Fordham Intellectual Property, Media and Entertainment Law Journal

Volume 4 *Volume IV*
Number 1 *Volume IV Book 1*

Article 34

1993

Panel Discussion

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PANEL DISCUSSION

MR. RICHARDS: I'd like to make one observation. You condemned the European Patent Office. It's not the European Patent Office that's the problem. The European Patent Office has been remarkably inventive in finding its way around the problems created by the European Patent Convention—

MR. MISROCK: It's the legislators.

MR. RICHARDS: —in method of treatment claims, animal variety claims, plant variety claims, the computer area. Everywhere it gets the chance, the EPO minimizes the destructive effects of the Convention as much as possible. But, it's got to go back to the legislatures. There's nothing much more the Patent Office can do.

MR. MISROCK: I agree. Any questions anywhere?

AUDIENCE MEMBER: I wanted to address all the panelists. As far as morality issues in the United States, I agree with Professor Wegner and Mr. Misrock. One point, one cannot obtain a patent for anything that impacts on nuclear energy. That's something that this country thought about a while ago.

MR. MISROCK: And that's statutory.

AUDIENCE MEMBER: That's statutory. The second issue is that we have the NIH Guidelines on Recombinant DNA Technology,[1] and that will always impact as to what direction DNA technology goes. As a future patent attorney, I think it's an exciting field. With the explosion in discovery going on today, we are about to realize the dreams of yesterday's cures and the hope and reality of curing today's diseases. I think that's an important focus.

Now, Mr. Misrock, you mentioned the *Amgen*[2] decision, as far as the Patent Office has said, a case where the technology was from 1980 that you couldn't have conception or reduction of practice in a DNA sequence.

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1. National Institutes of Health: Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958 (1986).

2. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991).

MR. MISROCK: And, of course, the same judge, Judge Lourie, writing in the recent decision of *Fiers v. Sugano*,[3] reiterated it and has held, of course, that you do not invent a gene—you can't conceive a gene and you don't invent it—until you have its structure.

AUDIENCE MEMBER: That was all based on technology from the 1980s. How would you conceive of advising your clients today? With polymerase chain reactions, if one had a particular sequence in a gene, might not you argue for enablement, and possibly conception, of the entire sequence?

MR. MISROCK: I would argue for it. But given the fact that I think that Judge Lourie has backed himself into a corner, and since most of the other judges don't have the background in biotechnology, I think that we're going to be stuck with that for some time. It was technology in the 1980s that he was addressing, both as to *Fiers v. Sugano* and *Amgen.*

PROFESSOR WEGNER: But there's another way of looking at that too, isn't there? Both of those cases really stem from *Oka v. Youssefyeh*,[4] involving conventional organic chemistry. Youssefyeh had the structure of the compound in hand but did not have an operative method of making that compound; it required further invention. So what the Federal Circuit Court held in *Oka v. Youssefyeh* was that until you have an operative method for making the product in hand, you don't have a conception.

I think a good lawyer in this situation will bring in an affidavit that can explain that his invention is operative as of the date of the structure being shown and should be able to prevail. I would hope he would do so at the Board of Appeals level; and if not at the Board of Appeals level, at the Federal Circuit Court. Certainly, one who has an affidavit that proves that this structure "X" pictured at this time was operative would certainly win in the Federal Circuit.

MR. MISROCK: Look at the mischief that was done with the

3. Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).
4. 849 F.2d 581 (Fed. Cir. 1988).

case called *In re Durden*.[5] *Durden* held that a process otherwise obvious was not rendered unobvious or nonobvious by reason of starting with a material which didn't exist before, new starting material. Thereafter, whether it was Group 180[6] or otherwise, the Patent Office almost cleaved into two parts: the routine application of *Durden*—no process being allowed on the grounds that the manipulative steps were the same—and, on a case-by-case basis, some examiners allowing claims when you have brought the argument out that you could not have predicted whether or not reasonably you were going to make molecular spaghetti or you were going to make a particular product.

There is even proposed legislation, as there has been for some time, that *Durden* ought not to be applied. I don't like to see the statute changed on a case-by-case basis because of problems that we're having in the Patent Office. *Durden* has created a lot of mischief.

