Fordham Intellectual Property, Media and Entertainment Law Journal

Volume 4, *Issue* 1 1993 *Article* 33

VOLUME IV BOOK 1

Panel Commentaries

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PANEL COMMENTARIES[†]

S. Leslie Misrock*

I will begin by asking you to keep your mind on the narrow definitions of what constitutes patentable subject matter under the European Treaty as I discuss with you my vision of some of the things that will happen within the next decade in biotechnology.

In my personal opinion, within the next decade—certainly by the turn of the century—we will see genetic therapy which involves a patient being operated on, laparoscopically removing tissue in the operating room from a specific organ, pancreas or otherwise, while still anesthetized, that tissue or those cells transvected with a viral vector to move the desired gene into it, and then put back into that patient and reimplanted so that that patient essentially will have the gene genetically, surgically inserted into the particular patient.

The manipulative steps in all of this, the patentable subject matter—and I'm going to focus on what the American law is—will cover not merely the particular viral vector that is used, the pieces, whether a new gene or a particular control gene; at the same time, it will also cover the manipulative steps of removing tissue laparoscopically, transvecting that tissue, and the moving it back into the gene. Will that be patentable under United States law? In my judgment, absolutely.

I think you will see transgenic animals—swine, for example—capable of making human blood; you will see transgenic cows capable of making human antibodies in their milk, such that when the cow is inoculated to DPT (diphtheria, pertussis, etc.), that cow will make human antibodies. No youngster has an immune system for the first three or four months, so ingestion by a infant of milk

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[†] The following three panel commentaries were presented at the Fordham Conference on International Intellectual Property Law and Policy held at Fordham University School of Law on April 15-16, 1993.

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from that cow will in fact lead to passive immunization. Will that transgenic animal be patentable? In my judgment, absolutely.

I think we are going to see a revolution in treatment.

Finally, as the Human Genome Project accelerates, even though there has been a great deal of controversy about whether you should be able to patent DNA libraries, et cetera, I think you will see, for example, from disease states—I am particularly interested in prostate cancer, but it will be so with every cancer—such that from a healthy patient all the way up to one that is in the final stages, that is terminally ill, you will get a genetic modification map that tells you exactly where that patient is staged so that the approach to treatment of that patient will be a systems approach rather than the approach of using a "magic bullet," one drug, to do something. That's inevitable.

Now, contrast some of the technologies that are talked about with what exists in the European Patent Office—with the definition of "morality," which is incomprehensible to me. I don't know what the morality would be in Ireland with respect to the ability to preclude birth upon demand; is that immoral? With respect to using animals to prevent human disease, is that immoral? Obviously, these arguments will be raised by the Greens or otherwise. So I see many, many problems coming about in view of John's description and the things that are happening in the European Patent Office.

And yet, this technology is real. It will be done not only in the United States; it will be done in Japan; it will be done at the major pharmaceutical companies and the universities in Germany, in France, et cetera. This revolution in biotechnology is real.

What will that lead to? I think that if there is difficulty in getting patents to cover this technology over the next decade, it is inevitable in this country, notwithstanding the fact that we have joined all sorts of treaties for first-to-file procedures; that's almost in the Dark Ages compared to obtaining patent coverage on the subject matter I'm talking about. I think that we are going to see what I will call a "reciprocal retribution." Will it come up in the Patent Office in this country? No, it will come up in the courts.

When a foreigner gets a U.S. patent—essentially plays by our rules to get something, even though it's not patentable within his or her own country—I think it is inevitable, when this will come up in litigation, for a defendant within this country to try to break that patent, one way or another. That defendant is going to argue, "We don't have a level playing field. We ought to be able to get the same treatment there that they get here." This is similar to what our President is now saying with respect to opening up Japan as a market, notwithstanding the fact that we probably make defective goods and can't meet the Japanese requirements.

So my basic instinct is that the restrictions and constraints that are being placed on the ability to get patent coverage on very important technologies, the restrictions that are being placed on them by the European Patent Office, will ultimately rebound against European companies when they come to the United States to similarly get patent coverage on these same technologies.

How it will be done, I won't speculate, other than to say that it probably will be done in the courts by imaginative, aggressive attorneys and trial lawyers attacking the patents that issue in the United States to such foreigners.

Now, a little bit of history with respect to some of the things that John talked about. The *Argoudelis* case[1] in the United States in the late 1960s sanctioned the deposit in a regulated recognized depository of specific cells as the basis for meeting the requirements of section 112.

