: But actually, Judge Patel in her memorandum and order said that the only plausible state actor in this case is the patent office.

MS. TSAY: Yes, Your Honor, she did state that in the order. However, if I refer you to page 1100 footnote twenty five, Judge Patel noted that the state actor could be the district court as a state court in enforcing this, and she cites that on the bottom of page 1100.

I notice that my time is up, Your Honor. Let me very briefly conclude. Your Honors, here it is the role of the courts to safeguard Mr. Dolly's rights, and as such, we request that you find this patent unenforceable as a matter of equity. Thank you.

JUSTICE KOZINSKI: Thank you. We'll hear from the other side now. Respondent, ready?

MR. COUNTRYMAN: May it please the court, Your Honors. My name is Craig Countryman, and I represent Respondent NuGenEra. Today, I'll be discussing the patentability aspects of the case, and my co-counsel will be discussing the constitutionality aspects of the case.

Your Honors, as this Court wisely noted in *Brenner v Manson*,[5] the basic quid pro quo in obtaining a patent is that it benefits the lives of the public. What this Court must keep in its mind is the massive benefit, which has been bestowed on the public as a result of the granting of this patent by the USPTO.

Now the USPTO in giving the patent found the claims to be novel, non-obvious, patentable subject matter, and also to have utility. Now, a major question in the district court was whether Claim 1 and Claim 2 possessed utility.

JUSTICE KOZINSKI: The thing I have questioned about this is whether this is a patentable subject matter . . . . Now, if you get a patent for a mousetrap and you go and buy a mousetrap, you have a thing, a mousetrap. I just did not understand from all these words that were spoken in this case, when you go out and buy the patentable invention here, what do you actually get?

MR. COUNTRYMAN: What you're actually getting is the diagnostic ability to see if someone's genome—

JUSTICE KOZINSKI: You know, that's a capacity. That's like

5. Brenner v. Manson, 383 U.S. 519 (1966).

saying I get the ability to lift 500 pounds. What I'm saying is, what do I get? You know, I pay the money. What do you give me back? You give me a recipe? You give me a liquid, a powder? I mean, what does the . . .

MR. COUNTRYMAN: You'd be getting the sequence of, in the case of Claim 1, the sequence of the Dolly genome.

JUSTICE KOZINSKI: I've never seen a sequence in nature. What does a sequence mean?

MR. COUNTRYMAN: The sequence is the actual composition of the genetic material, and it doesn't—

JUSTICE KOZINSKI: Are we talking liquid here? Are we talking a solid? Are we talking . . . you're laughing, but I have no clue. I really truly do not understand. What is this thing that your company is selling?

MR. COUNTRYMAN: I believe we'd be selling a solution of the DNA. So basically, a liquid, which would contain Mr. Dolly's isolated genetic material.

JUSTICE KOZINSKI: And what would this be? This would be a solution that is mostly water, some inert liquid, and the thing in it that would work, the thing that was a patent and invention, would be what? Something that once was inside of Mr. Dolly?

MR. COUNTRYMAN: That's correct, Your Honor. The difference between it being a—

JUSTICE KOZINSKI: Could I patent my left arm?

MR. COUNTRYMAN: No, Your Honor.

JUSTICE KOZINSKI: If I can get it to do unusual enough things?

MR. COUNTRYMAN: No, Your Honor.

JUSTICE KOZINSKI: Well, how is that different? I mean, if I can get it to bend into a pretzel, could I patent it?

JUSTICE CHIN: I'd like to see that.

JUSTICE KOZINSKI: My wife thinks I can do it when I have to reach. Well, tell me. How, how can you possibly patent a piece of somebody else's body?

MR. COUNTRYMAN: I think the distinction in this case is that we've isolated the Dolly genome, and we've isolated a particular part of it—

JUSTICE KOZINSKI: Well good for you, and maybe you have a copyright, and you may well be on your way to getting a Nobel prize in medicine or something of that sort and lots of bragging rights, but we're not the Nobel committee. We determine whether something is patentable, and just give me a single example of a case where something that exists in nature has been granted a patent, that has been unchanged, that exists in

nature, that somebody has discovered and gotten a patent for.

MR. COUNTRYMAN: The Patent Office and the courts don't recognize things that are unchanged from nature.

JUSTICE KOZINSKI: Okay.

JUSTICE KOZINSKI: Okay, so is that thing in that little flask of solution? Has that been changed by your client?

MR. COUNTRYMAN: Yes, Your Honor.

JUSTICE KOZINSKI: Okay. How has it been changed?

MR. COUNTRYMAN: It's been changed because NuGenEra extracted the DNA from Dolly's cells and then isolated that DNA for the use.

JUSTICE KOZINSKI: It just sounds to me like you said I cut off the arm, and then I cut off the elbow, and you just got to the part you really wanted. You got rid of all of the irrelevant stuff.

MR. COUNTRYMAN: That's true.

JUDGE KOZINSKI: But the little tiny sequence, the little thing that makes a thing work is when you sell it exactly the same as it was when it was inside of Mr. Dolly, right?

MR. COUNTRYMAN: That's incorrect, Your Honor, because in Mr. Dolly, it would be in his blood or in his hair, but it wouldn't exist in the isolated form—

JUSTICE CHIN: Can we break it down into the two claims? The first claim is for the entire Dolly genome.

MR. COUNTRYMAN: That's correct, Your Honor.

JUSTICE CHIN: How is that different than Dolly's blood that is tested every day in hospitals. His blood is his blood.

MR. COUNTRYMAN: His blood *is* his blood.

JUSTICE CHIN: And so you may have a case with the P1 through 10, but for the entire genome? How is that different than Dolly's current blood running through his veins?