The bigger problem that I see now in the Patent Office in the United States is Group 180 running off in its own direction with respect to human therapy. They are taking the position that even though you have animal tests, if you have a claim to the method treatment of a human by giving a diseased patient a drug in a therapeutic amount, et cetera, that they want human data. It started with the AIDS cases and it has now expanded to others.

Recently, we received in our office a forty-seven-page Office Action. I've never seen that, in thirty-eight years that I have been in practice. I'm scandalized that this thing looks like an FDA rejection as opposed to application of patent law. Now, I've talked with some people who routinely practice in the Patent Office with what I call small molecules in drugs, and those groups are acting the way the law states. I think that issue is going to have to be taken up to the Federal Circuit or someone is going to have to teach a lesson to the group director to bring them in line with what the law is on human therapy.

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5. 763 F.2d 1406 (Fed. Cir. 1985).

6. Group 180 is the Biotechnology Unit of the United States Patent and Trademark Office.

PROFESSOR WEGNER: There have been several Board opinions in that area.

MR. MISROCK: There are three unpublished opinions in that area. We can't get our hands on them, but they apparently have a policy which Group 180 has now adopted with respect to this human therapy.

PROFESSOR WEGNER: There are several more than that, I think, and there will have to be a test case.

MR. RICHARDS: In the Proposed Directive, the comments made by the Commission in putting it up to the Council goes to this issue somewhat. It goes without saying that if the applicant simply wishes to patent a mere part of the human body, per se—e.g., a human gene—neither the function of which nor the protein for which it codes is known, the exclusion of patentability will apply. This is clearly a blow to the NIH and its Human Genome Project.

But, I think that it does point out that if you know what the gene codes for, then you essentially know how to make it because if you know what the amino acid sequence is, you know what the DNA sequence is, and you can use a gene machine to synthesize it.

MR. MISROCK: But, John, I have taken the position that utility generally is easy to obtain in the United States. If it makes a protein, you can always eat it as a food; if you do that, that should meet the utility requirement of the statute.

MR. RICHARDS: But not all proteins are nontoxic.

MR. MISROCK: Well, then the patent's invalid.

PROFESSOR WEGNER: On the question of *Durden*, there is a Senate bill that was introduced February 3, 1993 that has cleared the Senate subcommittee.[7] There is also—and again, I don't want to get involved in my own cases—but I have a test case that was argued November 2, 1992 called *In re Ochiai*[8] which directly chal-

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7. S. 298, 103d Cong., 1st Sess. (1993).

8. No. 92-1446 (Fed. Cir.), *on appeal from*, No. 92-2372 (Bd. Pat. App. & Interferences July 8, 1992).

lenges *Durden*. That case is awaiting a decision.

MR. MISROCK: With respect to morality, Oreste, we have no statutory provision that something is not patentable because of public policy or it being immoral. I will tell you, though, that in thirty-eight years this has been the law in the United States.

I take the position, for example, that the patentability of animals ought not to be restricted, that there is a rule of reason about what you can get. I have used—and I hope you don't mind my facetious statement—but suppose that somebody took a pitbull and they took the eight-cell embryo of the pitbull and they moved in bovine growth hormone so we now have a pitbull that grows to the size of a cow—a cow-sized pitbull. Thereafter, that same genius took the eight-cell embryo of that cow-sized pitbull and moved in the genes from a viper so that when the pitbull grew up it was poisonous, so you have a poisonous cow-sized pitbull. Is there a need for it? Maybe some drug dealers up in Harlem, would like cow-sized poisonous pitbulls for protection or something like that.

There's not the slightest doubt in my mind that the Patent Office—and if not the Patent Office, the courts—would refuse to issue a patent on this subject matter because it's against the public policy of the United States, without it being enunciated by statute. It just makes sense. So I don't see the need for a statute with respect to the patentability of animals or transgenic animals, particularly when they have utility and use for the treatment of human disease, not just production of more milk or something like that.

MR. RICHARDS: I think we would probably all agree with that. One thing I can't understand with what's going on in Europe at the moment is why the prohibition on plant varieties remains. The UPOV Convention itself was amended to permit protection of plant varieties.