

TRANSCRIPT OF PROCEEDINGS

UNITED STATES DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

PUBLIC HEARING
ON
WRITTEN DESCRIPTION REQUIREMENT

Pages 1 thru 139

Washington, D.C.
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UNITED STATES DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

Public Hearing
on
Written Description Requirement

Wednesday, November 4, 1998

9:04 a.m.

Commissioners' Conference Room
Crystal Park 2
Arlington, Virginia

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P R O C E E D I N G S

MR. DICKINSON: Why don't we get started. Thank you all for coming, and welcome to this hearing on the "written description" requirements under Section 112, paragraph 1, of Title 35 USC.

I want to thank you all for your interest in this topic. I know that our staff has worked very hard in developing these guidelines, and we are pleased that the public's commentary has been consistent with that hard work that we have done. It has been thoughtful, and I know today's testimony will be as well.

We just have a few comments before we start. Once again, technology has outpaced the application of our patent laws. The surge of research and discovery in new industries such as biotechnology and computers has frankly created some growing pains in patent law. This volatile mix of technology and law has prompted the PTO to reevaluate examination standards regarding patentability in these new technologies.

In the last five years, we have issued

guidelines regarding the proper analysis for computer-related inventions, the utility requirement, and the enablement requirement. Given this history, it was probably only a matter of time before the challenging legal issues surfaced with respect to the written description requirement.

The recent decision by the Court of Appeals for the Federal Circuit in Regents of the University of California v. Eli Lilly underscores the complexities of patenting new technologies. As I think all of you are aware, the court in Lilly reiterated its longstanding view that the patent laws contain separate written description and enablement requirements and applied the written description requirement to a patent relating to recombinant DNA technology.

Relying on the Fiers v. Revel case, the court in Lilly held that an adequate written description of DNA requires precise definition, such as by structure, chemical name or physical property. In other words, what is required is a description of the DNA itself.

Although Fiers should have perhaps suggested a change in the written description jurisprudence, many IP practitioners were surprised by the result in Eli Lilly. However, even without Fiers, that result was probably driven in large part by In re Bell and In re Deuel. In those cases, the Federal Circuit held that a generalized process of isolating specific genetic material did not render it obvious. The generalized process laid out in the patent at Eli Lilly could not render the human cDNA obvious, and it would be odd if it nevertheless provided an adequate written description.

Now that Federal Circuit jurisprudence has refocused the patent community's attention in this area, we here at the PTO must assure not only that valid patents are issued but that any negative impact on the important growth in the biotechnology community is minimized.

The nature of the examination process, as I think many of you are aware, requires a great deal of independence and responsibility on the part

of examiners, and each invention is different. For a change in the very nature of a well-accepted paradigm such as "written description," this results in the potential of a loss of uniformity or a reduction in uniformity and perhaps a concomitant loss of predictability in IP protection.

I think this problem can be better understood or appreciated by remembering that we are responsible for roughly 2,500 examiners, and there are variations in how those examiners treat cases. We attempt to deal with that by the process we have developed of guidelines, offering examiners the more structured and formal means for analyzing the art and the application before them.

Our application of the law as now enunciated by the court has questioned the level of sufficiency for compliance with the written description requirement in unpredictable technologies such as nucleic acid sequences. Furthermore, I think we sense that some practitioners believe that this requirement for written description could be met with less

information than the court states is now necessary.

For all these reasons, we have formulated these interim guidelines to instruct examiners on the correct implementation of the Lilly decision and, more broadly, to promote uniformity and consistency among our examiners.

Although the guidelines address examples specifically drawn from biotechnology arts, they are intended to be equally applicable in all fields of invention.

The interim guidelines urge the examiners to not only review the application in light of Eli Lilly, but to assist the applicant to the extent possible in establishing the support necessary to satisfy the statute.

Believing that these guidelines could be further improved, we have invited the public here today to comment on them. Given the importance of this hearing and its impact on the examination process, I again want to thank you all for taking time away from your busy schedules to participate in these hearings. I also want to thank you for

accommodating us because, as most of you know, we have shifted the location of the hearings from Boston and San Diego to here in Washington.

We are all very interested in your viewpoints on the subject matter of these hearings, and I want to assure you that all comments will be taken into very serious account when we develop the final guidelines.

Finally, I'd like to remind everybody that written comments will be accepted until November the 12th, and I encourage all of you to continue to submit those comments. We have received a number of them, and they are very interesting and very helpful to our deliberations.

By the way, I probably should have started off by introducing myself. My name is Todd Dickinson, and I am the Deputy Commissioner of Patents and Trademarks.

Why doesn't the rest of the panel introduce themselves now?

MR. DOLL: My name is John Doll, and I am one of the three directors in Technology Center

1600 that examines biotechnology; and Mary Lee, one of the other directors, is in the back of the room.

MR. KUNIN: I am Stephen Kunin, and I am the Deputy Assistant Commissioner for Patent Policy and Projects.

MR. DROST: Al Drost. I am the Deputy Solicitor, and now Acting Solicitor, now that Nancy Link has left.

MR. CHAMBERS: Scott Chambers, Associate Solicitor.

MS. CRITHARIS: I am Mary Critharis, and I am an attorney in the Office of Legislative and International Affairs.

MR. DICKINSON: Let me run through the folks who signed up. It is a very distinguished group, and I am very pleased to see a number of our most prominent and favorite practitioners represented here today.

I hope everyone received an agenda, and this will be the order. Hal Wegner will be first; Herb Jervis will be second; Jack Spiegel; Dave Schmickel; Joy Bryant, and Dr. Agris.

Mr. Kushan, are you going to testify as well?

MR. KUSHAN: Yes.

MR. DICKINSON: Is 11 o'clock all right with you?

MR. KUSHAN: That's fine.

MR. DICKINSON: Are there any others?

[No response.]

MR. DICKINSON: Then, without further ado, Mr. Wegner, you have the floor.

MR. WEGNER: Thank you very much, Deputy Assistant Secretary Dickinson and other distinguished leaders of the Patent and Trademark Office.

My name is Harold Wegner. My affiliations are on leave as Director of the Intellectual Property Law Program at George Washington University Law School; a partner at Foley and Lardner.

The views I will express are my own personal views, not necessarily on behalf of any client or other colleague.

There are several issues I would like to talk about--the general nature of Section 112; the general nature of guidelines having to do with 112; and what we will be doing in the very near future if the Commissioner is successful in his appeal in Lehman v. Zurko.

First, and as a predicate, I think the Patent and Trademark Office has been doing perhaps the best job in history in trying, from the ninth floor on down, to educate the patent bar. It is like a time warp if I go back to the sixties, when the game was how to nail the applicant, how to reject the case.

Here, there is now a genuine spirit of cooperation and helping of industry, and what Deputy Commissioner Dickinson said is important. He wants to minimize the negative aspects of the growth of the biotech industry. This is exactly the perspective we want. And before getting into the guidelines, we should see what the Patent and Trademark Office has done. It has chemical practice roundtables, it has biotech roundtables.

The top levels of the new technology centers have never been more accessible, and as much guidance is offered as possible.

Now, in terms of the interim guidelines and what we are talking about today, these are a masterpiece in trying to decipher an undecipherable puzzle. The Federal Circuit case law has gone in various directions with panels. It is unclear that en banc, the court will follow some of these panel opinions. And the very complexity of these interim guidelines is necessitated by the various quirks and changes and shifts in the Federal Circuit law.

This points to a distinct contrast between the approach that Commissioner Manbek took in the era of Alappot, the notorious time, with the Board packing, and the present situation. One could simplistically look at what happened in the Manbek era and say, well, we have a certain type of subject matter that is or isn't patentable, and maybe you could say that's a policy decision. But when you get to biotech, this is at the extreme end of the spectrum. All of this stuff is patentable.

The question is under what conditions and what disclosure conditions.

There are probably 10,000 nuances that can be derived in the ever-evolving case law. So while the guidelines here are as good as they can get, and the Patent Office has some brilliant people doing them, and I like them in terms of an exercise to see what the panel opinions say today, it is absolutely futility to try to have a big framework of guidelines. It doesn't work in this system.

When I say "in this system," we can contrast to the Japanese Patent Office. What's the difference between this approach of guidelines and what the Japanese Patent Office does? The Japanese Patent Office has mastered the art of having a guideline on everything. Well, it works in Japan because it is a different legal culture. In Japan, there is no case law system. The individual cases don't mean so much. Administrative guidance is everything. Also, there is harmony between the administrative guidance and the reviewing court, the Tokyo High Court, because indeed, there is an

exchange of technical staff between the two bodies. So there is a real harmony; it is a real overlap in manpower and resources. So it works in Japan, but this is not Tokyo. This is Washington, D.C., or Crystal City, or somewhere else when we move somewhere.

It is a different system. It is an American system where we have case law. One of the fundamental breakdowns of this system has been the abysmal failure of the Board of Patent Appeals and Interferences to either get the job done with a 9,000-case backlog or publish cases.

I understand that now, some of the opinions are on the web site. I have not had the chance to look at them yet, but in terms of publications that have been released to West Publishing, that are on PTOFTO or on USPQ, there is usually one or no board appeals from ex parte patent appeals each year.

That is the way the law should be made and developed. You have technically trained, or mainly technically trained, administrative patent judges,

and they are the ones who, on a case-by-case basis, should work through these issues. They should determine what should be done.

So in the area of biotech, this is a paradigm and an example of why we have to go back.

Now let's look at the place of biotech in the macroscopic picture of Section 112 "written description." This is a speck--it is a very important speck; it is a huge problem, but it is a speck--compared to the macroscopic problem of a misunderstanding by the bar, by the Patent Office--indeed, everyone who has not kept up with the case law from 1998.

the overall problem or challenge is the harmonization at the Federal Circuit level of chemical and nonchemical case law on when may you amend to broaden or change a definition based upon an original disclosure. These are the Gentry Gallery and Tronzo cases that have come out this year, a couple of others also. What has happened is that in tracing the case law back to the beginning of this century, we have had two bodies

of case law. We have had a nonchemical body which says that you can broaden to include obvious embodiments, and you have had a chemical case law which had a very strict base, and the manifestation of that in the modern era is In re Rossetto, 18 PQ 101, Judge Rich's opinion from 1958.

In a nutshell, Tronzo adopts Rossetto across the board. This means that if someone has an obvious modification beyond the literal scope of the claim wording, in most cases, that claim lacks a written description. And the way this comes into play is where a continuing application is filed. So when a continuing application is filed which has a claim that lacks "written description" basis in the earlier case, priority is denied, and the intervening publication is a statutory bar.

This problem outweighs the problem in the biotech area by 20 to 1 or 100 to 1. So that is why, although I respect that this is a very serious problem, I think that it is just a very small part of the overall picture.

What you do about that--and I don't know

if you do this with educational seminars--it is to me very difficult when we cast something in stone by making a guideline, no matter how good they are.

Let's return to minimize the negatives on growth that Commissioner Dickinson spoke about. One of the very best ways we can minimize negative growth, expedite patenting, help applicants--it sounds like a win-win-win scenario--it is to get out of the 112 business unless there is a gross violation which cannot be overlooked.

Here you have a situation where you have panel opinions not adopted en banc. What are we doing in focusing on 112 first paragraph? Why are we wasting the examining Corps' time? Why are we hitting the public up with these problems?

If there is no clear danger to the system by allowing cases, as long as they read only on novel and non-obvious subject matter, the Patent Office should be in the business of examining and allowing cases for patentability, and not creating infinite traps for the unwary.

What is so dangerous about these

guidelines--the law is evolving at the Federal Circuit, and it should evolve, and it should evolve at the Board, but what is happening now is that if we have these guidelines, many examiners will just see the guidelines as the Holy Grail and as something they have to follow, and they won't be following the case law. And it will be impossible to keep up modifications of any guidelines with the case law. That is just an impossibility.

Now let's go to the final chapter. I was part of an effort supporting appellees through the bar association on In re Zurko, but now I kind of wonder what my own view will be at the Supreme Court, because I think if the Commissioner is successful in Lehman v. Zurko, and we bring the Patent Office under the umbrella of the Administrative Procedures Act, we will finally be able to force the Board of Patent Appeals and Interferences to act like judges and not to have the arbitrary and unreasonable opinion-making that is only a small minority--most of the board members to an excellent job--but there is a small minority

who are not doing their job properly, are not in the public interest, and this must all be exposed.