MR. COUNTRYMAN: I think in isolating the Dolly genome, NuGenEra input its human ingenuity into transforming something in nature.

JUSTICE WARDLAW: What does that word, isolation, mean? Isolating?

MR. COUNTRYMAN: That's a good question, Your Honor. It means—

JUSTICE WARDLAW: I'm glad. Everyone keeps telling me my questions are good.

JUSTICE CHIN: She wants the answer.

JUSTICE WARDLAW: But nobody can answer them.

MR. COUNTRYMAN: The isolation procedure works from extracting the genomic material from the nucleus of one of Dolly's cells, such as a blood cell or cells within his blood, and then sequencing that DNA to find out what exactly that DNA consists of.

JUSTICE CHIN: And my question to you, doesn't that exist in nature?

MR. COUNTRYMAN: I don't believe so. It doesn't exist in the isolated form.

JUSTICE CHIN: In the *Diamond v Chakrabarty*[6] case, where a microbe was developed to consume oil—

MR. COUNTRYMAN: That's correct.

JUSTICE CHIN: That did not exist in nature after it was developed by Dr. Chakrabarty from the University of Chicago correct?

MR. COUNTRYMAN: That's correct.

JUSTICE CHIN: Now in this case, when you extract the DNA from the nucleus of the cell, it still exists in nature in that form, does it not?

MR. COUNTRYMAN: The isolated form is fundamentally different from the form in Mr. Dolly's cells, though. I think that's the key distinction physically.

JUSTICE CHIN: Let me ask you to approach it from another standpoint. One of the reasons for granting a patent is to advance science. How does giving you a patent for Dolly's entire genome advance science? I mean, when the controversy arose with regard to the national research, with regard to the public-funded mapping of the human genome, the government insisted that it be made public, and it was published on websites right after each of the sequences were developed.

MR. COUNTRYMAN: That's correct, Your Honor.

JUSTICE CHIN: Why doesn't that same logic apply to this situation?

MR. COUNTRYMAN: I think in applying for the patent, Respondent has made public Dolly's gene sequences, and that's what's really is at play for the—

JUSTICE WARDLAW: But that ties into the utility question and Ms. Wang, I think, suggested that perhaps, especially with respect to Claim 1, we have this issue. Perhaps it was a premature claim that was issued, and it was more like a hunting license because there isn't any specific or even any well-established, much less a substantially specific, utility to

6. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

Claim 1.

MR. COUNTRYMAN: I believe there is a substantial specific utility, Your Honor. The district court didn't find that Claim 1 didn't do the function we said it would. The district court recognized that the entire Dolly genome could be used for RFLP. But the district court's distinction was that it wasn't cost feasible to do so.

However, in adding this, they've really added a requirement that isn't present in the statute, nor is it present in the case law, nor did the USPTO see fit to assess the cost feasibility. And so I think the district court was incorrect in applying this kind of consideration because whether there—

JUSTICE WARDLAW: But how would you actually use the entire genome RFLP process? I mean, wouldn't you have to compare hundreds of thousands of—

MR. COUNTRYMAN: No you wouldn't, Your Honor. The district court presupposed that you have to sequence the genome you're comparing to the Dolly genome to use this diagnostic process, and that would be costly. But that's actually not the case. You can just use RFLP as it's used in forensics to compare the Dolly genome to another person.

JUSTICE WARDLAW: How would you begin to know what region to even look at?

MR. COUNTRYMAN: You can use the entire Dolly genome and then particularly focus on P1 through P10 to see if the person they are comparing it to had P1 through P10, as well as Dolly.

JUSTICE CHIN: Aren't there enzymes to target particular loci?

MR. COUNTRYMAN: There are, Your Honor.

JUSTICE CHIN: And isn't that how you get to P1 through 10?

MR. COUNTRYMAN: That would be one way, Your Honor. But as Petitioner has mentioned, one of Petitioner's concerns is that we don't have a mechanism by which the Dolly genome confers full resistance, and so if you use P1 through P10 as the springboard, you then investigate the rest of the Dolly genome to see where exactly resistance is being conferred, and in comparing the Dolly genome to the genome of others, you can see more similarities—

JUSTICE KOZINSKI: Sounds like you're saying there's a lot more work to be done before you can get a patent.

MR. COUNTRYMAN: That's correct—

JUSTICE CHIN: But do you think—

JUSTICE KOZINSKI: You shouldn't agree, not until you hear the end of the sentence. Would you agree with everything I said?

MR. COUNTRYMAN: It's correct that there is a lot more work to

be done.

JUSTICE KOZINSKI: Well, let me ask you though, just what was the hard part? Once they figured out that he had this immunity, which you figured out pretty early, wasn't it just a matter of workman, just working through drudgery to find the relevant allele? I mean, anybody could do this, right?

MR. COUNTRYMAN: I don't believe so.

JUSTICE KOZINSKI: And any scientist would have been foolish once they realized that this is a guy who's got natural HIV resistance or immunity, not to go looking.

MR. COUNTRYMAN: That's correct, Your Honor.

JUSTICE KOZINSKI: Okay. So figuring out that he does or doesn't have immunity wasn't hard, was it? Anybody could do that?

MR. COUNTRYMAN: Anyone with Dolly's genome.

JUSTICE KOZINSKI: No, no, no. If the technique of figuring out whether he has immunity or not is not too difficult, anybody practicing their art could figure that out.

MR. COUNTRYMAN: Perhaps, Your Honor. That's correct.

JUSTICE KOZINSKI: Okay. And once you've figured it out, you've said you'd have to be crazy not to go looking for what makes him different.

MR. COUNTRYMAN: That's correct.

JUSTICE KOZINSKI: Okay, so those two things, and the third thing you've also said okay to, is that anybody with the technical ability of a workmanlike person in the field, knowing one and two eventually, would be able to find three, would be able to find the thing that makes him different?