For those who are not patent lawyers, we have in our Patent Act a section called 112,[2] the first sentence of which has two clauses. The first clause, known as the "enablement clause," reads: "The specification shall be written in such a clear and concise manner as to enable the persons skilled in the art to which the invention obtains to practice the invention." The second clause then goes on: "And shall set forth the best mode known to the inventor."[3]

1. In re Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970).
2. 35 U.S.C. § 112 (1988).
3. *Id.*

Deposits are not required in the United States to meet the requirements of section 112. The cases say that. The most recent case, of course, is the *Amgen v. Chugai*[4] case in the Federal Circuit, which is important not only for the holding that you cannot conceive or invent a gene until you know the exact sequence of that gene, whether you describe it or whether you have obtained it in such a manner that it's unambiguous; but, it also held that the failure to deposit in this particular case the transvected cells with the gene for erythropoietin was not a fatal defect in Amgen's patent on transvected cells to make EPO.[5]

Argoudelis came about because the applicant at that time didn't know how to describe a new yeast, which was *Saccharomyces cerevisae*, that he was using for fermentation to make ethanol.[6] He deposited with the Northern Regional Research Laboratory—which is an agency of the Department of Agriculture—and it was a cell depository. The Patent Office rejected his case. The then United States Court of Customs and Patent Appeals—the predecessor to the Federal Circuit Court of Appeals—held that this was a sufficient description when this was done. Thereafter, of course, there were deposits of unknown organisms, organisms which were used for antibody production, and the like.

With respect to the issue of the patenting of life forms, few people realize that we have had many earlier cases than *Chakrabarty*[7] in the United States, which was touted as the first case on the patentability of living material.

There was an earlier case, called *Funk Seed*,[8] in the U.S. Supreme Court which held that products of nature are not patentable. As a matter of fact, that case more or less was distinguished by all the subsequent cases that led to what we now do in biotechnology. That case related to a composition comprising four Rhizobia for nitrogen fixation. The Court never took up the question that these

4. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991).
5. *Id.*
6. In re Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970).
7. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
8. Funk Bros. Seed v. Kalo Inoculant Inc., 333 U.S. 127 (1948).

four components were four living things.

The earliest case going back to living material was in the early 1920s, Chaim Weitzman's patent for the fermentation production of butanol. Weitzman was a member of the staff of the British Government making acetone and butanol during World War I. These patents were then litigated in a case called *Union Solvents*.[9] The judge concluded that there was a sufficient description of the organism—there were no depositories in those days—held the patent valid, and speculated that he might not have reached the same conclusion if the invention had been the organism itself. That was only dicta, of course, and we didn't revisit that issue until it finally came up with *Chakrabarty*.

Lastly, after *Chakrabarty*, I had a case called *Hibberd*[10] which we expected to lose in the Patent Office and win in the Federal Circuit. That case held that plant seeds and plant tissue culture were patentable subject matter within the statutory classes of section 101, even though you could have obtained a Plant Variety Protection Certificate.

The Patent Office took the position that the UPOV Treaty, as they called it, was a treaty which by its very terms shrunk the meaning of section 101 of the Patent Act. On investigation, we found out that UPOV is not a treaty, it's an administrative agreement that was never submitted to the Senate, nor has this 1991 amendment been submitted to the Senate, and, consequently, you can get patent coverage in this country for plant seeds and plant tissue culture. Additionally, you can get a Plant Variety Protection Certificate on a specific species within the same genus that you may be covering within that particular patent.

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9. Guaranty Trust Co. v. Union Solvents Co., 54 F.2d 400 (D. Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932).

10. Ex parte Hibberd, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interferences 1985).

Oreste Montalto*

You say that this scientific province is going so fast that many times people do not understand it. This is also the case with morality. You talked, for instance, about the blood of a pig that could be useful for humans. Of course, that would be a very good thing, although I suppose some people have some doubt.

But then, we can say in defense, "What happens if I say that I would like to have the choice whether I have a daughter or a son"—Okay, why not? And then, after I say that, I could say, "I would like to have a two-meter son so he can play basketball." Why not?

In some ways the problem is a problem of a boundary, where it is or is not. Not all people are so sensitive as you are. Of course, we cannot stop progress. But many times there are many people who say, "Maybe we are going too fast; it would be better if we could stop progress." It's not possible, I understand this, "But it would be better," some people say.

You know that in the Commission, after the Parliament's Amendments, we are obliged to amend the Proposed Directive. This Directive will take into account what the Parliament says. The Parliament is very important for the Commission, because, first of all, it has the power of motion of censure. That means that they may vote that the Commission must resign, and so our politicized Commissioners are sensitive to this point.