Corollary to that, the Electronic Freedom of Information Act Amendments of 1996 permit and really suggest that the Office should publish Board opinions, and I will include something on that in my written comments.

Thank you very much, Deputy Commissioner. If you have any questions, I will be glad to answer them.

MR. DICKINSON: Thank you very much, Mr. Wegner. You are always one of our most thoughtful commentators, and we appreciate your input and your setting the stage today.

You are relying a lot on the CAFC's opinion making in this area. Do you have any comment relative to one of the more recent cases, State Street Bank, when the court basically applauded the software guidelines that the PTO has promulgated and suggested that that was a good way to approach that?

MR. WEGNER: Well, with due respect to

Madison Place, they very rarely review the Patent Office anymore effectively. If we look at the In re opinions, opinions from examiners and reexamination and ex parte patentability, the average number of precedential opinions by each judge each year is about one--one--and there are three or four judges who have never had a precedential reversal of the office.

I think the guidelines were excellent in the ones you referred to; they were excellent. But to me, that's a gold star saying job well done, and in some areas, you can make a guideline. It may be possible to say that black is black, and white is white, or here is a line between them. You can't do that in biotech, and the reason you can't do that is not just the complexity of the technology, but you have a total miscomprehension in these panel opinions that have been cited of what is the "written description" requirement. The "written description" requirement was originally a change in name from "new matter." That was done in In re Robbins and in other cases in the early seventies,

and in 1981, the CCPA, in an opinion by Chief Judge Markey, in In re Rasmussen, said that we will no longer call it "new matter," we'll call it "written description."

That "new matter"--there can never be a "new matter" or "written description" problem in an original claim. That can never happen by definition, because an original claim is part of the original disclosure.

So what the Federal Circuit panel opinions have mixed together are some thoughts from enablement and clothed them in 112, first paragraph, "written description" language. This is an upside-down approach.

Now, what do you do with each of these panel opinions? You have to give it the due respect to which it is entitled, and maybe an individual examiner thinks this panel opinion should be given some weight, and then it has to go to the Board of Patent Appeals and Interferences, so that on a case-by-case basis, each type of situation can be worked out.

But above all, if it is just a technical trap for the unwary, where is the biotechnology industry helped by holding cases inside the Patent Office, choked for five years in a backlog of the Board of Patent Appeals, to define whether this particular subrequirement of this line is an interpretation of this panel opinion, which is contradictory to this earlier opinion--why should that be held up? Why not pass it out?

The critical thing that the Office must do is determine "novelty" or "non-obviousness." That's the business of this Patent Office. But in this complex area of biotechnology, it doesn't fly where there is no clear guidance possible.

MR. DICKINSON: Let me see if we can get a few more questions in.

Mr. Kunin?

MR. KUNIN: Mr. Wegner, one of the areas that we asked for public comment on deals with the ability of an applicant to deposit biological material, in particular when applicant available himself or herself of that opportunity and makes

such a deposit. How far should applicant be permitted in either the doctrine of incorporation by reference or the law of inherency to perhaps do additional work on the deposited material and add that to the express written description or claims of the application?

MR. WEGNER: Is the premise of your question that there is a specific incorporation by deposit number or some other specifics in the original case--take them both ways?

MR. KUNIN: Well, let's assume--take it both ways, yes.

MR. WEGNER: All right. If there is an original reference to a deposit, and if the applicant can show that necessarily and inherently, every aspect of the disclosure he or she wants to add to the patent specification corresponds to that deposit, then, under In re Fouche, 169 USPQ 429--I know the number because it was my first case--a 1971 case, then it should be all right.

The problem when there is no original incorporation by reference is the Lundak [ph.]

case, which some would say is an aberration, and it's a lot shakier ground to try to just reach out of the ceiling tiles and pull out a case. That's a much more difficult situation

MR. KUNIN: We don't do that anymore.

MR. WEGNER: I don't know what you mean.

MR. DICKINSON: I think we have another question from Acting Solicitor Drost.

MR. DROST: I just want to make a distinction--you were talking about the Electronic FOIA publishing. I think the difference between precedential and publishing--under the Electronic FOIA, we are in the process, once there is no 122 confidentiality problem, to put that information up on the web site. But that doesn't make it precedential. The FOIA will not affect the precedential.

MR. WEGNER: Yes. Well, you have two important points. First, whether it's precedential or not, that's a secondary issue. The bar needs to see how things are being interpreted, not to rely on it in a case.

In terms of Electronic FOIA, my understanding is that the Electronic FOIA really requires an agency to make its opinions published if it has discretion to do so. And you indeed have discretion to do so because in 37 C.F.R. 1.14(d) or (e) or whatever it is, you have the right now to tell the applicant we are going to publish your opinion, and you have a redacted copy. So you have the discretion and the authority to do it right now, and I would like to see an aggressive and positive leadership role taken on publication of all Board opinions.

The mechanism right now is very cumbersome--in other words, the Solicitor would need to write a letter in each case--but there would be a simple rules notice which could be done which would say all Board opinions will be published within 60 days after issuance unless a party (a) protests that there is trade secret information remaining, and (b) if he or she provides an expurgated copy, just taking the trade secret material out on a disk form. That should

have been done now, and it would be a great sign of leadership if you would do that.

If we had, just think how much better that would be for guidance for the applicants. I remember back in the 1960's, we had some secret grounds of rejection which we didn't tell anybody, and there, it was a real game; it was a game show. The one case, Ex Parte Batchelder, from 1960, was "new matter" case, and we had about two dozen unpublished secret Board opinions. And following Federico's practice of the "See Notes," we would nail the applicant every time.

In other words, "See" means "Look at." What would happen was the examiner would simply say "Rejected, new matter, Ex parte Batchelder." This is fine.

You'd go to the Board, and you'd clip in a three-by-five card in the manila file jacket and say "See" and write the appeal number, and the Board would then just take a copy of that opinion and reproduce it. How stupid, how foolish. That stopped an honest debate about the issues. It took

from 1960 or 1961, when Batchelder came down until 1977, with In re Johnson and In re Driscoll, to judicially overrule that sub silentio. And even In re Papish [ph.]--that was a "See note" case. So there is no more important chemical case than In re Papish. Yes?

MR. DICKINSON: Let me interrupt you for just a second, Professor.

I think we have time for one final question from Group Director Doll.

MR. DOLL: I just wanted to follow Steve's question and ask your opinion on a specific case when we have a claim to DNA that has a deposit, the deposit number, which is proper, and at some time, applicant resequences that deposit and decides they would like to add 100, 200, 500 nucleotides to the claimed DNA sequence.

MR. WEGNER: I don't have an opinion on that.

MR. DOLL: You were my last hope.

[Laughter.]

MR. DICKINSON: On that note, are there

any further questions from the panel?

[No response.]

MR. DICKINSON: Thank you, Professor.

MR. WEGNER: Thank you very much.

MR. DICKINSON: As always, we appreciate your very important and very cogent input. Thank you so much.

MR. WEGNER: I appreciate the time to be heard.

MR. DICKINSON: Next, I call on Herbert H. Jervis, from Pioneer Hi-Bred International, Inc. Good to see you today. Thanks for being with us.

MR. JERVIS: Thank you.

Good morning. My name is Herbert H. Jervis. I am the Vice President and Chief Intellectual Property Counsel at Pioneer Hi-Bred International, the world's largest hybrid seed company.

We file about 200 patent applications a year, ranging in technologies from the hybrid and inbred plants per se to genomics, from technologies relating to male sterility in plants to global

positioning satellites and remote sensing.

I have a few general comments. First, I'd like to commend the PTO on this effort. It is extremely helpful to understand what the PTO's thinking is, but even more helpful to be able to express our views. In the long run, this strengthens the patent system and promotes effective prosecution.

It is our opinion that the guidelines should be broadly applicable to all classes of invention--that is, the products and processes, to areas of biotech and others. Obviously, these guidelines seek to adapt the PTO practice to some recent Federal Circuit decisions, and on numerous occasions, that same body has suggested that DNA is best viewed as a chemical polymer, and that the laws of chemistry ought to apply where appropriate.

We think that the PTO should refrain from making biotech special, as was done unnecessarily, some would say, with respect to 103(b). Although there are cases that tend to blur the distinction, we believe that the authority is that the "written

description" and "enablement" are separate and distinct. A particular specification can fail to meet or meet those provisions independently. Unfortunately, as Professor Wegner has indicated, the courts confuse the issues, and sometimes we think these guidelines confuse the issues.

Finally, there seems to be in these guidelines an overemphasis placed on the claims and particularly the preamble. While five of the six paragraphs of Section 112 deal with claims, the first paragraph deals with a specification, and that is the section that has to deal with "written description."

I have some specific comments relative to the guidelines themselves. With respect to Section 1, I think this section is fine as far as it goes, but we believe the PTO might be missing an opportunity to elevate the discussion of the "written description" and underline an important function of the "written description" and that is as an anti-submarine patent device.

Perhaps the reference to the Vas-Cath case

in the guidelines could be expanded to illustrate the negative implications of a written description that fails to particularly describe the invention at the time of filing. There is some nice language in that case concerning a drawing that is not specific enough in pointing out the features of the invention.

With respect to Section 2(a), the introductory prepositional phrase in that section illustrates one of those general comments that I had above. Claims do not have to satisfy the written description. As the footnote in the guideline immediately before that section says, and cites In re Kohler [ph.] for the proposition that filed claims, as Professor Wegner said, constitute their own written description.

At line 7 of that section, the reference to "possession" should be clarified to indicate that one does not necessarily have to have physical possession, but must have the complete conception of the invention in mind.

We find the remaining part of that section

a bit confusing, because I think that is where we start mixing "enablement" and "written description." We don't understand necessarily how the concept of predictability is relevant to the "written description" requirement. We appreciate the inverse relationship as it applies to "enablement," but we think it would be possible to provide a written description, even of a complex molecule in an unpredictable art. One might have some other problems with respect to "utility" or "enablement," but you should be able to provide a written description.

With respect to Section 2(b), we think there is a little too much emphasis on claim structure. The thrust is almost as if the claim was the sole source of the written description. We think the PTO, particularly in the biotech area, should reinforce the notion that sequences are not patentable any more than formula are not patentable. What is patentable, of course, is the isolated DNA molecule that is characterized by that sequence.

Therefore, if some inventor is in possession of a DNA molecule that's larger than the sequence that he provides, they should be able to demonstrate that by criteria other than the sequence. They can combine sequence with molecular weight, size, restriction, pattern, et cetera, but you need evidence of possession of that invention.

The third paragraph of 2(b) also seems to shift the emphasis of who is doing the envisioning in that section. Isn't the test for the fact that a written description is sufficient that the artisan can understand that the inventor had envisioned all the various members of the genus, not the person reading the claim.

The same comment could be made on the last paragraph of that section.

Section 2(c). C(1) is straightforward and acceptable. C(2) is also fine with us, and it encodifies the result in the Fiers case. The only point that might be stressed is when one suggests considering "other relevant characteristics," that those "other relevant characteristics" should be

identifying ones--that is, they should be sufficient to distinguish the invention.

With respect to Section 2(d), the written description of a genus is sufficient, it seems to me, when it describes in enough detail that possession of that genus is understood. The reference to "a sufficient number of species" relates, it seems, more to whether a genus is enabled than whether it is described.

The example that is used is probably not the best choice, because it tends to or wants to associate taxonomic groupings with specific gene sequences. Now, we appreciate that that was the appropriate that the court considered in the Lilly cases and in the Amgen cases, but that claim practice is really not being followed today, so I wouldn't build guidelines necessarily around those.

Briefly, DNA is DNA. The same four bases, sugars and phosphates, are present in all species. DNAs of individual species would be distinguishable at best only on very broad measures such as the total amount of DNA, the G plus C content of the

total amount of DNA. Looking at a particular coding sequence as isolated, one would be hard-pressed to suggest its particular origin. That is to say, just because the DNA from a calf has an overall G plus C content of 40 percent doesn't mean a particular gene has to have a G plus C content of 40 percent.

In order for one to create a true generic description of a ruminant mammalian gene, one would have to take the sequence information from as many species as contemplated by the inventor and by a system of sort of chemical "R" [ph.] groupings account for all those various differences where the changes would occur. That is to say, it is not a consensus sequence but a generic sequence.

Now, before I got into the patent business, I was a university professor, and I am genetically incapable of getting up before a group of people without showing one slide. So if I can disturb the Board, I'm going to show one slide.