MR. COUNTRYMAN: Correct.

JUSTICE KOZINSKI: So why does this not fail . . . ? There's nothing inventive that your client has done. There's nothing that crosses the threshold of obviousness.

MR. COUNTRYMAN: I think the obviousness—

JUSTICE KOZINSKI: All they've had is the dumb luck, and I'm being quite serious, the dumb luck to happen to run across Mr. Dolly's blood, and anybody with any competence who did that would naturally be exactly where your client is today?

MR. COUNTRYMAN: That could be correct, Your Honor, but I think what's important—

JUSTICE KOZINSKI: Well, let's nail it down just a little better than *could be correct.* Do you think it is, in fact, correct?

MR. COUNTRYMAN: I think it is in fact correct.

JUSTICE KOZINSKI: Then, don't you lose right now? Isn't this the end of the case?

MR. COUNTRYMAN: I think it—

JUSTICE KOZINSKI: There's nothing else to be said. You've just admitted that it's obvious.

MR. COUNTRYMAN: It's not obvious compared to prior art, though. I mean, there is nothing either remotely comparable to . . .

JUSTICE KOZINSKI: Well, if you took somebody before Mr. Dolly walked in the laboratory, if you took a panel of scientists tutored in their art, and you say, "hey, if you test some guy and he turns out to have natural immunity to AIDS, what would you do?" Would all ten of them say that they would do exactly what your client did?

MR. COUNTRYMAN: Probably, Your Honor.

JUSTICE KOZINSKI: Pretty obvious.

MR. COUNTRYMAN: Well, given that they know he has HIV resistance—

JUSTICE KOZINSKI: But figuring out he's got HIV resistance was neither a scientific discovery, nor was it something that they could affect in any way. It just happened to be the dumb luck that he walked in for this test that day. There is no scientific merit to that at all.

MR. COUNTRYMAN: They didn't find that in Dolly.

JUSTICE KOZINSKI: You agree with that?

MR. COUNTRYMAN: Could you repeat the question?

JUSTICE CHIN: Be careful.

JUSTICE KOZINSKI: There's no scientific merit. He walks in. He tests his blood. They didn't lure him in. They didn't do anything to, to take the whole population and define it down to him. He just happened to walk in. And once he walked in and tested his blood, anybody tutored in the art would have been able to distill this allele.

MR. COUNTRYMAN: Perhaps, Your Honor.

JUSTICE WARDLAW: Could I please ask a question about that? Given that you've conceded so much, I'm just wondering

[Inaudible]

We're talking about obviousness now. We have to look at the prior art. Was there a knowledge in the prior art that resistance to HIV could be found genetically, or is that where the work is right now?

MR. COUNTRYMAN: There was no knowledge, Your Honor.

JUSTICE WARDLAW: There was no knowledge that it was a genetic resistance. They've been looking in all sorts of places for

resistance to HIV, right?

MR. COUNTRYMAN: That is correct, Your Honor.

JUSTICE KOZINSKI: So you are conceding that this is not something they found because they were looking for it? It truly was dumb luck!

MR. COUNTRYMAN: Yes.

JUSTICE KOZINSKI: And there's no one who said, "gee, it must be genetic, and so we'll go looking for people who might have this." No. It was just that the guy walks in off the street.

MR. COUNTRYMAN: NuGenEra took the initiative to look and see if there was a way for this genetic resistance to HIV to manifest itself—

JUSTICE WARDLAW: Isn't that how all science works? I mean, don't you sort of have hypotheses, and you work and work, and not everybody's as lucky as NuGenEra to actually make the discovery?

MR. COUNTRYMAN: Yeah. I mean there's definitely luck involved in science, but there's also—

JUSTICE WARDLAW: But hard work preceded it.

MR. COUNTRYMAN: There's also hard work and skill—

JUSTICE CHIN: But if the object of the exercise is to find a cure for AIDS or find why this person is resistant to HIV, wouldn't it be more advantageous to make it available to the entire scientific community, so that everybody, every scientist who is interested can participate in trying to find the cure?

MR. COUNTRYMAN: This patent has made that information available.

JUSTICE KOZINSKI: Just at a price.

MR. COUNTRYMAN: Sure, Your Honor, but that's how the patent system works. Without the patent system, no one would make anything available because what would be the point in investing in research if you're not going to get something back? Anyway—

JUSTICE KOZINSKI: Have you guys thought of ADR?

MR. COUNTRYMAN: What's that, Your Honor?

JUSTICE KOZINSKI: Alternative Dispute Resolution. Thank you. I think your time is up. We'll hear from your co-counsel. We have very big steps outside the Supreme Court.

MR. KUCSAN: May it please the Court, Your Honors, my name is Brian Kucsan, representing the Respondent NuGenEra. As explained by my co-counsel, I will be addressing the constitutional issues involved in this suit. Your Honors, AIDS is an illusive and serious disease that has baffled the scientific and medical communities around the world for

decades. Respondent has identified a major step—

JUSTICE KOZINSKI: Two decades.

MR. KUCSAN: Two decades, Your Honor.

JUSTICE KOZINSKI: Just barely decades.

MR. KUCSAN: Yes, Your Honor.

JUSTICE KOZINSKI: Okay.

MR. KUCSAN: Respondent has identified—

JUSTICE KOZINSKI: Why do counsel like to overstate? I mean, how many diseases have been around for centuries, and then they say, "yeah, but . . . " Has anybody figured out smallpox yet? And it's been around since the Middle Ages!

MR. KUCSAN: It's been around more than two decades.

JUSTICE KOZINSKI: I mean, AIDS is a piker compared in terms of longevity. But go ahead.