Secondly, in the Parliament there are what we call the Greens—the ecologists—who have a lot of power. They are pushing the Parliament to adopt their solutions. They are a very large majority who are opposed to the decision of EPO to patent the "Harvard mouse." Some of the Green groups attacked their opponents in front of the High Court of Justice in Brussels when we were waiting for the European Patent Office ruling. And so, of course, the Commission had to take account of this.

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It became clear that the combination of a biotechnological invention should not be left out in the dark. The concept of exclusion from patentability concerning the public policy and morality was not sufficient to meet the concern of the public opinion, that is true.

The Commission did consider whether the object of the Directive is not to talk about a moratorium for this action. They just proposed to harmonize the Member States' patent laws. We say we want that.

Article 2, as amended by the due date in the Directive, is just guidelines for assisting the national patent offices and the national courts in interpreting the concept of the patent policy and morality. This article provides only that products be excluded from patentability as being contrary to public policy and morality. We consider that as just: (a) the human body or parts of the human body, per se; (b) processes for modifying the genetic identity of the human body for a non-therapeutic purpose which is contrary to the dignity of man; and (c) processes for modifying the genetic identity of animals which are likely to inflict suffering or physical handicaps upon them without any benefit to man or animal.

The other important amendment which was introduced was the Farmer's Rights or Privilege. It provides a possibility for the farmer to use part of his harvest obtained from the patented seeds that he receives to resow his fields for his own benefit. The Commission was against that because we consider that this is against the very essence of the property right.

Now we are discussing it in the working groups of the Council. There are two working groups already formed, and you have already heard there is a third one. Even the new reduction has been made about ethics. But in any case, even with that there are problems.

MR. MISROCK: Let me interrupt you for a second. Whose ethics? The ethics of the European Patent Office members?

MR. MONTALTO: No. The working groups are made and composed of the representatives of each Member State's governments, the patent office of each national Member State. They have

final approval; if they say "okay" on the final, then the Council approves it. The Council of Ministers, on the other hand, of course, doesn't understand anything more or less about the design, and so they await additional information.

Even with that there are problems. Some people have some dedication that they are not convinced until now, even if there is a reduction, there will be some amendments.

We are also waiting because the Commission last year created a special council. This very important working group, counseling group, will give—maybe in the next month, its feelings about the amended Directive. Because of the importance of this group, it may be followed and it will be easier for us.

The other problem was the question of rights. We had a lot of problems because many Member States, Germany and some others, said it is not possible to accept this point. We are finally reaching a near-compromise. It has been accepted since by many Member States to say, "We have to find a solution, looking at it as substantive rights." We do not talk about privileged farmer protection, but, we say that in this case, for instance, patented microorganisms might be marketed with a view to a specific application the success of which depends on the purchaser multiplying the microorganisms. So, when the agreement is signed, the patent-holder sells the seeds to the farmers, the purchaser has the right to reproduce the microorganism, and then, as a subsequent right, the right to again resow his field. But, he cannot sell it in any way; he just can use it himself, but, not sell it to other people. This solution maybe will be accepted in the future.

Finally, I want to say that we are waiting for a common position. Denmark already has said that they are not presently able to push to have a solution because they know that it will be very difficult since the public opinion's sensitivity to this issue in Denmark is so high; so, they don't go on. It will be possible to reach a position.

Harold C. Wegner*

I have five brief points. Overall, we can look at the world as a triangle comprising Japan, Europe and the United States. On all five points Japan seems to be in a pretty good position. Japan values biotechnology and has done a very good job of moving its law, and shaping its law.

The first point responds immediately to the question of patent coverage. I think in an ideal world Germany, France, Great Britain, the United States, Japan and other developed countries all would *want* to have a definition of patent-eligible subject matter to cover everything. I don't think there's any question about that among the experts.

The problem arises in both the United States and Europe that when we push the bubble into new technologies, we have horror stories and fear stories. We have heard about Europe. What about the United States? We have had the "Harvard mouse" patent issued, then no further "living invention" patents for a long time. And then, during the transition between the administrations, the Patent Office slipped out a few more mice and other animal patents. Already, there is not only talk, but there is legislation proposed by Senator Hatfield and others to have a moratorium on animal patenting.[1]

There are all kinds of moral—or immoral—issues involved. I say "immoral" because some of the opposition is purely economic. If we have genetically manipulated cows that can produce twice or thrice the amount of milk, isn't that *good* for mankind? It hurts the farmers, but isn't that good for the starving children of the developing world?

