Comparison of the Patent System of the U.S. and Select Countries
Joseph Straus, Ph.D.

DR. TUCKSON: So I negotiated with the people in line. There are a few people in line, and the thing is that somehow or another they ran out of food at one of the stations. So everybody sort of crowded around one thing and not the other thing, and I can't control that. So I felt guilty, but I told them this. For those of you that are in the audience, I told them that when they came in, they should whisper to their neighbor who would fill them in on the parts they missed, and they all seemed happy with that.

So without further ado -

DR. FITZGERALD: You mean there are some things out of the chairman's control?

DR. TUCKSON: Exactly, the humility of the chair. You see, I had done all that lead-up to turn it back to our chair, Jim Evans, and Jim is not there, so now I've got to fill in again.

DR. SEGER: Actually, I'm standing in for Jim.

DR. TUCKSON: Oh, you're standing in for Jim?

DR. SEGER: Yes, Jim has now become a blonde woman.

DR. TUCKSON: Well, there you go. That explains what it is. Take it away.

DR. SEGER: All right. Our next session will explore how gene patents are issued, licensed and enforced outside of the U.S., with a specific focus on Europe and India, and whether these patent policies aid or hinder the availability and use of genetic tests.

Our first speaker is Dr. Joseph Straus, who is the director of the Max Planck Institute for Intellectual Property, Competition and Tax Law in Munich. He is also a professor of law at the University of Munich and has served as a visiting professor of law at many international universities. Dr. Straus has served as a consultant to the OECD, WIPO and the European Patent Organization, as well as others, and was selected as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property for the past three years.

Dr. Straus, we are delighted that you are able to join us today.

DR. STRAUS: Well, thank you so much for this, let's say, exaggerating introduction.

Ladies and gentlemen, good afternoon. It's the first experience that people have to eat and to listen. I've been told that everything is under control, nearly everything, not everything.

(Laughter.)

DR. STRAUS: Nearly everything is under control. Of course, somehow I prefer to have less audience but not a sleeping audience already digesting. So that's also one of the aspects.

Actually, this morning my colleague, Professor Gold and the lady, they actually have taken away quite a lot of information which I intended to give to you about Europe. So I can concentrate

maybe on some less issues and maybe we can have more time for a discussion or for your questions.

The overview here is showing you, first of all, that there is one - I would say from the mental difference between the United States and Europe, but also the rest of the world, that we have actually a statutory approach on patenting genes in general, as reported that started with the European Directive adopted in 1989, 1998. We have therefore a number of issues in the air not actually yet decided because our courts did not have the opportunity to apply those rules in practice yet. So I will be reporting a little bit about the patent practice, the differences here, about the exploitation and enforcement, and try to summarize a few things.

Now, the first slide you have seen already, reported by Richard Gold this morning, that under the European Directive actually we have specific provisions dealing with eligibility of genes for patent protection. Here only one additional comment. He said there was a certain, let's say, disagreement; what does that mean? Does it mean that genes cannot be patented to say more specifically genomic sequences? I would say genomic sequences of course can be patented if they are not just to be viewed as a simple discovery, meaning discovering or uncovering a genomic sequence and indicating the function of that is an invention. If you have only the discovery of a simple genomic sequence, that's not enough. So that Article 5 first paragraph is actually dealing with the demarcation line between discoveries and inventions.

The second really effort of the Europeans was to make sure that gene sequences as biochemical substances can be patented is enshrined in the Paragraph 2, clearly stating that if they are isolated or technically produced, then they can be patented even if they are structurally identical to that of a natural element; in other words, genomic sequences.

Importantly, however, and that which has not yet been mentioned, is that in a recital to this directive, it is clearly stated - and that was the reaction on the original attempt of NIH and Greg Fenton to get ESTs patented, that under the European regime, a DNA sequence without indication of a function is not viewed to be a patentable invention. Simply stating the function but not necessarily the biological function is an integral part of the invention. As that has been clarified actually here only by the Federal Circuit decision in Ari v. Fisher one and a half years ago. So we had this from the very beginning in our European statutes, and also later on implemented in the national laws with some delays, but nevertheless implemented.

Now, Justice Newman this morning has alluded to a number of differences of more general character between the European situation and the United States situation. She mentioned first the first invented, first defined. I'm not going into that anymore. Of course, I fully agree with her that the United States should make all efforts to bring the Europeans to the point that they introduce a grace period because we had a grace period in Germany for years and had no problems. A similar grace period existed in the United Kingdom with no problems, and we have now overall some 30 countries around the world with a grace period except the Europeans. So it's a good reason to pressure on them, again, the first invent to first to file and bring them to the conclusion that having a grace period is actually a good thing.