MR. KUCSAN: Respondent had identified a major step towards combating and hopefully one day curing this massive [disease]. Respondent should not be denied enforcement of his patent, and enforcement of the patent does not violate any of Petitioner's constitutional rights. Number one, first, under the California precedent set by the California Supreme Court in *Moore*, enforcement of this patent does not violate any of Petitioner's property rights; and secondly, the enforcement of the patent does not contravene any of Petitioner's privacy rights.

JUSTICE WARDLAW: With all respect to the California Supreme Court, and recognizing Justice Chin was not on the panel of on the Court at the time that the *Moore* decision came out, that case was actually pretty limited, wasn't it? Didn't it just say that Mr. Moore did not have a right to sue for conversion of property? It left open a wide array of possible property interests under California state law.

MR. KUCSAN: Well Your Honor, you are correct in that it was a suit brought for a conversion where a key element in conversion was, what the court looked at was the ownership and the right of possession to the tissue that was discarded, in *Moore*. What's important to look at in that decision, is that the court went on to say the reasons why Mr. Moore had no right of ownership or possession in that sample once it was taken out with his consent. It was because, first of all, his property interest doesn't continue. There's no California law that allows it to continue. But also, if he was allowed to have ownership rights, then it would hurt the scientific and medical community because it would discourage them—

JUSTICE WARDLAW: Yeah, but in *Moore*, Moore was attempting to assert ownership rights over a protein that every human being possesses.

Here, we're talking about something quite unique, that so far as we know, only Mr. Dolly possesses.

MR. KUCSAN: Correct Your Honor. His genome is unique to him, but the DNA, everyone possesses DNA, just like everyone possesses the cells—

JUSTICE WARDLAW: But what you patented was his genome?

MR. KUCSAN: Exactly, Your Honor.

JUSTICE WARDLAW: Right. So you patented what was unique to Mr. Dolly.

MR. KUCSAN: We did patent his genome. That is correct.

JUSTICE WARDLAW: And under California law, there's many different theories under which he could sue for your having taken his likeness–identity theft, unjust enrichment—there's all sorts of other ways he could assert that interest under California state law, and that's what we have to look at when we're looking at the property right. Isn't that right?

MR. KUCSAN: Well, Your Honor, what you have to look at, first of all, you have to establish a property right under California law. And the closest thing that we have on point in *Moore*—

JUSTICE KOZINSKI: Well, he starts off owning . . . you own your hair, right?

MR. KUCSAN: Yes, I do.

JUSTICE KOZINSKI: If I were to walk up to you and start snipping pieces of your hair—

MR. KUCSAN: No.

JUSTICE KOZINSKI: You'd be against that?

MR. KUCSAN: Yes. I don't—

JUSTICE KOZINSKI: And so he starts off owning his blood, right?

MR. KUCSAN: Yes.

JUSTICE KOZINSKI: As it's flowing through his veins?

Mr. KUCSAN: Absolutely, Your Honor.

JUSTICE KOZINSKI: So you have to establish that he gave up that right. At some point the property right he did have disappeared?

MR. KUCSAN: Yes, Your Honor, and that's—

JUSTICE KOZINSKI: Then why isn't the most reasonable view of the matter that, if he said, "yes, I am allowing access to my blood to people who are going to test it according to the terms of our agreement. They can't drink it. They can't smear it all over their bodies. They can't sell it. They can't use it for artwork, because I did not give up that right. All I really gave up was the right for them to use it for the purpose for which I entrusted them and also, to have it discarded." It's sort of like having a

liver operation. You don't agree then to have the surgeon take it home and eat it.

Mr. KUCSAN: Hopefully not.

JUSTICE KOZINSKI: Well, it's a fact. You don't. How can you say that when somebody signs that kind of agreement, whether for an operation or to have testing done, that he expects that he has given up [his property rights]. He starts off owning it, just like you own your hair, and he gives up not just the right to have people test it as he has agreed and then get rid of it, but also the right for them to do anything they want with it?

Mr. KUCSAN: I think what's key here, Your Honor, is that what we're looking at is that there was consent to take his blood out, but after, there was no specific agreement as to—

JUSTICE KOZINSKI: So the surgeon can eat the liver? I'm just asking, you know. You think if the surgeon did that, you know, you have a liver operation, you have a liver transplant, and the Surgeon took it home and served it for dinner, that would be okay?

Mr. KUCSAN: Provided that there—

JUSTICE KOZINSKI: What? There's no *provided.* I mean, let's say it was just any hospital in Los Angeles. You go in. It's a liver transplant. You expect that when they take out parts of your body that they're going to use it for personal purposes like that? No?

Mr. KUCSAN: You don't—

JUSTICE KOZINSKI: You don't give your consent to that.

Mr. KUCSAN: I'm not expecting that anyone's going to go home and eat someone's liver. But, what you expect—

JUSTICE KOZINSKI: You don't give up that right. You don't give up the right for them to put it into, take a photograph of it and say, this is Mr. Kuscan's liver. You don't expect them to do that. Let's say it's a particularly funny-shaped liver, or it has a sort of tumor on it, you know. Right. You don't expect to have given up that right, do you?

Mr. KUCSAN: Well, they're not necessarily identifying my, in this case, my abnormal liver—

JUSTICE KOZINSKI: What is this allele called again? Isn't this the Dolly genome?

Mr. KUCSAN: Yes. It's called the Dolly genome, Your Honor. Yes.

JUSTICE KOZINSKI: He didn't sign up for that, did he?

Mr. KUCSAN: Well, all that's being published is his genome strand, which can be used for identification purposes or it can determine susceptibility—

JUSTICE CHIN: But isn't the thing that makes this case different the fact that now Mr. Dolly wants to sell his blood? And you don't want him to sell it?