[Slide.]

MR. JERVIS: I have tried to illustrate

the point here. Let's just say those are five sequences of a peptide from five different mammalian sources. A consensus sequence would take into account the most frequently occurring amino acid in each of those. So in position number 2, you can see there are three phenylalanines for tryptophan, so "PHE" would be the consensus amino acid. So each of those positions, you could see what the consensus sequence would be.

A generic sequence, on the other hand, would be written "MEX XAA XAA" and take into account each possible variation at positions 2, 3, and 5.

Assuming that you could do those substitutions independently, there are actually four additional sequences that are encompassed in that generic formula that weren't present in those original five. Whether those additional species are legitimate members of the genus might have to do with questions of utility--do those particular four have the same function as the other five, or is there enablement, is the art unpredictable, or a

novelty--maybe one of those sequence is in fact in the prior art.

But what it doesn't have a problem with is written description. That generic sequence provides a written description of all those possible combinations.

Thank you very much. I appreciate it.

Returning to Section 2(d), the sequence variation very much depends on the gene and protein in question. To take a highly conserved protein, for example, cytochrome C, my molecular biology folks inform me that there have only been about 40 amino acid changes in all of God's critters in the last 21.4 million years. As a result, there is no amino acid sequence difference between cows, sheep and pigs. Thus, a claim that sheep cytochrome C would be anticipated by the cow sequence.

Viewed from this perspective, references to sheep DNA or cow DNA are really only a shorthand way of saying "when isolated from a cow." Therefore, these are really forms of process limitations, not product characterizations.

It sort of illustrates the difference between biologists and chemists. Biologists tend to talk about things functionally and how they are arrived at; chemists tend to talk about structure and describe things as they view that they are.

I think we see claiming now not in terms of taxonomic groups but more related to things like percent identity. And I know that the PTO currently favors hybridization-type claims. Therefore, you have a reference sequence, and you get your breadth by claiming sequences that hybridize under a certain set of defined conditions.

I would just suggest that our view is we tend, I think, to favor the identity characterization rather than hybridization, because we think that when we litigate these claims, the other side, of course, being nefarious so-and-sos, will get an expert up before the court and say, well, under these conditions, I find that it doesn't hybridize. Whereas if you use some more statistical base and describe in the specification

what the algorithm is, it is less likely to confound that issue.

With respect to Section (d)(1), there is a problem, we think, with the preamble of that example. That is to say, we use the word "probe" in the preamble. Does that explicitly or inherently place a size limitation on that, or could that claim in fact read on a whole gene? It might be a lousy probe but still work.

I guess, in closing, I just want to make a few comments about the last example in the time remaining, and that's the example of a DNA comprising a sequence ID number. This will probably sound heretical to my fellow practitioners, but I think that by allowing "comprising" with respect to an EST claim, you are essentially end running your whole written description requirements. You are saying that because you can't provide a written description, we will let you off the hook by giving you a "comprising" claim, which could read on an infinite number of DNA molecules undescribed, based on a

small DNA sequence.

For example, if an EST is, say, 200 nucleotides, if there are lots of cloning strategies and sequencing strategies these days based on, for example, the 5-prime end of the gene, based on the 3-prime end of the gene, or based on some motif in the middle of the gene, and all I am looking for are those 250 nucleotides all the time, if Applicant 1 goes to Examiner 1 with the 5-prime EST and gets a "comprising" claim, and Applicant 2 goes to Examiner 2 with his 200 nucleotides in the middle of the gene and gets a comprising claim, and Applicant 3 goes to Examiner 3 with a 3-prime 250 nucleotides and get a "comprising" claim, they could very, very well read on the same gene.

Now, I understand the law--one patent, one invention, goes to the first inventor. You are going to make it very difficult to do an interference search--almost impossible for the courts to deal with it.

So I think that if you have a DNA that is characterized by 250 nucleotides, and it is longer,

then tell us what the characterization of that longer piece is. Is it "x" molecular weight; does it have a restriction pattern? That's what you are in possession of.

I hate it when people give me "comprising" language and say "I don't want comprising language." These guidelines are very effective. This is where the patentability determinations need to take place within this group. Don't leave it to the courts.

I was in Wilmington last week, where there is a patent trial going on that has to do with how to kill an insect with a corn cell that has a Bt toxin in it. At one point, I counted 18 patent attorneys in front of the judge. There were three parties involved. There were innumerable patent attorneys like myself in the peanut gallery listening to this.

Mid-day Tuesday, the judge said, "Excuse me, we have to recess for a minute; I have a criminal matter to attend to." And in comes a fellow on a drug charge who is going to jail for 30

years. He has one attorney, and the State has one attorney.

And here were 18 attorneys trying to understand how to kill a caterpillar, and I'm asking: What's wrong with this picture?

What we need to do is understand patentability and have it decided here and not in the courts.

Thank you.

MR. DICKINSON: Thank you for that and for putting it in a certain perspective. We appreciate that.

Are there any questions from the panel?

Mr. Kunin?

MR. KUNIN: Mr. Jervis, with respect to the last example, what is your opinion about a claim that would be a nucleic acid molecule consisting essentially of the Sequence ID Number 1?

MR. JERVIS: Well, it would certainly be in my mind a narrower claim. I am still not sure-- if the nucleic acid molecule you have described is 250 nucleotides, you can't tell me what the 251st

one is. You can tell me that it might be one of four, but you can't tell me which one it is. So I am not sure how much consisting essentially of, unless you were talking about variations within the 250 that you have described in terms of some sort of conservative.

Now, I am not saying that ESTs cannot be patentable. That small piece of DNA should be patentable just like any other piece of DNA if that has a particular utility. I'm not sure finding the whole gene is the appropriate utility. But those are good probe-size pieces, and if that happens to meet a highly polymorphic region that could allow you to discriminate a couple of hundred cystic fibrosis patients, that's a perfectly legitimate utility for that fragment of DNA.

MR. DICKINSON: Let me jump in front of Mr. Doll for just a second.

Can you elaborate a little bit on that utility question you just raised--what is sufficient utility for ESTs, in your opinion?

MR. JERVIS: I think the function of the

EST--there has to be a practical utility for that EST.

MR. DICKINSON: Can you define "practical" for us, then?

MR. JERVIS: Well, I mean, that's partly your job.

[Laughter.]

MR. DICKINSON: Fair enough. So, we get paid the big money here.

MR. JERVIS: That's correct.

[Laughter.]

MR. DICKINSON: Mr. Doll?

MR. DOLL: We use the expression "credible utility," not "practical utility."

MR. JERVIS: Yes, okay, that's fine.

MR. DOLL: And actually, I had two questions. But the "comprising" language is very interesting just from an operational sense, because we see a lot of claims come through the office drawn to DNA fragments that are not called ESTs. We see whole gene claims come in where they haven't defined anything except possibly the coding region,

and those applicants also want the term "comprising."

I'd like to know if you could suggest a mechanism that you would see as a practitioner, that if I rejected one of your EST claims, saying I was not going to grant you the "comprising" language but give you only "containing" or some very limited language where somebody could very easily get around your claim protection.

MR. JERVIS: Yes. It's what is it that I'm trying to claim. If you look at a straight chemical case, you don't see in the compound claim a compound "comprising." What you see is a compound having the formula. And they use the formula to define the breadth, because they can conceive of a number of different species within that generic formula.

You don't see in chemical cases a benzodiazepen comprising half a structure--trust me on the other half; I'll tell you when I get it. That's not the way chemical practitioners draft claims.

If we believe the Federal Circuit, that DNA is a polymer, then those rules, it seems to me, ought to apply.

MR. DICKINSON: Any other questions from the panel?

MR. CHAMBERS: I have one.

MR. DICKINSON: Yes, Mr. Chambers.

MR. CHAMBERS: What do you think of the possibility of coming in with additional material for deposit--the same question that was asked of Professor Wegner--if someone deposited a particular clone or a particular fragment of nucleic acid, could they come in at a later point and add sequence which was an inherent quality of that clone?

MR. JERVIS: I believe that's the case. If they were in possession of that piece of DNA, and they deposited it, then they can add characterization to that DNA. If you found that piece of DNA in the prior art, just my sequencing wouldn't make it novel. You'd give me novel rejections all over the place, right?

MR. CHAMBERS: Could you put a whole corn seed into deposit?

MR. JERVIS: I beg your pardon?

MR. CHAMBERS: Could you put simply isolated corn DNA on deposit and then, at some later point, come in and sequence it?

MR. JERVIS: Yes, sure. I mean, we deposit seeds if we are--

MR. CHAMBERS: No, no, that's not what I am saying. I'm saying the deposit would be the entire genome, and later on, you came in, and you provided--

MR. JERVIS: Oh--gene by gene, afterward?

MR. CHAMBERS: Yes.

MR. JERVIS: I think--that's not what I understood your question to mean. I'm not sure what the invention--

MR. CHAMBERS: Well, I'm not understanding where we make the line.

MR. JERVIS: What I'm saying is I'm claiming a gene, and I've done a sequence. The inventors tell me and swear on a bible that, "We've

done it three times, and this is the sequence." I don't trust them. I make a deposit of it, because the fourth time, they go, "Oh, we've done a sequence error. That 'A' should be a 'G.'"

That is a "new matter" rejection, absent some other description in the specification. The description in the specification is the deposit; it stands as its own written description, and I should be able to amend my spec based on my deposit.

MR. CHAMBERS: What if you only made an indication in the specification of 20 nucleotides, and you deposited 1,000 nucleotides; could you come in later on and put in the rest?

MR. JERVIS: I think so--if that's what I've isolated, if my claim is to an isolated polynucleide that is one kilobase long, characterized by these 25 amino acids, I should be able to come along and add to that sequence, because I was in possession of the 1,000 nucleotides.

MR. DICKINSON: Mr. Doll, did you have another comment?

MR. DOLL: That was essentially my question, because you had spoken earlier that you have to have evidence of possession such as physical properties, such as weights. Without any physical indication as to how long the sequence was or what its weight was, would you still feel comfortable coming in and adding the 980 nucleotides to the 20 that you had already sequenced?

MR. JERVIS: If I have a deposit--

MR. DOLL: If you have a deposit.

MR. JERVIS: --it has a weight; I mean, it's there.

MR. DOLL: Good. Thank you.

MR. DICKINSON: Thank you very much. We appreciate it.

MR. JERVIS: Thank you very much.

MR. DICKINSON: We're running slightly behind, so we'll try to keep moving right along, and we may actually try to get a little time for a break at some point, I hope, maybe after Mr. Spiegel is finished.

Mr. Spiegel?

MR. SPIEGEL: Good morning. I am Jack Spiegel. I am the Director of the Patenting and Licensing Division of the Office of Technology Transfer at the National Institutes of Health. My testimony represents the views of the NIH.

The primary mission of the NIH is to acquire new knowledge and conduct support of biomedical research. NIH recognizes the necessity and the usefulness of patents in accomplishing this mission. Strong patents provide an important vehicle for the transfer of many of our new discoveries to the private sector for further development and commercialization into health care products and services.

This technology transfer aspect of our public health mission is codified in the Federal Technology Transfer Act of 1986. Since passage of this enabling legislation, the NIH has entered into over 400 cooperative research and development agreements with industry, obtained over 900 issued patents, executed over 1,300 licenses and received

over \$200 million in royalties which are used to reward Government scientists for their inventive contributions, recover the cost of seeking intellectual property protection, and reinvest back into the research laboratories to advance further discovery.

In addition to these activities by the NIH intramural scientists, the NIH directs approximately 85 percent of its budget to fund biomedical research at universities and contractor-operated research facilities through research grants and contracts.

The NIH supports the transfer of inventions made by our funding recipients through the provisions of the Bayh-Dole Act of 1980.

As a result of these two contributory streams of research and research funding, the NIH is the world's leading source and underwriter of biomedical inventions.

Therefore, as a major stakeholder in ensuring the vitality of biomedical research and the advancement of the public health, the NIH

endeavors to be vigilant regarding trends which may impinge upon this mission.

One such trend the NIH feels disturbing is a reduction in open access to research tools by academic and commercial investigators. This trend is particularly disturbing in the rapidly developing field of genomics. Advancements in rapid screening techniques have produced and are producing a flood of fragmentary sequence information in the form of express sequence tags, ESTs, and single nucleotide polymorphisms, SNPs.

While numerous utilities may be envisioned for these sequences, they remain predominantly intermediate research tools in the discovery of full-length genes and functional associations from high-density mapping of polymorphisms within those genes.