We have, let's say, the same situation with the scientists as in your country, so we suffer from the problem that as soon as something is made publicly available it cannot be patented anymore, with one exception for the so-called misuse, but that goes too far into the detail.

Now, in addition to that, we have also a difference that's quite important for working in the area of genomics and proteomics that our relevant prior art differs from the relevant prior art in the

United States not only as far as the grace period is concerned but also that you can get a patent in Europe on a substance, a chemical substance which forms already part of the prior art but where the medical use, therapeutic or diagnostic use has not been yet forming a part of the prior art, meaning if you have a herbicide and all of a sudden that's patented or not patented but it is prior art, if somebody finds out that you can use that not very probably to cure some skin problems, you can get a patent, and that patent is actually covering all medical uses of that product. So if then a second one comes and finds out maybe that could be good for curing (inaudible), he could get a second patent on that. It's a bit complicated to explain, but the basic message is that even if a substance is already part of the prior art, it can be patented as a substance, not as a use, as a substance, and that substance patent covers all the subsequent uses whether disclosed/claimed or not. So this is quite a different situation as compared with the United States.

In addition to that, we have also a difference as far as novelty is concerned, that we in the United States in oral disclosures and public use outside of the United States is not prior art. So therefore the possibility existed to get a patent on the so-called leantree substance because that was only known in India in some places. In Europe, you cannot get a patent on such things. So oral disclosures outside of the United States, according to U.S. law, are not prior art. You still can get a patent. So if you give a lecture in London, it doesn't count. If you publish that in printing, that's prior art; otherwise not. If you use it in public, it's not prior art if it is in Salvador or Argentina or Germany. In Europe, that is all prior art, although outside the United States.

We also had as far as the second most important requirement for patentability is the inventiveness or non-obviousness, although in the law a very similar provision, there was quite a substantial difference in the practice. The European Patent Office applies a so-called could/would test, meaning that the question is whether an expert, average expert in the art would have done it, not could have done it, and the answer was he would have if there was a reasonable expectation of success; otherwise not. I'm coming to the U.S. situation in a moment. Then again, the industrial applicability in Europe is a little bit more strictly applied in this area; namely that under the law, the statute, if you claim a DNA for the production of a protein or part of a protein, then the patentability requirement is only met if the protein or partial protein is disclosed and also its function from the very beginning. Otherwise, you cannot get a patent.

Richard Gold mentioned this morning or noon that we have a decision by an opposition division of the European Patent Office applying the specific substantial and credible test. That has not been yet clarified entirely because under the statute it's quite a far-fetched, let's say, interpretation of the European statute. It may be so, but it's not yet finally clarified.

Under the U.S. law, of course, the Chakrabarty decision is known. Anything manmade under the sun can be patented. You have this much more narrow prior art, as I said, with oral disclosures, and use does not form part of that. On the other hand, the non-obviousness requirement as applied by the federal circuit was a quite low yardstick. So it was, let's say, used in parallel to the chemical substances, the so-called structural approach, and under the dual doctrine quite the substantial number of patents have been granted on DNA sequences although a partial sequence was already known, or a partial amino acid sequence was already known. The U.S. utility examination guidelines should be known and applied in a different way to the so-called first, second and third generation of genomic inventions.

More specific, much more specific in terms of the scope of protection is the European Directive and the following national statutes. Under the U.S. law you have no specific rules. You have no statutory research exemption. You have this (inaudible) exemption, the so-called safe harbor. You probably are all aware of the Merck v. Integra Supreme Court decision where the Supreme

Court, my understanding, went the limits of the interpretation of the safe harbor provision. I was in the oral hearing and had the definite impression that the justices were quite unhappy that they had to apply only this safe harbor provision instead of being asked to interpret the common law research exemption defense, which would have been much more appropriate and probably they would have clarified many other things which they were not able to clarify because of the quite strict wording of your statute.

In Europe, we have a specific provision, and this answers also the question posed to Richard Gold a couple of minutes ago that under the Directive, product protection for products containing or consisting of genetic information extends to all materials except to the human body, meaning the question was what about control of humans who would have a patented gene? Under this provision, it's clear that hopefully one day, if the gene therapy will be successful, somebody will have a patented gene, that would not be under the scope of protection of a patent. That's clarified in the Article 9 of the European Directive. However, all other materials in which that information is incorporated and in which the genetic information is also performing its function are covered. We don't have until now any court decision clarifying what does it mean "performs its function"? Is it the function claimed, disclosed, or any function which that gene performs? As you know, 40 percent of our genes are multifunctional, so we don't know actually. If that would be interpreted that only the function which was claimed, then we have quite a narrow protection. If it would be interpreted as also disclosed, it would be a little bit broader. If any function which is actually linked to that gene, we would have a quite broad scope of protection.