Mr. KUCSAN: Well, what we don't want him to do, Your Honor, is infringe the patent, because we have a valid patent.

JUSTICE CHIN: But doesn't that go way beyond *Moore*?

Mr. KUCSAN: No, Your Honor. It does not. Well, it does not when you take into consideration whether it's a valid—

JUSTICE CHIN: You mean, if Mr. Moore wanted to then go out and sell one of his kidneys, the University of California could prevent him from doing that?

Mr. KUCSAN: He could have sold whatever. They had a patent on cell lines, a specific cell line. He could have gone out and sold other parts of his body as long as it didn't infringe the patent, just like Dolly in this case can go, if he wants, to donate his blood, he can. If he wants to have his blood removed for some kind of a surgical reason or hospital reason, that's fine. The only thing he can't do is he can't sell his blood, if [it's] for the sole purpose, like he has done through his Dolly deal, a partnership that he has set up. He can't.

JUSTICE CHIN: I follow you all the way through *Moore*, and then I get to Justice Kozinski's question. When did he give up the right to his genome, his blood, and what it contains?

Mr. KUCSAN: He gave up the right when he signed the consent form to have it removed, his blood removed, and then it was going to be discarded through normal practice—

JUSTICE CHIN: But didn't the consent form say that it was to be confidential? All the information resulting from that test was to be confidential?

Mr. KUCSAN: And all the information resulting from that test was kept confidential—

JUSTICE KOZINSKI: Well, the point is, the form did not discuss this situation. It didn't say and we reserve the right to take it and use it for experimentation or anything like that. The question of how the blood would be disposed of is silent on the form.

Mr. KUCSAN: That's correct. And that is—

JUSTICE KOZINSKI: But what you want to infer from that silence is that he, through silence, gave up what you have admitted is his property right.

Mr. KUCSAN: Yes, Your Honor. Well, he didn't give up. Well, there is no property right—

JUSTICE KOZINSKI: No, no, you said that it was his property when it was pulsing in his veins, just like your hair is your property as it's on your head right now.

Mr. KUCSAN: Right.

JUSTICE KOZINSKI: Okay. So something must have separated him, something must have. some instrument, some legal instrument or some act on his part must have caused the property right to stop. Agreed?

Mr. KUCSAN: Agreed, Your Honor. But once—

JUSTICE KOZINSKI: Okay. Even if you cut your hair off, unless you give it up or sell it, it's still your hair.

Mr. KUCSAN: Right. Even if I discarded it, I would agree.

JUSTICE KOZINSKI: Right. So what you want to say is that the thing in that agreement, the silence as to what will happen to it . . . [cellular phone rings]

JUSTICE KOZINSKI: We've held people in contempt for less.

JUSTICE WARDLAW: You know, it's my phone. I'm sorry.

JUSTICE KOZINSKI: Oh.

JUSTICE WARDLAW: My husband has his cell phone in my purse. Sorry . . . I don't think you have the power. You are a powerhouse, but not that powerful.

That may have been some spiritual intervention, actually, and that goes to my question. Justice Moss, the late Justice Moss, wrote a fascinating dissent in the *Moore* case, and he raised the spiritual blow and ethical issues that are attendant to any time someone uses another's body for profit or gain, and I'll just quote the statement he wrote: "Research with human cells that results in significant economic gain for the researcher and no gain for the patient offends the traditional mores of our society in a manner impossible to quantify. Such research tends to treat the human body as a commodity, a means to a profitable end."

Are we, as the Supreme Court of the United States, supposed to, in considering the enforceability of this patent, ignore the ethical and moral issues that are attendant to what you've done by taking or attempting to take the exclusive right to Mr. Dolly's identity?

MR. KUCSAN: No, Your Honor. This court should never ignore the ethical or moral issues like that.

JUSTICE WARDLAW: So how do we account for that in our ruling?

MR. KUCSAN: Well, Your Honor, first of all, there has to be a property or a privacy right that exists in order for Petitioner to say—

JUSTICE CHIN: It's his body. It's his identity. It's what is the

thing that is the essence of Mr. Dolly. That is what you have taken from him.

MR. KUCSAN: We've taken his DNA and found it has a resistance to HIV, and we now have a patent on that because we are the ones who discovered that. You also have to consider policy implications—

JUSTICE CHIN: But should we just allow anything in the interests of the progress of science? I mean, if scientists come to the Court, and admittedly, we don't necessarily have the top scientific background and that's why there are more judges probably, and, for the most part, [than] Nobel prize winning scientists, but you come to us, and you say, we need this in the interests of advancing the progress of science and that's what the patent laws do and that's what Thomas Jefferson wanted done, even though he didn't believe in monopoly.

So you come and you present all of this, but we're supposed to not deal with the moral and ethical implications of allowing a company to profit off the very essence of another human being?

MR. KUCSAN: Well, Your Honor, the essence of a human being is DNA. We're not taking this as DNA. We're not [doing] this to him in a way to harm or trample on any of his privacy or property rights, and I think that should be the focus.

This court should consider issues like that, and it does all the time. But in this situation, you have to weigh that against an infringement on a certain right, and here, we simply do not have infringement.

JUSTICE CHIN: But wouldn't this whole problem have been solved if your client simply would have gone to Mr. Dolly and said, "We have this potential of a great scientific breakthrough. Will you give your consent to this process and to have it tested?" And didn't Dr. Myers testify . . . that most people who are asked to give their consent under these circumstances, grant it.

MR. KUCSAN: Well, Your Honor, if I understand your question correctly, you're asking if once they—

JUSTICE CHIN: Wouldn't this whole problem be solved, if your client had simply gone to Mr. Dolly and said, "we have this opportunity to find a cure for AIDS and it might lie in your blood, in your genome. Would you give us your consent to have it tested?"