One of the considerations I have when we address the Geneva Harmonization Convention or otherwise, is whether we should put

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1. S. 387, 103d Cong., 1st Sess. (1993).

patent eligibility aside for the time being, and get forward with all of the other more important changes we need?

Point Two: On reciprocal retribution, I think the real loser is not the United States, but Europe, if they don't have patent protection. Maybe the U.S. patent owner doesn't have the opportunity to share his technology and get economic benefits from European patent protection. But the real loser would be Europe because, after all, if the technology cannot be exploited in Europe, and unless there is an exclusive position through patent or the health ministry or somehow, there is no way to absorb the regulatory cost of the tens of millions of dollars and years of time for approvals that need a patent base. So the real loser will be Europe. Europe, in its self-interest, eventually, will find a way to introduce protection when the time comes, when it's necessary. But for the moment, again, I think it's dangerous for us to push the bubble on scope of patent-eligible subject matter.

Point Three: The Proof of Utility. Judging whether an invention is useful or industrially applicable as compared to Germany or Japan, the United States is behind. What happened is that in the 1960s, when we had the really low point of our judicial system for patents and the Supreme Court was in its darkest hour, we had a case called *Brenner v. Manson*.[2]

In doing a comparative study of the standard of usefulness in the United States versus the European and Japanese standards, America is very much behind. Here I would like to see America learn from Europe and Japan.

Let's give an example. Let's say that I have a chemotherapeutic agent. We'll take the *Jolles* case[3] in 1980. We had one set of clinical trials and one compound in a broad generic definition of compounds. We had Dr. Morell do tests on six different compounds on animals, and we eventually got the genus, but only on appeal.

Today, the U.S. Patent and Trademark Office is routinely deny-

2. 383 U.S. 519 (1966).
3. In re Jolles, 628 F.2d 1322 (C.C.P.A. 1980).

ing patent protection for chemotherapeutic agents where there exists a broad generic definition of various possible chemotherapeutic agents. The Patent Examiner is saying, "You should test all these compounds." Well, if only *one* of the compounds is the clinical trial compound, it's almost Mengelian to say you should test all of these compounds for patent purposes. Are we to use people as guinea pigs to see if the patentee should get a *patent*? How foolish, how counterproductive. If we don't use humans, we use Rhesus monkeys. Are we supposed to sacrifice dozens of monkeys to get a generic claim? The question answers itself. I think the United States should learn from a comparative basis what's going on in Europe and Japan.

Point Four: The Patentability of the Products of DNA. I share Mr. Misrock's view that these are patentable. I also share Mr. Richards' view.

I think the House of Lords decision on t-PA was fact-specific.[4] In contrast, counterpart patents in Japan were used effectively. Genentech shut down Toyobo in the Osaka District Court.[5] So, I think fears of lack of protection are exaggerated. Japan has taken a leadership role.

Point Five: The Scope of Protection. In all areas of technology we look first and foremost to a claim. We chart out the claim, the definition of what our scope of protection should be. We talked about "Swiss cheese" claiming earlier today and how Japan has improved its practice to fill in the holes. If you have a claim for a range of one to ten widgets or units, I will have protection for one, two, three, and so on to ten, and six *will* be included; there will be no exclusion within the literal scope of my range.

The question then is: To what extent do we permit expansion of the claim—the scope of protection—in biotechnology? I think this is one of the very critical issues. It's something that we can't summarize in 180 seconds—we probably can't summarize it in 180 hours.

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4. *See In re* Genentech Inc.'s Patent, 1989 R.P.C. 147 (Eng. C.A.).

5. *Japan's Court Rules Toyobo Infringed U.S. Medical Patent*, Japan Economic Newswire, Oct. 30, 1991, *available in* LEXIS, Asia Pacific Library, JEN File.

My contribution on this is entitled *Equitable Equivalents*, which deals with equitable equivalents particularly in biotechnology.[6] I submit that a resolution of this issue, and the gaining of some common understanding among the various countries as to how equivalency should be determined in this area, is of very, very great importance.

Finally, I would like to thank everyone for their patience, and particularly Mr. Montalto for speaking in a second language. I am very grateful for your participation in this conference and for coming from so far away.

6. Harold C. Wegner, *Equitable Equivalents: Weighing the Equities to Determine Patent Infringement in Biotechnology and Other Emerging Technologies*, 18 RUTGERS COMPUTER & TECH. L.J. 1 (1992).