NIH is concerned that reduced access to such genomic tools will slow the pace of research and chill areas of further inquiry. As a primary defense against this concern, the NIH supports all efforts to place EST and SNP sequences into public

databases. Where intellectual property protection is sought for these research tool sequences, we feel it is imperative that the scope of the patents be commensurate with the disclosed sequence and thus be narrow.

Toward that goal, we are confident that PTO can ensure appropriate breadth of claims by following its existing guidelines on enablement as well as the line of CAFC decisions regarding enablement, obviousness, and written description requirements associated with DNA inventions, memorialized in Amgen v. Chugai, Sugano [ph.], In re Bell, In re Deuel, and most recently, University of California v. Eli Lilly.

It is important that the PTO guidelines on written description also support a proper relationship between the scope of claims and what the inventor possessed at the time of filing. The interim guidelines establish a good basic outline of steps and points for consideration in determining whether a disclosure complies with the written description requirements of 112, first

paragraph. The interim guidelines indicate that a proper analysis requires evaluation of the entire application, including the specification and the scope of each claim.

This evaluation is conducted from the perspective of one skilled in the art at the time when the application was filed. Each claim is given its broadest reasonable interpretation, and all parts of the claim are considered.

Also analyzed are the field of the inventions and the level of predictability in the art where the level of predictability is inversely related to the amount of disclosure necessary to demonstrate possession of the claimed invention.

The guidelines instruct that each species claim should be analyzed to determine if either the entire structure is described or sufficient identifying characteristics are disclosed. For each genus claim, an analogous determination is made regarding the presence of representative numbers of species described either by complete structure or sufficient identifying

characteristics.

Conspicuously missing from the interim guidelines is any mention of or specific application of written description considerations to ESTs. In view of the large number of ESTs pending before the PTO and the controversies surrounding the scope of protection that may be afforded this category of genomic research tool composition, it is important that the final guidelines address these inventions.

Specifically, the issues of open versus closed transition language to the appropriate scope and written description of EST claims needs to be addressed. The NIH believes the proper scope of EST claims would be provided by the use of closed transition language such as "consisting of". By contrast, open transition language such as "comprising", "including", "containing", or "characterized by" create problems relative to undue breadth and insufficient written description to support possession of the scope of the invention.

This conclusion arises from the fact that open transition language permits the structural formula or sequence of the EST to be extended in length indefinitely and randomly at either or both ends of the molecule.

Such indeterminate modification of the EST sequence is not in concert with the previously indicated line of CAFC cases which instruct DNA inventions to be described and claimed based upon their specific structure and/or other physical properties.

Such gross modification of EST sequences would necessarily be expected to affect the predictability of the structure/function relationship that underlies consideration of undue breadth under the enablement provisions and possession under the written description provisions of 35 USC 112, first paragraph.

As the predictability of the structure/function relationship is increased due to the modification and broadening of the EST structure, the scope of claims must be

proportionately reduced. Alternatively, proportionately more working examples must be described in the specification to establish a predictable structure/function relationship across the scope of each enhanced EST sequence. In this way, the appropriate scope of each EST would be examined on a case-by-case basis.

By contrast, the interim guidelines go to particular lengths to address distinctions between different preamble terms such as "gene", "cDNA", "mRNA", "nucleic acid" and "DNA" as they relate to written description. This preoccupation with preamble terms ignores the contribution or effect of the transition phrase "relative to claim scope and written description considerations".

The net result would be the establishment of apparently per se rules whereby an EST sequence could be claimed as a nucleic acid sequence comprising Sequence ID Number "X".

As indicated, the nature of the claim transition phrase significantly affects the scope of nucleic acid claims. Each nucleic acid claim

and its specification must be examined on a case-by-case basis to establish the appropriate breadth and written description relationship.

In addition to situations involving recognized open transition language, this case-by-case rule is also applicable to situations where the transition phrase does not have a well-defined relationship to nucleic acid claim scope, such as transition phrases, "having", "being", "composed of", or "consisting essentially of".

The PTO must avoid per se rules whereby one specification disclosure fits all ESTs. In this regard, the PTO does not need to establish special rules for EST and other nucleic acid inventions. Claims to such inventions should be examined according to the same Section 112, first paragraph patentability rules applicable to any chemical structure where the state of the art is such that there is not a well-established correlation between structure and function.

NIH is aware that its policy position on research tools generally and EST and SNP patenting

specifically is not universally endorsed. We appreciate that what represents a research tool to us constitutes a commercial product to others. As in many issues of controversy, where you stand on an issue depends on where you sit. The PTO should be aware of such policy considerations because its actions impact the outcome of many of these issues in the biotechnology community.

The PTO, however, must avoid the appearance of partisan participation in the name of customer service. The NIH, as a member of the biotechnology research community, appreciates enhanced customer service. It has been adopted by the PTO over the last several years. That customer awareness has improved communications, quickly resolved issues, and reduced examination time.

When there was near universal agreement several years ago regarding the need to visit patentability issues related to utility, the PTO responded in a timely and definitive manner to satisfy the biotechnology community. Customer service in the face of apparent conflicting

interests, however, may be misinterpreted as an appearance of conflict of interest on the part of the PTO.

No one wishes the PTO to become embroiled in partisan controversy. Indeed, everyone involved desires and benefits from a vigorous and vital PTO, issuing strong patents with an unclouded presumption of validity.

Ignoring the relevant patentability issues and the written description guidelines is not the way to avoid a controversial issue. This merely begs the issue and delays resolution for years before the courts can dispose of a problem.

The PTO must address this issue of open claim construction relative to patentability of ESTs in its final guidelines. There appears to be sufficient guidance from the CAFC regarding claiming DNA in structural terms for the PTO to address this patentability issue. If the PTO believes this issue ultimately must be resolved by the court, then the PTO may best serve the biotechnology community by establishing an

appropriate and clear test case and expeditiously advancing it to the Board of Appeals for judicial review.

Thank you.

MR. DICKINSON: Thank you.

I'd like to ask a question. Probably one of the great technological advances of the last half century in this country has been polymer chemistry. Many have analogized the discussion we are having today to polymer chemistry and the fact that, by and large, open claiming was not found to be, despite a lot of discussion along the same lines we're talking about today, an inhibition against the development of that technology but in some ways, an incentive.

Could you comment on whether that fear that you are expressing today might or might not come to fruition by analogy to other related technologies like polymer chemistry?

MR. SPIEGEL: I think even in the polymer--although I am not an organic chemist--the comprising language, the open language, as it was

applied to the structural formula of the polymer, was still considered to represent the addition of excipients, the addition of additional compounds beyond that which was defined by the formula of the polymer, whereas in nucleic acid and amino acid claims, it is pretty well established that open comprising language, in addition to permitting excipients, permits the extension of the DNA structure. I don't think that that was perceived in the polymer part.

MR. DICKINSON: Mr. Kunin?

MR. KUNIN: Mr. Spiegel, you briefly made mention of where problems may arise with respect to permitting use of transition phraseology such as "consisting essentially of". Mr. Jervis attempted to perhaps draw a line in terms of when it would be appropriate and when not.

What are your views as to when and under what circumstances, if any, "consisting essentially of" would be appropriate as a transition phrase for EST type of claimed inventions?

MR. SPIEGEL: Probably in a situation in

which the applicant was able to delineate it in the specification. Again, I hate to beg the question, but that is something that you have to work out with each applicant. I think there are a number of transition phrases that are fuzzy, and fuzziness should be worked out by definition in the specification so that it is clear what was meant by that terminology in the claims.

And quite frankly, if that fuzziness continues, you may consider a problem in the 112 second paragraph as well as a problem in the first paragraph.

MR. DICKINSON: Other questions?

Mr. Chambers?

MR. CHAMBERS: Dr. Spiegel, in the past, I believe Dr. Varmus has suggested that ESTs might be acceptable if they had the semi-open-ended, "consisting essentially of". Your statements today suggest that NIH's position is that they should simply get the "consisting of" transitional phrase. Is that correct?

MR. SPIEGEL: I'm not sure Dr. Varmus

understands the distinction between those two.

MR. CHAMBERS: But NIH's position is that "consisting of" is all that would be possible for something that was simply a marker in the genome; is that right?

MR. SPIEGEL: Absent further delineation in the specification of appropriate formula and/or working example that would permit expansion of--

MR. CHAMBERS: To "consisting essentially of"?

MR. SPIEGEL: If that can be defined, yes--including "comprising" if that could be described in a way that shows that there is enablement and possession of that invention.

MR. DICKINSON: Does the NIH, to your knowledge, support a modification in the law to create a more defined research exemption under the prohibition--

MR. SPIEGEL: I think that's a separate issue, but we would probably be in favor of that, yes.

MR. DICKINSON: Would that color the kinds

of issues you are raising today with regard to where NIH stands?

MR. SPIEGEL: It would probably lessen the urgency with which we think broad claimed research tools such as ESTs and SNPs would have an effect on the research community. Whether that answers your patentability questions, I don't think so. I think the PTO should deal with these issues on a purely patent basis, understanding the conflicting policy issues of the people who are filing applications and commenting on them.

MR. DICKINSON: Does NIH feel that statutory solutions to some of these questions are appropriate, particularly what we are talking about today, if we go in a different direction than NIH would urge us?

MR. SPIEGEL: Hopefully, we don't have to get to that bridge. Hopefully, they can be dealt with in the PTO. I think you've heard before that whenever you can stay out of the courts or stay out of legislation and deal with an administrative agency who are experts in the field, you are better

off.

MR. DICKINSON: Any other questions?

[No response.]

MR. DICKINSON: Thank you very much.

Let's take a 10-minute break and then resume with Mr. Schmickel.

[Recess.]

MR. DICKINSON: Thank you all very much.

Just checking in, are there any other folks who are prepared to testify? I know Gerry Weiser was saying he might, but I don't see him in the room; and if time is becoming an issue for anyone who is prepared to testify, let me know that as well.

We'll resume with, again, one of our most important constituencies in this area and maybe overall, certainly, BIO, and ask Dave Schmickel to come forward.

MR. SCHMICKEL: Thank you. I am Dave Schmickel, and the views I am expressing today are the views of the association.

The association that I represent, the

Biotechnology Industry Organization, represents over 800 companies, and the companies we represent range from small start-ups, virtual companies, to multinational companies, including Pioneer and Genentech, which will speak today, and perhaps others who have submitted comments for the record.

Last year, our 316 public companies invested \$5.6 billion in research and lost about \$2 billion. The amount of money we invest in research and development is not equal to our revenues; in order to make up the deficit, we go to the capital markets on a regular basis to raise money. This money is raised in the hope that eventually, products will be on the market and have product sales in order to fuel further development.

This hope that premises the investment of the biotechnology area is based in part on the hope that an exclusive position will be found in the marketplace to support high profit margins and continue investment for research and development.

BIO is submitting comments for the record which address or better address the interim

guidelines, and five narrow points are raised in that document. One concerns the new importance that the interim guidelines seem to place on the preamble. We are concerned as to whether that importance is warranted.

The second is, as Herb Jervis mentioned earlier, the distinction that appears in the document between biotech and non-biotech inventions.

The third is an absence of middle-ground guidance. The two extremes in the document are very well represented, but we are quite concerned whether examiners reading the interim guidelines will have enough basis to judge whether a rejection is appropriate in a middle-ground case.

The fourth is the concordance of the guidelines with the CAFC opinions.

And finally and most importantly is the need for guidance regarding what is an appropriate genus of claims.

These concerns are adequately addressed in our written comments, and I will not be covering

those views of the associations again.

At this time, I just want to thank the Patent and Trademark Office for the process. BIO is an organization that works with a number of agencies, and no agency has been as open and responsive as the Patent and Trademark Office. UC v. Lilly did cause a number of our companies a great deal of concern as to how and in what fashion the Patent and Trademark Office would deal with that case. The Commissioner answered a lot of those concerns through these interim guidelines in Mr. Dickinson's comments regarding the need for uniformity and examination heard in our organization, and we very much appreciate that you have this constant concern for uniformity and predictability.

As I said, our companies base their investment decisions on ability to get an exclusive position in the marketplace. If our patent position is uncertain, it adds risk to the investment, which ultimately diminishes the present value of the research that is ongoing. This

diminishment is not only an unwise business decision, but also limits the amount of money that can ultimately raised for these ventures.