MR. KUCSAN: Yes, Your Honor. Assuming that Mr. Dolly—

JUSTICE CHIN: Of course, you'd have to have all of the profit somewhat divided.

JUSTICE WARDLAW: Maybe he wouldn't have signed it. I mean, that's another aspect of the *Moore* case that they left open—unjust

enrichment. Maybe he wouldn't have signed it unless you agreed that if your company were to discover something and profit off of it, you would share the profits with him.

MR. KUCSAN: I'm not sure.

JUSTICE WARDLAW: He didn't have that opportunity to participate in that decision.

JUSTICE CHIN: And didn't *Moore* say—

JUSTICE KOZINSKI: Those are big steps, very big steps.

JUSTICE CHIN: And didn't *Moore* hold that the individual could retain a property right if he had anticipated it and said, "I'll give you my spleen, but you're not going to test it without my permission?"

MR. KUCSAN: And that's a key distinction, if you sign such a form, then if they would have performed tests on it, it would have violated that agreement, and you'd also have a breach of fiduciary duties claim, and there—

JUSTICE KOZINSKI: You know something. You're really sneaky. You have these scientists, I mean, they know what these issues are. Most of us don't know about testing. You know, we go to the doctor and we go to the lab because we have a problem that we want solved. It doesn't occur to us. It's just not something that we think about: that the thing that we give them is going to be used for any purpose other than why we give it.

And doesn't it seem just totally sneaky, and just to follow Justice Wardlaw's question about morality and justice and things like that. Why should we reward sneakiness in this case? Your clients are not doing what Justice Chin has suggested, which is to be upfront and say, "look, we'd like to use the blood. We think this may have great promise to do great good for mankind. You know, join us in this great discovery." Instead, they sneak behind his back. Why should we countenance that?

MR. KUCSAN: Your Honor, I see I'm out of time.

JUSTICE CHIN: And you can't wait to sit down.

JUSTICE KOZINSKI: But just to show you how generous I am, I will give you an additional sixty seconds just for the purpose of answering that question.

MR. KUCSAN: Thank you, Your Honor.

JUSTICE KOZINSKI: So take your time and answer it as long an answer as you wish to give.

MR. KUCSAN: Your Honor, to follow up on that, we don't want to reward sneakiness, Your Honor. But it's standard practice in the industry to have these certain kind of forms.

JUSTICE KOZINSKI: They're all thieves? Is that the defense?

We're all thieves here?

MR. KUCSAN: Well, Your Honor, if you—

JUSTICE KOZINSKI: I mean, you understand that it won't be the standard practice if we say that we don't reward it, right? So the fact that everybody does it is not really a good answer, and you've only got about thirty seconds left.

MR. KUCSAN: Well, Your Honor, Mr. Dolly did not have rights in this situation. If they would have come forward and asked him and tried to get an agreement, would he have signed it? Probably not. Would a lot of people sign it? They probably wouldn't. And in this case, you have to reward the efforts that they made to obtain this patent, and it's not sneaky. What they did, seeing as his property and privacy rights discontinued when he—

JUSTICE KOZINSKI: You don't seem convinced when you say that *"Oh, it's not sneaky."*

MR. KUCSAN: I just, you know, it's not sneaky—

JUSTICE KOZINSKI: I'm not convinced.

MR. KUCSAN: Is my time up?

JUSTICE KOZINSKI: Thank you very much. Out of time. Out of time.

MR. KUCSAN: Your Honor, I'll just conclude by saying that it's just simply not sneaky. Thank you.

JUSTICE KOZINSKI: Now, Ms. Tsay, you have five minutes left for rebuttal. You are aware, of course, that most cases are lost on rebuttal. So you can take as much of those five minutes as you wish.

MS. TSAY: Thank you, Your Honor. Your Honor, contrary to what Respondent says, this case *is* sneaky. It's a case in which NuGenEra is trying to profit from something that Respondent has conceded is very obvious and yet, at the same time, violates Mr. Dolly's privacy and property rights. NuGenEra's preventing Mr. Dolly from—

JUSTICE KOZINSKI: Well, your client hasn't done anything so great, either. He got born. He didn't have much to do with that.

JUSTICE CHIN: And isn't he trying to profit from this, as well. He's trying to sell his blood.

MS. TSAY: Yes, Your Honor. Mr. Dolly is trying to sell his blood for research purposes.

JUSTICE KOZINSKI: And not for the rates that you get for selling blood when you give blood to the Red Cross, right?

MS. TSAY: That's true, Your Honor. However, every day, we see people selling their egg cells, their sperm cells, all in the name of profit.

And here, Mr. Dolly has a right to do so. It's Mr. Dolly's body, and he owns the property rights. Moreover, it would be a violation of his privacy rights.

JUSTICE KOZINSKI: But his blood would not be very useful or very valuable today if not for the work done by the other side.

MS. TSAY: That is incorrect, Your Honor, because his blood would still contain the HIV resistance.

JUSTICE KOZINSKI: But nobody would know if he went and tried to sell his blood. I mean, he would have no reason to think it's anything special, and nobody would want to buy it at an exorbitant price, right?

MS. TSAY: That's correct.

JUSTICE KOZINSKI: If not for the work done by the other side.

MS. TSAY: That is correct, Your Honor. They were the first to discover this. However, that does not give them a right to do this at the expense of being sneaky, in your words Your Honor, and especially not getting the full, informed consent of Mr. Dolly.

Here, Mr. Dolly was not told that they were going to use his blood for these purposes, and instead, they took his blood, took all the genetic information, and even named it the Dolly genome, letting the entire public know that Mr. Dolly had these certain characteristics, which he might have wanted to keep private.