A big difference between the United States and Europe is also that we have a statutory search exemption which covers actually all further developments, improvements, et cetera, even if they are aimed at commercial exploitation, and it's quite clear that even in the area of so-called basic research, nothing is entirely - let's say everybody has in the end some idea of maybe how that research result should or could be commercialized. So therefore the German Federal Supreme Court in two decisions, then later on confirmed by the Federal Constitutional Courts, clarified that it's all covered by the research exemption, and I think that all the other courts in Europe would follow because the root of that statutory exemption is a convention on the community which actually never entered into force but has been enforced in many parts into the national law. So that's the big difference between the United States and Europe, also leading to the situation that patent owners are not able or willing to try to prosecute somebody for performing research with their inventions.

However, one should make it clear that this research exemption does not cover the use of research tools for the purpose for which they have been patented. So that's something we don't have any court decision, but it is the general understanding that research tools are not covered, the use of research tools for the purpose for which they have been patented is not covered. But if you go to the Integra case, it would quite clear that Merck has further developed the respective invention, and this further development/improvement itself would be covered by the research exemption. Another question is whether the research results, then, would infringe a patent or not.

We have also another specific provision taking care maybe of multifunctionality of genes or also alternative splicing. Under the (inaudible) 25, the Directive is covering the problem that patented genes are overlapping also only in part, and under that rule if the overlap is not essential for the respective invention, the patents are independent. So again here, we don't know exactly what is essential. Is it essential that you use an axon? Then probably it would be essential, or not. But we don't have any case law so far. To my understanding, it's quite an important provision. It has to be tested in practice.

We have in some countries like Germany, Luxembourg and France, after the extensive discussion on the impact of gene patenting, especially after it has been clarified that 40 percent of our genes are multifunctional, the scientists have said, oh, it's not a good idea that a patent covers all the subsequent functions. Therefore, something has to be done. The German legislature adopted in 2006, as you can see, quite late, a provision that in such a case, to make it short, the function must be included into the claim, meaning that that would narrow the scope of protection of that gene to the claimed function. Whether or not this will be of far-reaching impact I do not know because this will probably not have any impact on the European patents granted by the European Patent Office for the very simple reason because the national courts may invalidate a European patent designated for Germany, U.K., Spain and so forth. That's a matter for the national courts only under certain strictly set forth provisions in the European Patent Convention. It's not up to the national law how to deal with it. They have also to interpret the scope of protection under the so-called Article 69 and the respective protocol to that 69, which clearly states that for the scope of protection it is the size of the claims and taking into account the description.

Now, if the European Patent Office will not force, and there is no reason for them because there is no statutory provision, the applicants to include the function into the claim, well, the national courts will probably not be able to invalidate or to narrow the scope of protection of those patents. But there is no case law so far. We will see. I could imagine that there would be some psychological influence, but legally, strictly speaking, that will not have a direct impact on the European patents. In other words, it is obvious that the applicants will choose the European route and not the national route, which is already the case now.

I witnessed this morning that this discussion is very timely. I don't know whether it is really very timely because we are witnessing actually a steep decrease of patenting in the area of genes. This is, of course, not linked only to the problem of BRCA1 and BRCA2 and the (inaudible) genes, but in general. So it's quite clear that probably after the applicants have found out that they are running ahead of the scientific and technological development, they lost really the impetus to file more and more patents; and also after the Federal Circuit's decision in Fisher and the European decision not to patent ESTs, probably we are witnessing a period of time where less and less applications are filed and less and less patents or applications are maintained, because it's also a question of paying money for annual fees, and if you file that at best you may have something in 10 years, it doesn't make much sense to spend money for that.

Here you can see the difference in the European situation as compared with the United States. We had a rising curve of applications, but you see that the numbers of patents granted for genes has been always much, much lower than in the United States, partly also because of the obstacle of non-obviousness, which was much stricter in Europe.

This just should be an illustration that in Europe, actually the patenting of genes had no - I will come to that in a moment - negative impact to my understanding, because a number of small companies quite actively cooperate with the big pharma, and I would say to the benefit of both, and not least the benefit of the public.