As mentioned, starting with the San Diego hearings, this office has been a great friend of this industry in trying to help our industry make sound decisions based on predictable decisions coming out of this office.

I'd like to say again that I think our comments regarding the specific interim guidelines are fully addressed in our written comments, and again, we are tremendously grateful for this process being so open and for having this opportunity for this in industry to comment.

Thank you.

MR. DICKINSON: Do we have the written comments?

MR. SCHMICKEL: I have them.

MR. DICKINSON: Good. We'll distribute those.

Are there any questions?

MR. KUNIN: Perhaps this is answered in

the written materials that we have yet to have a chance to peruse, but we would appreciate it if perhaps you could express some of the views that BIO has with respect to appropriate transition phrase language for EST-related inventions.

MR. SCHMICKEL: In a letter from Carl Folban [ph.], our president, again expressing the views of the association and not particularly individual members, we expressed a view that was very similar to what Jack Spiegel expressed at NIH, that it is very important for the claim language to be commensurate in scope with the disclosure. That would entail numerous transitional language where appropriate.

We would beg to take exception with some of the things that Jack said, specifically, his assumption that all EST claims should be written narrowly, or his assertion at one point that all EST claims should be drawn narrowly. We think that some EST claims should have very broad protection where appropriate and where the disclosure warrants it.

MR. DICKINSON: Can you elaborate a little bit on where that might be warranted, or where some of your members might feel that is warranted?

MR. SCHMICKEL: The membership would believe that is warranted, in the words of one of our members, with certain ESTs and disclosures. There is no application sent in that says this is an EST disclosure. An application that has a disclosure in it, DNA sequences, might be 250 nucleotides with, again in the words of one of our members, a blinking red arrow to a specific utility and a specific use. In those cases, obviously, broader protection is warranted.

MR. DOLL: Could you exemplify what specific uses or specific utilities they were talking about--and I'm going to go back to saying forensic testing, tissue typing chromosome mapping--is that specific enough?

MR. SCHMICKEL: I think Jack's example, or maybe it was Herb's example, where a particular sequence of DNA was very useful in detecting a polymorphism associated with cystic fibrosis, is a

good example of a very powerful utility that deserves broad protection.

MR. DICKINSON: So you seem to be suggesting--and I don't want to put words in your mouth--but you seem to be suggesting that there is a tension between the specificity of the utility that is described and what the transition language should look like as a function of the breadth of the claim.

MR. SCHMICKEL: There should be a tension between the disclosure and the amount of disclosure and the breadth of the claim, yes. And obviously, the heart of the disclosure would be utility, and the more meaningful the disclosure, the more broad the claim should be.

MR. DICKINSON: Would you have any guidance for us if we were going to take a look at trying to define the meaningfulness of the disclosure requirement?

MR. SCHMICKEL: I would imagine that, like in this circumstance, we will have a tremendous diversity of opinion within our organization, and

it will be hard for us as an organization to speak for one voice. Unlike the utility requirements, where there was great unanimity and opinion, the written description requirements really do support a much broader scope of opinion.

MR. DICKINSON: So would it be fair to characterize your membership as some are very supportive of where we are right now with the written description guidelines, and others take significant exception to them?

MR. SCHMICKEL: With the exception of the five more or less narrow points that are drawn in our written comments, I would say that yes, by and large, there is a great diversity including very strong support for what has been done today. There is absolute agreement that the open process that this administration is leading the industry through is very helpful and very supportive.

MR. DICKINSON: Any other questions from the panel?

[No response.]

MR. DICKINSON: Thank you, Mr. Schmickel.

We appreciate your being here today.

Next, we'll hear from Joy Bryant, from the National Association of Patent Practitioners, NAPP. It's always a pleasure to see Ms. Bryant again here in the Office. Thank you for being with us today.

MS. BRYANT: The views that I am expressing today are on behalf of our organization and are not my own personal views.

We appreciate having the opportunity to appear at these important hearings. The National Association of Patent Practitioners is a nonprofit organization dedicated to supporting patent practitioners and other individuals working in the field of patent law and matters relating to patent law, its practice, and technological advances.

Seventy-five percent of our members are registered patent practitioners whose practice is directed primarily toward patent prosecution. As part of our mission, we aim to create a collective nationwide voice to respond to proposed changes in the patent statutes, rules, and PTO operations, with a view to their impact on patent prosecution

and practice.

I will be presenting our broad overview of these guidelines, and Dr. Agris will address the specifics, so I would appreciate it if you would hear me and wait on your questions until after she has spoken, and then she and I will both address your questions together.

MR. DICKINSON: Fine.

MS. BRYANT: Before addressing the specific questions that are asked by the PTO, I would like to point out some general observations that we made related to the subject.

The written description requirement of 112, first paragraph, is a distinct and separate requirement from enablement and best mode. Traditionally, a specification which set forth the identical words as those used in the claim was in fully compliance with the written description requirement.

While such *ipsis verbis* support was not required in order to meet the written description requirement, it was a sure way to convey that the

applicant was in possession of the claimed invention as of the time of filing. Nothing more was needed in order to satisfy the written description requirement, and in this way, the requirement served primarily as a test to determine if "new matter" had been added to the application. Whether or not the description of the invention was adequate to enable the reader to make the invention was wholly a separate inquiry from the written description requirement.

Recent decisions suggest that compliance with the written description requires something more than mere words in the biotechnology field. Specifically, these decisions appear to add a quality element to the written description requirement in the biotechnology invention.

We believe these decisions are in error in that they attempt to introduce enablement requirements into the written description standard in spite of the established precedent that the two are separate and distinct. That is, the quality of the description should be measured by the

enablement requirement, not the written description requirement.

Accordingly, to the extent that these interim guidelines and/or the recent decisional law are requiring the interacting of elements of enablement analysis onto the test for written description, the intrusion must be kept to a minimum both in terms of technological area and legal requirement.

Referring now to specific questions asked by the Patent and Trademark Office, with respect to the methodology, we do not believe that the methodology in the interim guidelines is accurate. In particular, we have identified the following legal and technical inaccuracies. First, the guidelines instruct the examiner to review the specification in order to determine what the invention is and then review the claim to determine if the applicant has complied with the written description requirement. Such an approach is improper and was criticized by the CCPA in In re Borkowski, where the court stated: "We cannot

agree that 112 permits such an approach to claims." The proper approach was set forth in In re Moore, and it calls for the examiner to read the claims first and then determine if the specification provides adequate support for the claim's subject matter. In this way, the applicant maintains the right to claim the subject matter that he regards as the invention instead of what the examiner regards as the invention.

Secondly, the terminology in the guidelines is inconsistent--or incorrect. For example, a gene comprises all nucleic acid sequences necessary to produce a functional protein for RNA, but the guidelines consider a claim to a genecomprising Sequence ID 1 to be more difficult to support than a claim to a nucleic acid molecule comprising Sequence ID 1. It does not seem logical that one could readily envision a sufficient number of members of the claimed genus with respect to a nucleic acid but could do so for a gene. This will be addressed further by Dr. Agris.

In order to improve the accuracy of the

guidelines, we would like to make the following recommendation. With respect to the examiner's review of the application, we recommend that the claims be read first and then the specification, to determine whether adequate support is provided for the claimed invention. If the claimed invention is not supported or is only a wish in the specification, then the specification fails to enable the claimed invention.

It appears as if no factors and descriptive attributes have been omitted from the guidelines. However, we have identified the overall analysis to be overinclusive. There are too many limitations with respect to the identifying characteristics. There is no guidance provided as to what would constitute sufficient identifying characteristics, nor are the number of the examples needed to have a sufficient written description set forth. Thus, with respect to these matters, the guidelines provide no guidance.

The analysis could be improved by keeping the enable requirement separate from the written

description requirement. It is important not to be overinclusive and require all these extra identifying characteristics. If a structure is provided or a function in combination with a particular structure, or a function and some characteristics, the written description should be considered as met. Enablement should be considered as a separate issue. In other words, you could have a written description, but you may not meet that enablement requirement.

These guidelines should be limited to the biotechnical art only, and more specifically limited to nucleic acids, constructs, vectors, and host cells containing the genetic material. The rationale behind the guidelines is based on case law that is specific to these areas of biotechnology invention.

The terms should be treated the same as far as "having", "consisting of", "consisting essentially of", "comprising", as they are treated for chemical cases. It should be noted that the term "having" can in certain contexts mean

"comprising" and in other contexts can mean "consisting of". This term has not yet developed an art-recognized standard like the terms "comprising", "consisting of" and "consisting essentially of", and in view of this, any new rule that is made should not be retroactive, because we are drafting these claims now based on the old practice.

Should the guidelines be expanded to specifically address process and/or product by process claims, product by process claims get divergent treatment. Perhaps the real question is should the guidelines be expanded to specifically address process and/or product by process claims. In answer to this question, we think not. Process and product by process claims should be examined in accordance with the current rules of written description. The guidelines should not be expanded to these types of claims, and in particular, if there is *ipsis verbis* support for these types of claims in the specifications, the written description requirement is met.

With respect to how it would have an impact on issued patents, currently pending applications or applications that are filed after publication of the final written description requirements, probably many issued patents will be challenged in court and declared invalid; however, these challenges will most likely be a result of the Eli Lilly case more than the publication of the guidelines. Currently pending applications may have to be refiled as CIPs to meet the more stringent requirements that are set forth in the guidelines, and many of the currently pending applications were prepared and filed before the applicants were aware of the proposed guidelines and were mostly likely not prepared in accordance with the guidelines. Applications filed after publication of the guidelines will most likely be much more detailed and a lot longer in length.

Summarizing the position of NAPP with respect to the interim guidelines and giving you a general overview, these guidelines should be applied only to the biotechnical arts and more

specifically limited to nucleic acids, constructs, vectors and host cells containing the genetic material.

Second, the written description requirement needs to remain separate from the enablement requirement.

Third, *ipsis verbis* should always be sufficient for written description.

And fourth, the claim should always be read before the specification to determine whether there is adequate support in the specification for the claimed invention.

At this time, I'd like to again thank you for the time and call up Cheryl Agris to address more of the specific questions that you had.

MR. DICKINSON: Does Dr. Agris also have testimony?

MS. BRYANT: Yes.

MR. DICKINSON: Very good.

DR. AGRIS: I am Cheryl Agris, and I am actually one of the 25 percent of the members who is a patent attorney. I was in-house attorney for

Nova Nordisk [ph.] for six years, and since March, I have been in private practice, and I have prosecuted and currently handle a number of biotechnology patent applications.

I would also like to thank the U.S. Patent and Trademark Office for holding these hearings. These guidelines will certainly, as everyone here has stated, have an impact on the prosecution of applications in the biotechnology area, and we certainly appreciate the opportunity to be able to comment on them.

In your Request for Comments, you asked a number of specific questions, and my colleague Joy Bryant made some general comments, and I will focus on some of the specifics, and I will also address the questions with respect to microorganism deposits and ESTs.

With respect to the first question of terminology, I agree with the position set forth by Jack Spiegel and to some extent Dave Schmickel that there seems to be a big preoccupation with the terminology in the preamble and that there should

be more of an emphasis on structure.

For example, statements are made about claims specifically reciting mRNA and cDNA, and I just want to point out that an mRNA is just a type of RNA, and a cDNA is a DNA that is copied from RNA and that, actually, in the Lilly decision, there really wasn't a problem with reciting cDNA per se; it was just the breadth of the claim itself. I think that there should be less of an emphasis on semantics.

The other thing is with respect to gene. In these guidelines, it is stated that claim to, say, a nucleic acid comprising such-and-such is fine, but not a claim to a gene for such-and-such. I find this a little ironic, because actually, claim to a gene, so to speak, would actually technically be a bit narrower than to a nucleic acid.

The other point I want to make is that in these guidelines, there is a lot of emphasis on genus/species distinction. We found it rather unclear at NAPP as to when the claim is directed to

a species and when it is directed to a genus, and if these guidelines stand, it is rather important to be able to make that decision, because whether something is considered a genus or a species might determine what sort of breadth of disclosure has to be made. And actually, in these guidelines, with respect to the example for the species--this was the DNA sequence--I think in (c)(2), "the isolated double strand of DNA consisting of the single-strand of DNA with a molecular weight," and so forth--that is considered to be directed to the species, but then you had in section (2)(d) to the monoclonal antibody. But one can make arguments both ways, that a species could be considered a genus and vice versa, so I think more guidance has to be given that way.