Also they were preventing Mr. Dolly from making decisions about his blood. He no longer can sell his blood to a research facility. He no longer can make decisions about his own body, which violates his rights to privacy.

All of these are at issue in this case, Your Honor. These ethical issues, which it is the job of this Court to protect Mr. Dolly's constitutional right to privacy and his property interests in his body.

It is for these reasons that we ask that this Court find that this patent is unenforceable as a matter of equity. Thank you, Your Honors.

JUSTICE KOZINSKI: Thank you.

Well, in the normal course of events and a difficult case like this, we would go back and confer with each other and reach a tentative decision, and I say tentative because the way it would work is that each of us would express a view and then we'd talk to each other and go back and forth and sometimes, we change position at that conference. But even more often, what will happen is you'll have a tentative review. Someone will be given an opinion to write, and sometimes, we won't write that way. Sometimes, the [centrists] circulate afterwards and change the process, and sometimes we all change, or sometimes the reasoning changes.

So truly, what happens at conference is very tentative. I'm sure that's true on the California Supreme Court as well. It must be true in every court. It's certainly so in our court. But obviously, we don't have the time to do the whole process here and still let you all know what we're thinking. So what we're going to do is essentially do a little bit open conference.

We'll have each of us express our tentative views of what we've heard. We've been asked to speak about the merits of the case, and I don't think anybody should be either overjoyed or too unhappy with what you hear here, because the thing that we actually issue winds up being often very different from what the tentative views expressed.

So anyway, this will give you some indication of what happens after the lawyers finish arguing. Incidentally, I thought the arguments were all very good. This was a very difficult case, and I think this has been a tougher set of questions as we've, and as I've seen in a long time, and counsel stood up very, very well, particularly the two who were not law students, the engineering students. And I must say, all counsel were very good, and I, often just for my part, if I had to, say, pick which ones were the lawyers, if I hadn't known, I don't think I would be able to pick, and that really says something very good about the non-law students, because certainly, the two law student counsel were excellent. In any event—

JUSTICE WARDLAW: Do you want me to go first?

JUSTICE KOZINSKI: Go first.

JUSTICE WARDLAW: On our court, it's the junior judge who always goes first, and I guess I'm the junior judge on this panel in terms of appellate court. First, I want to concur with Judge Kozinski in his comments about our advocacy today. Each of you did an excellent job, an outstanding job, and I just want you to know that Judge Kozinski did not hold back. I have sat on panels with him. In fact, I'll be sitting with him soon again, and I enjoy it very much, but I have seen lawyers, lawyers with many, many more years of experience not able to respond to questioning or going down a path, and each of you did so very well. And I just particularly want to compliment the students, the Caltech students too, who actually faced this crucible and did it well. So, really excellent job.

My tentative on the validity of the patent would be to uphold the rulings of the district court, and basically, the flaw that I see in the patent is what the district court saw as to Claim 1, the lack of utility, whether we're talking about well-established utility or substantial specific and credible utility. It seems to me that at least as to the whole human genome, it is a hunting license. It's premature. There's a lot of research to be done. I don't see the practical effects either in the criminal identification utility or anything else that was offered in terms of gene therapy. We're just not

there scientifically, and certainly, there wasn't enough evidence in the record that would substantiate that.

I do think Claim 2 does have utility in a variety of areas. At least as to the P sequence, it does show the possibility of resistance to the AIDS virus, and that was shown to be useful with respect to the mice studies, and that's an identifiable use that our patent courts have upheld as meeting the utility requirement.

On the enforceability part however, I am very troubled about the consent in this case, and I think *Moore* certainly left open the cause of action based on lack of consent and breach of fiduciary duty, and if you read the consent in this case, it does not provide for sale of Mr. Dolly's blood to any other entity, which is what the record demonstrates occurred. It wasn't like NuGenEra just went scrounging through the garbage cans and found Mr. Dolly's blood. It was sold to them, and he did not consent to that. And so I have a hard time enforcing this patent on that ground.

With respect to the federal constitutional rights however, I don't see the state action, other than a possible argument. I see a right to privacy that's been violated here, a right to genetic privacy. I think we're probably someday getting to the path where the Court may uphold a right to genetic privacy. Certainly, the Ninth Circuit has done so, has upheld the right to genetic and medical privacy. So I see the right, but the issue there, the stumbling block there is the state action.

The only possible state action I see at this point is the fact that the Patent Office acted jointly with NuGenEra when it permitted disclosure of Mr. Dolly's full identity by disclosing his genome sequence in Claim 1. So that is the possible state action that I see, but I haven't fully analyzed that, and certainly, that was not argued today. And with that, I'll turn it over to Justice Chin.

JUSTICE CHIN: Well, I'm certainly glad we're following Ninth Circuit rules, because on the California Supreme Court, the senior justice speaks first. I was only the junior justice for two months, so I didn't have that much of a benefit, but it is a benefit to hear your senior colleagues talk about the case, and I certainly benefited from Justice Wardlaw's preliminary analysis of these facts.

Preliminarily, I also want to agree with the Chief Justice and Justice Wardlaw about your performances this evening. I thought they were superb. I've been on an appellate court now over 12 years, and I don't often hear arguments that are better than your responses to very difficult questions. Justice Kozinski is a tough questioner. He often times seems to be toying with you and being jocular with you, but his questions are very serious, and I thought, for the most part, your reactions to them were

superb.

On the merits of this particular case, on Claim 1, I'm in full agreement with Justice Wardlaw, and I would uphold the decision of Judge Patel on the trial court. I think it does lack utility. I have real problems with granting a patent for someone's entire genome. And I'm not sure that it advances the purposes of patent law, which is to advance science.