Let me now switch shortly to the Myriad problem. You have been informed, I would say, extensively of Myriad. They had four patents granted in the European Patent Office, methods of diagnosing a predisposition for breast and ovarian cancer. That was issued in 2001 and revoked in opposition, and I would say not really because so many stakeholders, the so-called stakeholders, were involved, but just one, namely the co-inventor from the U.K., from Cambridge. He actually testified how simple it has been to file this one in view of the prior art. Therefore, actually the revocation was based on non-obviousness, meaning that it was not really

invented to find it out. So the push by others I would say maybe viewed as something that was not decisive. Then they had three other patents. Here you see the appeal is still pending. So Myriad appealed, and I asked the lawyer who is representing Myriad last week, there is no hearing yet scheduled.

The second patent was apparently in opposition with some amended claims, meaning some narrowing claims. Again, both parties appeared but no hearing yet scheduled. The same applies for the third patent, and the last patent here related to the chromosome was upheld in 2003 and is now actually finally granted.

You should also be aware that in the final grant in the European Patent Office, meaning after the opposition, after the appeal, that doesn't mean that that patent is actually relevant because actions can be filed in all the designated member states of the European Patent Convention. So also here, nobody really knows whether or not that will be upheld.

The reactions you've heard. We had an outcry by Greenpeace, the German Federal Chamber of Medical Doctors. Patient organizations protested. The European Parliament adopted a resolution against that. The main concerns raised in Europe were, I would say, first the concern that that would be an obstacle to accessing the secrets of the human genome, a high cost of testing because of patents, and also negative impact on improvements of diagnostic methods.

We had in Europe no single request for a compulsory license, which would have been possible actually in all countries. To my knowledge, there are no court cases pending. Somehow Myriad and others have agreed to somehow cohabitate, and in Germany we had a special situation between 1996 and 2004 that Myriad allowed the German Cancer Aid to test for BRCA1 and BRCA2 in 12 centers so that more than 3,000 gene tests have been performed, but not actually using the method of Myriad. To my understanding, they have not paid any licensing fee, although there is a licensee of Myriad, Bioscientia, in Germany. The main reason for hesitations, consents, and also opposition was the idea of Myriad that all tests have to be performed in Salt Lake City and not in Europe. So that was one of the reasons why we have written this strong reaction, but after all, if there are no court cases, no requests for compulsory licenses, the impact must have not been such a tremendous one.

In the course of this debate, under my supervision our institute has performed interviews in 25 institutions, big pharma companies that house research institutes and clinics. We have not found any proof. Those interviewed have not really shared the concern of the public, whoever the public is. The majority, even to my surprise, was in favor of product patents on DNA sequences. The only critical point, and I shouldn't say the only because it's quite a critical point, was that they clearly stated as soon as they found out that there is a gene patented already, they lose their interest to search for further functions, meaning they don't want to become dependent on the patent owner.

The results cannot be viewed as entirely representative because there are still only a few products on the market, and one should be aware of the fact that if there are no products on the market, if you have a research exemption, nobody sued, and as long as you don't have a product on the market, you do not infringe. So there are some reasons for this situation, and also in Germany we had no single request for a compulsory license.

To summarize, and I hope I'm more or less on time, in the United States many more applications have been filed for the very simple reason that they filed applications also for years. From the very beginning it was quite clear that in Europe they would not get patents on ESTs. Under the

old U.S. law, that has changed. There was no publication of the applications as long as no patent was granted. In Europe we have 18 months, as you have it now, too, as a general rule, meaning that if you don't get a patent and the information is disclosed, it's not a good idea to file a patent application knowing that most probably you will not get a patent. So now under your law, I guess you are all aware you also have 18 months after the filing. But if a university knows, for instance, that they have pre-published papers, they can declare that there will be no application abroad, and therefore also the American application will not be published. That's the law in the United States. So if you declare, you will not apply for a patent abroad. Your application will not be published. It will be published only as a patent if there will be a patent granted. Otherwise, there is no publication. So the idea in Europe not to grant EST patents led automatically to the hesitation to file those applications in Europe because otherwise everybody could get the information on the EST sequence after 18 months. Now the situation is here only still in place if for any reason ever an applicant declares he or she will not apply for a patent in Europe, anywhere outside the United States.

There are more patents issued here. The question of whether they will be valid or not after the official decision, probably people will invoke the validity of patents. I don't believe that we have witnessed excessive litigation activities, not more or less than in the IT area. If you look at the IT landscape, of course we had the litigations here. I don't know about the negative impact on R&D. In Europe there are many less applications filed, less patents granted. Litigation activity I would say is relatively comparable to the United States because they are always the same actors, be it here, in Japan or in Europe. To my understanding, we cannot state and observe that we had a negative impact on R&D because of that.

So if you have any questions, I am ready to answer them.

DR. EVANS: If it would be okay, I'd like to hold off on questions until the next speaker and then have the two of you field those together, if that's all right.

DR. STRAUS: Thank you.

DR. EVANS: Thank you.