Now, with respect to the third question, as my colleague Joy Bryant said, we at NAPP advocate that these guidelines should only be restricted to the biotechnological art and specifically with respect to nucleic acid sequences or constructs, host cells, et cetera, containing--

we won't get into the transitional language at this point--these nucleic acid sequences. Actually, this was addressed in the Lilly decision where they actually distinguished claims to genetic material from claims to machinery or chemicals.

The next thing I want to address is the question about "consisting essentially of" and "having". There has been a lot of questions about nucleic acid sequence claims or amino acid sequence claims and what exactly should "consisting essentially of" be. And in our view, with respect to nucleic acid sequence claims, this would be analogous to, say, pharmaceutical formulation claims where it would be sequences which would not affect the function of, say, the protein expressed--for example, a noncoding sequence or something like that.

We are now going to go to the question of microorganism deposits. It seems as if there is a bit of a concern as to how these guidelines should address this issue. The first question was about how the data deposits should be considered. This

actually was addressed in the In re Lundak [ph.] case, where actually, in Lundak, they held that it was permissible to disclose the claim's B-cell line after filing the application, and actually, Lundak has said that "an accession number and deposit date add nothing to the written description of the invention." Essentially, in looking at establishing possession of the invention, one should look to the specifications and see whether there is sufficient description of the subject matter.

So our view would be that--maybe not as radical as Lundak's view--but that one should look at what is actually described in the specification and take into consideration also the date of deposit and that the date of deposit should not necessarily be controlling.

The second issue was what significance should be assigned to a deposit in assessing compliance with the written description requirement, and actually, this issue was addressed in Sections 2401 to 2411 of the MPEP. They

actually say, I think in 2402, that a deposit may be used to supplement the written disclosure in an application with a deposit of biological material which is essential to meet some requirement of the statute with respect to the claimed invention.

But again, it should go hand-in-hand with what is described in the specification, and I believe in the Feldman v. Austrup case, they say that it must be clear from the application that as filed from the invention claimed in describing the specification that it was fully capable of being reduced to practice.

And I guess the third part is the extent to which the positive biological materials may be relied on to support the addition of sequence information or the correction of sequence information. Here, I would agree with Dr. Jervis that if, for example, a particular microorganism has been deposited containing a nucleic acid sequence, then one would be considered in possession of that sequence even if, say, it turned out that the disclosure had an incorrect sequence,

because since that sequence has been deposited, one would be in possession with the correct sequence itself.

The other question that we would like to address is with respect to expressed sequence tags, and our view is actually very similar to what was expressed by Dr. Spiegel and Dr. Jervis. It appears, and our view is that a claim to, for example, a nucleic acid comprising EST Sequence 1, 2, 3 would cover any nucleic acid sequence comprising this EST and would provide extremely broad coverage and that this could potentially dominate full gene and protein patents even though EST patents don't disclose the full nucleotide sequence of any genes, and therefore, if someone later on isolates another EST which is part of the nucleic acid comprising the first EST, this person would be considered a potential infringer. And actually, in our view, this appears to be contrary to the Eli Lilly decision, where one would only expect to get coverage on the sequence disclosed.

The second issue is with respect to other

statutory requirements, and I think everyone would agree this is the question of utility-- specifically, what use do these sequences have. In our view, it is not enough that they be used as probes in general. At the very least, they should be used as probes for a specific purpose, or if used for other purposes, they should be identified--for example, tissue typing, chromosomal mapping, et cetera.

Just to briefly summarize our two statements, there should be less of an emphasis on semantics. These guidelines should only be applied to the biotechnological art. Generally, with deposit, the status quo is adequate, and with respect to expressed sequence tags, broad claims with respect to these tags would be detrimental to the industry and counter to the Lilly decision, and that these guidelines should only be restricted to the biotech arts and only to nucleic acid sequence type claims. And actually, finally, we also believe that these should only be applied to applications filed after implementation of the

guidelines.

Thank you. We will both entertain questions?

MR. DICKINSON: Questions?

MR. KUNIN: I have lots of them.

[Laughter.]

MR. DICKINSON: Go ahead, Mr. Kunin.

MR. KUNIN: If you'll bear with me, I thank you both for your presentations, and of course, by having the benefit of your presentations, it certainly perhaps gives us the opportunity to get additional views through our questions.

The first question I have is there is a desire on your part that the methodology be changed such that the claims are looked at first, and then the written description, but you rely on In re Moore as the basis for this, and In re Moore is a 112 second paragraph, not a 112 first paragraph written description case, and they serve very different purposes.

Could you perhaps indicate to us why In re

Moore would be the basis for looking at the claims first?

MS. BRYANT: Actually, we're going to call on another member for help, Mark Busher.

MR. DICKINSON: I'll ask you to come up so we can get your testimony, and if you wouldn't mind introducing yourself.

MR. BUSER: Thank you. My name is Mark Busher. I am a patent attorney. I am presently an associate with Howry and Simon, but my views today are solely those of NAPP and not any client or position of the firm.

In re Moore was cited because it generally teaches that 112 analysis begins first with the claims. You look at what the claims say, and then you start your analysis. And it is true that the precise issue was a 112 second paragraph; however, I think that sets the tone for all of the 112 analysis and that--well, in fact, an originally filed claim, as has been earlier mentioned, is itself its own written description.

So in terms of written description

analysis, our approach is as follows: You should read the claims first and not first read the specification and come up with some idea of what you think the invention is. The claims define that. Then, read the specification for all of 112 first paragraph support--meaning enablement as well as best mode as well as written description.

The primary focus, we believe, should always be on enablement with respect to any originally filed claims. With respect to amended claims, you have a written description issue in that new matter may have been introduced.

MR. KUNIN: Maybe you should stay for the next question.

MR. DICKINSON: Hopefully, we're not going to get into a debate on the whole question--

MR. KUNIN: No. I'm just interested in hearing their views.

The position of NAPP with respect to the presentation of original claims and using that as the basis for an indication of the satisfaction of written description may perhaps be at odds with the

Federal Circuit case in Tronzo v. Biomet [ph.]. In Tronzo, you are dealing with the aspect of the omission of an element which the written description says is critical, so even if it were present in the original claim, if the written description says that that element is necessary and has been omitted, perhaps, according to Tronzo and Gentry v. Berkline, that may not necessarily be the case.

Do you have any specific comments with respect to the applicability of Tronzo or Gentry to your views on this issue?

MR. BUSHHER: I don't really have any specific comments with regard to either of those cases. I would only mention, I believe it is the In re Gardner case from way back, where this precise issue came up of does an original claim without corresponding antecedent in the specification comply with the written description requirement, and the court said yes.

On these more recent cases, as I said, I think I'll withhold any comment.

MR. KUNIN: You indicated these written description guidelines should be limited to perhaps even subsets of biotechnology. Why should we have a special patent law for this technology and not the same patent law for all technologies?

DR. AGRIS: I'll address that. I think it's because of, number one, the unique nature of this subject area, and number two, actually, just the fact-specific nature of the Lilly decision and the Fiers decision and the Amgen decision--it only addressed a discrete subject area. And even in Lilly, they took pains to state that it really should be distinguished from other areas, like mechanical and chemical areas.

MR. BUSHER: If I could elaborate on that also, in our view, we would say that the rationale of cases like University of California v. Eli Lilly was wrong. If they were going to attack the case, they should have attacked it under enablement. Now, you can say, well, but that's what the Federal Circuit has said. Okay. The Federal Circuit has said this is what the law is, but only for

biotechnology. So it is the Federal Circuit that is carving out special law for biotechnology. The Federal Circuit opinion said this doesn't really apply anywhere else only because of the unique facts in biotechnology.

I would agree with you--shouldn't there just be one law--and that if they can't clearly enunciate why it should be different for biotechnology other than it is very complex and very new, and it has very unique issues, I don't see what would prevent it from leaping over first in the chemical practice and then, ultimately, all the way to mechanical practice. But I believe that the real reason why this is being set up is that that is how the Federal Circuit decisions are going.

MR. KUNIN: You indicated that these written description guidelines should not apply to process claims or product by process claims. As to process claims, in view of cases like In re Ochiai and In re Brauer [ph.], where to a large degree, patentability taken as a whole included the

significance of the product, where that situation occurs, how do you reconcile that the description requirement under these guidelines should not apply?

DR. AGRIS: I would say that, again given the fact-specific nature of the Lilly decision, the Amgen decision, Fiers--and there is also another decision, Fittis v. Baird--which really didn't address the issue of process claims or product by process claims, so there is really no guidance from the Federal Circuit as to how to deal with it.

So I think these decisions should only be specifically applied to the facts of those cases or the fields of those cases.

MR. BUSHNER: Also, I think that viewing this heightened written description requirement for biotechnology products as just that--some kind of extra requirement--I think the rationale on our part is that you should limit the amount of intrusion as much as possible. And to the extent you are dealing with a process, obviously, there could still be some enablement problems--if you are

claiming a process of starting from a cDNA and coding for whatever, you could run into the same kinds of enablement issues that we think are really being encountered now, only cloaked under the guise of there is no written description.

Product by process I think is a traditional way of claiming a product when you just don't know what the heck it is, but you know that you got it, and you know it works, and you know how you got it.

So again, I think it seems unfair to try to impose an extra level of description--not so much to provide enablement; this is just description because Eli Lilly says you have to have more.

MR. KUNIN: One final question on In re Lundak. I got the impression from your testimony that you view the Lundak case as related to date of deposit as an enablement and not a written description issue.

DR. AGRIS: Actually, yes and no. In re Lundak was generally addressing the enablement

issue, but they also did to some extent address the written description issue when it came to date of deposit and also with respect to how it related to the specification, but I think they addressed the enablement issue a bit more thoroughly than the written description issue.

MR. KUNIN: Thank you.

MR. DICKINSON: Mr. Doll?

MR. DOLL: I'd like to follow just one of Steve's questions and ask you if you think the court would have felt there was adequate written description for a product by process claim for human cDNA--because I think we probably all feel that it was a fully enabled disclosure. I was just curious what you would think of a product by process claim where you are claiming human cDNA or mammalian or vertebrate cDNA by the process which was fully enabled.

DR. AGRIS: By the process which was fully enabled, where you actually describe the process by which it is obtained.

MR. DOLL: But you have no description of

the actual cDNA.

DR. AGRIS: But no description.

MR. BUSER: I vote yes.

[Laughter.]

DR. AGRIS: Yes, I would say yes. I would say yes.

MR. BUSER: The most intriguing part, though, is what happens to that claim out in the real world. Obviously, the divergent treatment between within the PTO of a product by process claim versus outside makes an interesting twist. But I think that should be fine--

DR. AGRIS: yes, because if you actually describe how you obtain it--

MR. DOLL: But you have not obtained it.

DR. AGRIS: But that's, again, constructive reduction to practice. Certainly, it would be enabling, but would it be written--I think yes, it would be.

MR. DOLL: Thanks.

MR. DICKINSON: Mr. Chambers?

MR. CHAMBERS: I have a question for Dr.

Agris. You've suggested that the DNA polymer should be treated differently than the amino acid polymer. Now, one interpretation of Eli Lilly is that the sequence of a single gene for Protein X does not support a claim for all vertebrate genes to Protein X. Is that right?

DR. AGRIS: Well, yes.

MR. CHAMBERS: Would it be NAPP's position, then, that the sequence of a single amino acid chain would support a claim to the amino acid chains of all vertebrate forms of Protein X?

MR. BUSHNER: If I could jump in--could we clarify what is the claim in this application, and what is the disclosure in this application?

MR. CHAMBERS: The disclosure would simply be a disclosure of a single nucleic acid sequence, or a single gene--

DR. AGRIS: Oh, I see.

MR. CHAMBERS: --and then a claim to all genes from the vertebrate kingdom that would correspond to that. Then, we would contrast that with a single amino acid sequence to the product of

that gene and the corresponding claim to all possible genes for all possible amino acid sequences.

I have difficulty in seeing the difference, except in a question of complexity.

DR. AGRIS: I see what you're saying.

MR. CHAMBERS: There is the opportunity for 20 different amino acids at a particular point. There is the possibility of about 64 different codons at a particular point.

DR. AGRIS: Right. I understand the distinction.

MR. CHAMBERS: How do we draw that distinction between amino acid sequences and nucleic acid sequences?

DR. AGRIS: I see your point.