And my example to the participants was the dispute over making the mapping of the entire human genome project public. Doesn't that advance science more? That was certainly the position of the government-funded project, and I would realize that Craig Venter, who was the president of the private entity, had other ideas, and the government handled it by simply posting on the Internet as each sequence was completed. So I have real problem with the utility aspect of the first claim.

On the second claim, with regard to the sequences P1 through 10, I think that the problems with the RFLP analysis are less pronounced. I can't even begin to know how you would do diagnostically the entire genome under the RFLP process, but if you can, certainly do sequences P1 through 10.

I also think that there is enough evidence in the record to show that there was an isolation of a particular compound that proved resistant to the HIV virus in sites P1 through 10, so I would affirm.

And I think the discussion that Justice Wardlaw had with you about consent is very important. I mean, after all, that question was left open in *Moore*. And the court did hold, I suspect in the future, [that] people will write those specific areas of consent into those agreements, as these kinds of cases start coming before the courts.

I also agree with Justice Wardlaw on the genetic privacy issue. I believe the Ninth Circuit—was it in *Norman*?[7]

JUSTICE WARDLAW: *Norman*?

JUSTICE CHIN: Norman-Bloodsaw, something like that.

JUSTICE WARDLAW: Versus Berkeley Labs.

JUSTICE CHIN: Right. That was an interesting case, and it was really based on the fact that each of our genomes is unique. I mean, even though 99.9% of it is common, that part that is not common makes us unique, so I think it's possible, I'm not going to prejudge it. We'll hear it when it comes before us, but it's certainly a possibility.

I think hanging the hat on state action as far as the Patent Office is concerned is a little slim. We'll figure it out when it comes before us.

7. Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260 (9th Cir. 1998).

That's all I have to say, Mr. Chief Justice.

JUSTICE KOZINSKI: Thank you, Justice Chin. Well, I'd like to affirm, if I can or could, but I'm not entirely sure.

I agree with my colleagues that in fact, I don't find the utility question difficult at all as to the second claim. I think there was more than enough there to support the finding of utility, given that great deference that we owe the Patent Office, and the even greater deference we owe the position of the district court affirming the Patent Office. So I don't have much difficulty with that.

I have difficulty, and I'm not entirely sure whether it is within the question presented, and maybe that's the answer, but it was alluded to in the briefs, so I think that it's something we need to look at. But I have some considerable difficulty as to whether this is patentable subject matter at all, where you can take something out of nature and the very process of finding that thing that is particularly useful.

Because that's all they did. They took something that exists and they found the process. They determined through a certain process to find the one item that was very helpful. But they didn't change it in any way, and the process itself is not something they invented. They didn't come up with a new way of identifying whether somebody is immune. That was known. They didn't, as far as I can tell from this record, identify any new method of sequencing a gene. That was known.

So to me, I have great doubts about patentability in terms of whether they did anything at all inventive. They had plenty of luck, and maybe that itself is a form of inventiveness. But to me, I don't see the inventive force here. They took a lucky situation and they capitalized on it, but I don't know whether that is enough in the patent laws to merit a patent. So I have doubts about that. And if it is within the question presented, I'm not sure I'm going to be able to affirm the district court on this issue.

I agree generally with what my colleagues have said about privacy. I do note that the one precedent on point is from the Ninth Circuit, and of course, that's a court that we frequently agree with. Of course, we more frequently disagree with it too.

But accepting that precedent as given, that was a very different case. The *Norman* case was a case involving the use of somebody's genetic material to identify derogatory personal information about them, like the fact that they have certain genetic illnesses or similar traits. But to me, the situation strikes me as very different. The privacy interest involved in not having somebody take your blood and thereby find out things about you personally, strikes me as very different, somewhat different anyway, than the privacy interests involved here, where really the purpose was not to

identify anything about this particular person. The information was released. But the whole thing could have been done without knowing anything about who the originator of the blood was.

So I'm going to have to think about that. But I agree with my colleagues that in the end, in order to have a constitutional claim, you do need state action, and using the Patent Office or even the district court as a state actor in this case takes the unique case of *Shelley v Kraemer*. It is sort of unique. It's an old case that served its time, a little bit further than I think it's going to be possible to stretch it. So, probably [on] the privacy claim, I think we're all going to be entering that it does not succeed.

Again, you should take the views we express tentative and you know, we may well come to different conclusions when the time comes. We have, I think quite appropriately, paid compliments to the advocates here. I do want to say a word or two, and I know I'm speaking on behalf of my colleagues, thanks to Loyola Law School and Caltech, and the professors involved in this program, because I know these kids didn't get here just on their own work, performing as well as they did.

I know that a function of the schools is that they train people. The program of marrying law and technological issues, often two disciplines that are like oil and water. They don't want to mix, and having a program that focuses on this and on the fact that often, lawyers are not very good at talking about technical issues, and scientists are sometimes, often, not very good at speaking to lawyers, and training people and focusing on this, and training people who are able to speak to both disciplines is extremely important, because we are increasingly moving into an age where questions like the one here and questions like this arise every day now, and not only is there a lot of money at stake, but welfare, health, the way our society functions depends on having these kinds of issues decided and decided correctly, and decided in a formal fashion. So I think Loyola Law School and Caltech are really to be commended for being ahead of the curve here, and for training people who are able to deal with these very important, very difficult issues.

JUSTICE WARDLAW: Hear, hear.

JUSTICE KOZINSKI: Okay. Thank you very much. We are now adjourned.

COURT CLERK: Please rise.

MR. MANHEIM: Thank you, Judge Kozinski, Judge Wardlaw of the Ninth District and Judge Chin of the California Supreme Court. And I'll thank you as well for supporting this conference. Tune in to our website, http://techlaw.lls.edu. There you will find all the court records for this case. You'll find the court's opinion when it is published, and you'll

find information on upcoming events. Thank you all for coming.