MR. CHAMBERS: We have to look at these things prospectively, and I'm just wondering how--

DR. AGRIS: Yes, I do understand your point. I guess your question is why can't we extrapolate--

MR. CHAMBERS: How can we not, I think is

the question.

DR. AGRIS: --or, how can we not extrapolate. Well, certainly, I think you would agree that with respect to DNA sequences, there is just a lot more complexity and chance for variability than with amino acid sequences. So I think they are, so to speak, two different ball games.

MR. DICKINSON: I just have a quick question, actually, for Ms. Bryant. NAPP is one of our favorite organizations, and we are very pleased to have you with us today.

How does NAPP come to formulate their organizational position on these issues?

MS. BRYANT: We have a quarterly newsletter, and when your guidelines came out back in the summer, we put an announcement into our newsletter and told our members that they are to write their comments and submit them to us by a set deadline, and those comments that they submit constitute their vote with respect to our position, and then we take those comments that we have

received and go to committee, which is where these two come in, and compile those comments and discuss them. We also run a List-Serve for membership only, and when we run into a sticky issue where we have a lot of different opinions, we run that through our List-Serve and get feedback from our membership. So we get a lot of constant feedback on these; it's not just the three of us sitting down and writing these out. There is a lot of input from all of our members who subscribe to List-Serve.

MR. DICKINSON: I appreciate that. Thank you very much.

Are there any other questions from the panel?

[No response.]

MR. DICKINSON: Thank you very much all three of you. We appreciate it.

Mr. Weiser, you indicated you wanted to make a comment or testify--I'm a little unclear. We also have one more witness, Mr. Kushan.

MR. WEISER: Shall I explain it?

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MR. DICKINSON: All right, if you can do it briefly.

MR. WEISER: My name is Girard Weiser. I am the chair of the subcommittee working on this issue of the Biotechnology Committee.

MR. DICKINSON: Which organization?

MR. WEISER: AIPLA. I was going to make a statement on behalf of the AIPLA. The board at this time is considering the proposals we would like to bring to your attention, and one question I will ask you--we are not ready for that, and we want to know when we can make the submission. When is the deadline?

MR. DICKINSON: The deadline is November the 12th, so any time prior to November the 12th.

MR. WEISER: I have been authorized, though, on my own behalf of make a very brief statement. We would like to ask the Patent Office to issue--when I say "we," I mean I, consisting essentially of myself--

[Laughter.]

MR. WEISER: --consisting of, really--to

issue an appropriate order that the Examining Corps not apply the provisional interim guidelines until the final issuance.

Thank you.

MR. DICKINSON: Fine. The concern is noted. Others have voiced it as well.

Thank you.

Last, but certainly not least, we welcome back to the Patent and Trademark Office, as always, Mr. Jeff Kushan.

MR. KUSHAN: Thank you very much.

My name is Jeff Kushan. I'm with a private law firm, Powell, Goldstein, Frasier and Murphy, and today, I am speaking on behalf of Genentech.

It is kind of enjoyable to be on this side rather than on your side for the first time. I guess I can also say that I was privileged to work on the easy topics, like utility and software patentability.

My representation today, as I said, is on behalf of Genentech, and Genentech is a

biotechnology company based in South San Francisco, California. Its mission is to use human genetic information to develop, manufacture and market pharmaceuticals that address significant, unmet medical needs.

MR. DICKINSON: Can I stop you for just a second? Are you going to supply the written testimony as well, because you are going a little fast, and I am worried that our reporter can't keep up.

MR. KUSHAN: Yes, I'll be providing my comments in writing.

MR. DICKINSON: Thank you.

MR. KUSHAN: Those rules that we made up a few years ago are coming back to haunt me.

My testimony today is going to focus on a few general comments about the role and policies of the PTO, and then I'll provide some specific comments on the guidelines and on the issues raised in the second Federal Register Notice.

You did raise a number of broader questions in the Notice announcing these hearings,

and I would hope that you would accept comments up until November 12 on those issues as well.

First, Genentech attaches great importance to the role of the PTO in issuing valid patents. When the PTO issues a patent that is ultimately found invalid, it costs millions of dollars to correct and does the entire biotechnology industry a disservice. PTO therefore has to ensure that its general guidance to the Examining Corps is based on an accurate interpretation of the law and also is based on a comprehensive examination of each application.

Second, PTO has an obligation to help clarify the law when that law is uncertain, and as we have heard today in the comments we have heard so far, it is fairly safe to say that the law concerning written description requirements in relation to nucleic acid sequences is far from clear.

One thing that we have seen in the past is that when new fact patterns arise in certain kinds of applications, it is usually a good practice for

the PTO to send a test case up to the Federal Circuit to achieve some further clarification of the law. We saw this in the case of In re Ochiai not too long ago, when there were substantial questions about how the Corps was applying In re Durden [ph.], and we did get some clarification on that.

There are lots of other examples that we can point to in the past where a test case has gone forward with the specific intent of clarifying an unsettled area of law.

Clear legal precedent helps both the PTO in conducting its examination and also helps the patent bar in drafting applications that will avoid problems when they come to the PTO. Given the uncertainty that we have seen in relation to the written description requirement as it may be applied to these infamous EST applications, we believe it would be sound policy for the PTO to adopt a strict posture during examination, at least to an appropriate test case being sent to the Federal Circuit.

The third general point I'd like to make is that the PTO has to ensure that its examination guidelines do not produce the unintended results of imposing rejections in all cases, whether the rejection is warranted or not. PTO can do this by differentiating the evaluation process for an application, including ascertaining the scope of the claims, from a decision to impose rejection due to a particular deficiency under law. We are concerned that these guidelines are focused on a very specific point of law and devise a framework for examination that may result in application of a rejection in almost every instance. That is certainly not the goal that we would have in seeing guidelines being formulated.

The fourth point I would like to make is that we do not believe guidelines should be issued that suggest one technology class would be subjected to specific interpretations of the law. Instead, in its guidelines, the PTO should articulate the law in a clear and technology-neutral fashion and then the PTO should use

appropriate examples and training materials to show how that law will be applied for particular types of technologies and particular types of applications.

We saw this practice followed in the development of the utility examination guidelines and the training materials that followed the guidelines, where the training materials did address a number of very specific fact patterns and showed how the guidelines were to be applied correctly in relation to those types of fact patterns. I guess my views here would differ fairly substantially from the views of our previous speaker before Mr. Weiser in that in terms of the law and the exposition of the law, that should be done in a technology-neutral way to the extent possible rather than trying to carve out a special case scenario for biotechnology as a legal matter.

Finally, we--and I can say I personally-- appreciate the difficult job that today's patent examiner has in conducting a comprehensive examination of each application with the very

limited amount of time that each examiner has. Overemphasis of certain statutory requirements will distort the examination process and lead to less attention being paid to the critical issues of novelty, non-obviousness and enablement.

The PTO should strive to establish guidelines that will help the examiner complete the examination of all relevant issues within the time allotted for each case. What this means in practical terms is that the guidelines should provide a well-grounded, general summary of the law and then help the examiner to quickly pinpoint specific types of legal deficiencies or issues rather than force the examiner to proceed through an elaborate process for evaluating compliance with every possible issue that might come up, whether that is a relevant issue for the case or not. Again, this goes back to the importance we see of developing some training materials that can identify types of cases that are likely to provide problem issues or difficulties in the examination process and helping the examiner to identify when

they have a case that falls into that category.

It is not feasible for me to address every issue raised in these two notices, especially if you want to leave today. We intend to file our written comments by November 12th and will deal with all the topics raised in the two Notices.

With respect to the guidelines, I do have a number of specific comments. Perhaps the most significant issue that we have seen in the guidelines that warrants some further work is that they have presented a suggestion that a claim drawn to a nucleic acid comprising a specified nucleotide sequence will have less of a problem complying with the written description requirement than a claim limited to a smaller set of nucleotide sequences defined through reference to shared functional or structural characteristics of those nucleotide sequences.

The logic of this approach is, in our view, fundamentally flawed. In essence, by omitting claim language that would serve to better define a genus of compounds through reference to

their structural or functional characteristics, an applicant would be able to get broader protection. The basic problem with this approach is that the loosely defined claim will, of course, encompass a vastly larger number of species of compounds than the functionally or structurally delimited claim, yet the broader claim is going to face a lower burden to establish compliance with this core written description requirement as it has been recast in Lilly as a possession requirement.

So that in essence, what you get is a scenario in which an entity can, with a single description and way of drafting the claim, be found to possess a larger number of species, whereas the almost identical disclosure can be found to not satisfy this possession requirement in written description for a narrower set of species. There is a problem here in any kind of analytical framework that produces that kind of result.

What we would think is an appropriate way of perhaps remedying this problem is to look at reshaping the guidelines to look more closely at

the definition of whether you have a genus and whether that genus actually defines a legitimate genus in the context of the disclosure.

I think Herb Jervis had a very good example when he gave his talk earlier, and that is that possession of an entity, a compound, an EST, and partial characterization of that thing that is possessed is a fairly known variable that is easier to tackle than an instance where what you possess is a single thing, and what you are attempting to claim and look at in terms of possession are things which are not really possessed by the applicant. For example, if you look at the example provided in the first section of the guidelines, where they have a nucleic acid comprising an EST, that claim literally covers billions of potential sequences, and unlike the scenario Herb provided which involved possession and deposit of a particular sequence with later characterization of the remaining portion of the sequence that was not known, here, you don't even know what sequences are going to be contemplated, and that would be a

fairly significant burden, we think, under the written description requirement as meeting in terms of the new version of the written description requirement from Lilly focusing on possession.

The summary of the legal foundation of this written description requirement should be set forth--and I mentioned this earlier--in a fairly clearly written and, I would suggest, example-free introduction. In other words, lay out the law, where it is today, and do not try to incorporate examples into your definition of the law, which is what has happened in this case.

One of the problems with the guidelines is that in the first section which concerns evaluation of the scope of the claims, you provide a somewhat unqualified conclusion that certain types of claims, "genes," comprising a sequence, are likely to have problems under the written description requirement, while other types of claims, nucleic acids, comprising that sequence will not.

The insertion of these examples at that stage of the analytical framework you have set

forth suggest conclusions which may not be warranted when you actually work through the rest of the guidelines, and those should probably be pulled out of the analytical framework you have put in place.

The final specific comment I am going to make about the interim guidelines is that they are very heavily focused on biotechnology. This emphasis in our view creates a risk of making biotechnology a special case for application of the written description requirement. PTO should draft the guidelines, as I have said before, in a subject matter-neutral fashion and then include examples in other technology areas, not just biotechnology. I think, even for biotechnology examples who have grown up on the molecular biology side of the fence, getting some better feeling for written description as applied in polymer cases and steroid cases and all this very rich body of chemical practice might help clarify how written description is really intended to function. I know there are many examiners that you can draw on to help you

draft those examples, and those should be brought into the process.

I am going to turn my comments now to the second notice which raises some broader questions, and I will not be speaking to each of the topics raised, but I will offer comments on behalf of Genentech on the EST patentability issue.

The EST issue has been under the surface of many public policy discussions relating to patents for much of the 1990's. The original application filed by NIH in the name of Dr. Venter [ph.], and then later withdrawn, raised a number of questions in the patent bar and the biotechnology industry.

With the benefit of a few years of consideration, we realize now there are substantial questions of patentability for what we understand to be the general description of the EST case. Before offering these comments, please note that it is critical in our view to fully appreciate the unique features of each application that is going to be evaluated in the PTO. My comments are going

to be directed to a type of application that fits a profile that we are aware of and should not be extrapolated to cover any kind of nucleic acid-containing application.

The general description of what we have seen in this "EST application" is a disclosure of hundreds or thousands of short sequences of nucleotides and not much beyond that--perhaps an identification of where it came from, but really, no effort to characterize what those sequences are or how they might relate to genes or other elements or issues that might be of interest.

We believe that an EST does have some utility for conducting research into and identification of a full sequence gene and for other applications. Thus an assertion of utility by an applicant having filed an application fitting to this profile of a case is likely to satisfy the requirements of 35 USC 101 for claims limited to the EST sequence in the context of that use.

We do not believe this type of disclosure can support claims that will encompass full

sequence genes, downstream expression products or other subject matter.

Building on our concern from the interim written description guidelines, we note that a claim under that analysis could be issued by the PTO that would read "a nucleic acid comprising Sequence ID 1." For all intents and purposes, this claim will cover at least the same scope as a claim cast to a gene comprising that sequence. As a practical matter, someone will be having in their hands a claim that is identical to the scope of a claim that one would obtain after doing the other \$100 million worth of research to express and characterize the products derived from that gene.

This is an issue which obviously, we as a company have significant concerns about simply because it does raise the prospect of deterring the work that is necessary after the EST has been procured to actually produce a product that is usable and commercializable. Whether there is a defect under 112, first paragraph, written description, 112, first paragraph, enablement, 112,

second paragraph, definition of a claim as an appropriate genus, these are all issues which may be relevant and may be worthwhile imposing rejections upon, if only to clarify when there will be problems and when there will not be problems.

Some people earlier today raised a couple of comments that were raised in what we view as the new submarine patent application. It has been illustrated by comments that suggest that two parties could obtain a claim which would be almost literally identical in scope viewed in hindsight, based on completely different paths to that claim, and this was characterized in the example of two entities each having their own EST, getting a claim that would comprise any sequence that includes that EST.

Viewing it from a litigation perspective downstream, if a company like Genentech uses an EST, pays for use of that EST to the person who sequenced it and sold it to Genentech, which is routine, and later on elucidates the full sequence of the gene and makes a useful product derived from

that, knowing the way that patent practice can be used today, we could still see a pending application from that original EST holder when we finally get to that point seven or eight years down the road and, assuming that that entity filed a patent application and can show that the EST shows up somewhere in this gene, all of a sudden, they have a dominant claim that they can pull out of the PTO and cover a product that has been developed at great expense by Genentech.

Now, obviously, you understand the role of dominant patents when they are based on an adequate disclosure, but in this scenario, you can see a great potential for misuse of applications filed with thousands upon thousands of short sequences that will only be used once another party has undertaken the very difficult process of sequencing the entire gene and then working to express it into something of value. That is an issue which as a policy matter does raise a number of significant concerns.

In our view, then, a claim of this

character is going to suffer from a number of deficiencies under the first and second paragraphs of 112, and for this reason, we think the PTO should adopt a fairly firm stance in requiring an applicant claiming a nucleotide sequence based on one of these types of EST profile applications to limit the scope of those claims to a closed rather than open format. The PTO should insist on claims based on an EST disclosure being structured in the form of "consisting of" or possibly "consisting essentially of" rather than "comprising". And like some speakers before me, the critical issue in the use of phrase like "consisting essentially of" is going to depend on how that's characterized in the disclosure of the application. You always have to understand how to read the scope of the claims from this type of definition, and I don't think there is any easy way to describe a generic meaning to "consisting essentially of" in this way.

This concludes my prepared remarks.

Genentech does look forward to working with PTO to refine and improve these guidelines. I would like

to also thank my former colleagues here at the table and also in the room, who have spent thousands of hours, I estimate, grappling with this topic and trying to craft some guidelines that will help the examination process work better. We think you are not quite there yet and hope you can take this seed of a guideline and refine it in a way that will actually be a very useful resource for the examiners when they are conducting their work.

Thank you. I don't think I'm going to get away without questions.

MR. DICKINSON: Thank you, Mr. Kushan. Genentech is certainly in this area one of our most important customers, so we are very pleased to have their input on this matter.

Let me start the questioning. You raise a concern which is often raised with regard to dominance in new technologies. History has seemed to suggest, however, that that fear never becomes fully realized--the area, for example, that was raised with the Cohen-Boyer [ph.] patent, where we were all concerned when a licensing program was

developed by Stanford which everyone seemed very comfortable with. There seem to be traditional mechanisms which overcome the fear that that dominance will impede the development of an industry. Do you see that happening in this case, or do you believe that for some reason, it won't happen in this case, and therefore we shouldn't be particularly concerned?

MR. KUSHAN: Well, dominant patent claims--and you cite a great example of Cohen-Boyer. Cohen-Boyer was not a submarine patent. In 1972 to 1975, there was work being undertaken, and when the patent issued, it was in a somewhat not quite crowded field of activity. Now, at the point in time when they developed the core broad and dominant claims, they did represent the first entrant into a field, and the disclosure they made, no one could question as being enabling of the procedures as they applied. Remember, of course, Cohen-Boyer was a process focused set of claims for licensing.

In the scenario where you have product

claims and pioneer product claims, there are a number of cases out there that try to define and draw a line between a pioneer invention versus a non-pioneer invention and also, looking at it from a slightly different perspective, single means claims--there are a number of cases concerning claims of that format. What they all tried to do was emphasis that the disclosure is enabling, the disclosure is fully enabling for the breadth of the claims.

In the scenario that we see, particularly for one particular permutation of a claim, a nucleic acid comprising EST, there is no corresponding disclosure, there is no corresponding contribution of the inventor to entitle that inventor to get an almost limitless scope of protection.

When you are in scenarios where there has been much more extensive disclosure, I don't think there is any concern in dealing with dominant patents. They are issued routinely by the PTO, and we work our way around them. This is, in our view,

a slightly different scenario because you don't see this quid pro quo between disclosure and dominance.

I don't know if that answers your question.

MR. DICKINSON: Thank you.

Other questions? Mr. Kunin?

MR. KUNIN: I have two questions. The first question relates to the applicability of the written description guidelines to process claims and product by process claims. In particular, in view of cases like In re Ochiai and In re Brauer, where the claim taken as a whole heavily relied for patentability on the product itself, as opposed to a process claim which may be predicated more on patentability by virtue of the process steps themselves, could we perhaps get some comments from you with respect to these two areas and whether they should or should not be included?

MR. KUSHAN: I think when you look at the question--I am going to have to state fairly clearly that when you look at the constellation of cases from the past few years, it is not huge; you

have three cases that you are trying to extrapolate some conclusions on, and it is an elucidation more of the possession requirement than the written description requirement that has come out to light in these recent cases.

I can't answer the question of whether or not the process claims would be in any way more difficult a case to evaluate in this kind of context of a possession-oriented written description requirement.

I think most of the concern that has been expressed by us today is on the product claim format, and we could probably dig into whether or not you should try to provide examples dealing with process claims and how one would apply written description requirement to process claims.

Generally, if you have an example-free summary of the law, I know you can bring into that summary how process claims have been handled, and it is probably not a concern that you would all of a sudden have to dig in an area where you have no precedent to work from.

So at the end of this rambling comment, I guess I would say you might as well try to address process claims as part of this exercise rather than leave them as an open question or try to keep them as a separate issue.

MR. KUNIN: The second question I have is that you commented on the problematic aspect of these EST applications as a potential for creating submarine patents. You also mentioned the Cohen and Boyer application. Do you believe, for example, if this is a real problem that perhaps the Commissioner, under Section 122 of the law, should exercise the Commissioner's authority to basically open up cases that are of this specific type that have these kinds of concerns?

MR. KUSHAN: I think that would be a very unhealthy step. We've got so many different potential interests of applicants in proceeding to try to get this protection. There is a much safer path to take, and that is to reject certain of these cases under well-reasoned legal deficiency arguments and send them up to the Federal Circuit.

That process of sending test cases up has worked fairly nicely over the past 20 years or so, and I don't see why it would not be successful in this effort.

MR. DICKINSON: Other questions?

MR. DROST: I have a question. You recommended that we perhaps take up a test case in this area, and obviously, that could take years. What do you propose that we do with the cases that are affected by the test case?

MR. KUSHAN: As I recall, the test case concept works when the PTO is rejecting applications for its view, and probably if it had a choice between a conservative and a liberal view of the case, it would have to take the conservative view on patentability and requirements that have to be established in the application to satisfy that requirement. In the interim, that would suggest that the PTO take a more firm stance on rejecting the cases while the test case has gone up.

If the PTO essentially decides the other way, to take a more liberal reading of the case

law, and starts granting patents, then we in the industry are going to become the test cases, because we will have to work it through in inter-party litigation. In the interim, you basically have to make sure that you identify only those cases that are really in the profile that are being subject to your test case, so you don't have a sweeping application of written description requirements in every, single case that's in the biotechnology group; and second, that you would have to take a stance which is going to be a more conservative or literal reading, for example, of the Eli Lilly case.

MR. DICKINSON: Did you have a follow-up question?

MR. KUNIN: Yes, I just had one follow-up. Could you perhaps, based upon what you have just said, comment on what Mr. Weiser indicated with respect to what the Office ought to do with applications at this specific point in terms of whether a Lilly or a description issue under the case law, as we are taking the conservative view,

what we should be doing?

MR. KUSHAN: I think I'm going to "split the baby," because Mr. Weiser suggested basically tossing out your guidelines and not applying any explicit guidance from above to the Examining Corps. I think some guidance has to be provided because there has been too much discussion in the public about what Eli Lilly means, and I'm sure it is a topic of raging discussion in the group now.

If you have no guidance from above, you are going to have completely arbitrary practice coming out of the Examining Corps, and that's not going to serve any of the goals of clarity and consistency in the law.

On the other hand, I don't think the methodology that is laid out in the guidelines as they stand today is going to make any of us happy and that you do need to rework the methodology that is laid out in those guidelines and get something which is better in a generic sense than what you have now and then that, hopefully, can be done in a fairly short time frame and given to the examiners

to get them at least some interim guidance on how to handle these cases.

MR. DICKINSON: Just a brief comment. I know our Examining Corps fairly well now, and I hope they would never be arbitrary in the kinds of decisions they would bring to this area.

MR. KUSHAN: They don't work for the Patent Office anymore.

MR. DICKINSON: Let me ask you to comment on an issue that others have raised today, which is this question of the specificity of utility, and even more particularly, would you care to comment on this relationship, maybe even an inversely functional relationship, between the breadth or specificity of utility versus the transition language question?

MR. KUSHAN: I have spent a fair amount of time working on the question of utility, and you should not confuse the question of whether an invention has utility with whether a claim defines a set of things that are the invention that you assert to have utility.

In this scenario--let's take your nucleic acid comprising and then an EST sequence--I think many people on fairly good grounds would argue that that EST, not every nucleotide sequence that has that stretch of nucleotides in it has some utility, is going to be used as a research tool, and it would satisfy this fairly low threshold for demonstrating a credible utility for that EST.

The question then becomes what are you claiming as your invention. Am I claiming a 27,000-nucleic acid-containing sequence that has a 700 nucleotide sequence embedded somewhere in it, anywhere in it, and then saying that that compound has the same utility as the EST itself? We would probably argue no, because that massive structure is not really going to be usable as a probe--it's not something that we would normally ascribe the same utility as the EST.

And I guess the way to approach this is not necessarily to challenge on inventor's assertion of credible utility for an EST claim, but rather, to look at the claim definition and see if

what the applicant is claiming is the invention that they have ascribed this utility to. One thing I would really not like to see is a new wave of rejections coming out on utility, saying that we have to dive into that fairly low threshold of a patentability requirement on every case.

MR. DICKINSON: Other questions?

Mr. Weiser?

MR. WEISER: I did not suggest in any way that there should be no guidelines. I simply suggested that they be held in abeyance until the final guidelines have been approved. The AIPLA does approve, and I personally approve good, sound guidelines.

MR. DICKINSON: We'll note that for the record.

Any further questions?

[No response.]

MR. DICKINSON: Thank you very much.

Are there any further comments or testimony today?

[No response.]

MR. DICKINSON: I think the court reporter and I know the panel would appreciate copies of any testimony that people have prepared, which would allow us to reflect on it a little more carefully after the hearing.

I want to thank all of our witnesses today. I appreciate their taking the time to travel to Washington, many of you from a distance, and bringing additional clarity and comment to our deliberations. We appreciate it very much.

I would also like to acknowledge my appreciation for the work of my colleagues. They worked, as several of you have noted, very hard on these guidelines. I think you also noted in your comments the challenge that the Office faces in trying to bring some clarity and hopefully some transparency to what is universally acknowledged as ambiguity in this area. So I want to acknowledge them and thank them as well.

I specifically feel that our constitutional mandate at the Patent and Trademark Office is to incent innovation and not retard it;

so to the extent we are able to craft guidelines that facilitate that process in this area and to allow an extremely important and increasingly important technological area like biotech to continue to thrive, I am hopeful that we can achieve that goal. So your comments today as we move toward that goal are greatly appreciated. We are very, very mindful of our obligation to continue that incentive and to help you move that technology forward.

Do any of my colleagues have any comments or questions?

[No response.]

MR. DICKINSON: Thank you very much again. We appreciate your time.

[Whereupon, at 12 o'clock p.m., the public hearing was concluded.]