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## OPPOSITION AND POST-GRANT REVIEW PANEL

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PROFESSOR MERGES: We are going to start out with Professor Bronwyn Hall from our own Economics Department here at U.C. Berkeley, and she is going to be joined with her co-author on some very interesting research, Dietmar Harhoff from the University of Munich. So in all the discussion of European oppositions that is thrown back and forth in the U.S. re-examination reform kind of movement, Dietmar has really got the goods, he has got the real data on European oppositions and what they are all about. And following them, we are going to have Bob Blackburn from Chiron Corporation, who is a veteran of many of the biotechnology wars and he has personal experience with the European oppositions and lots of detailed experience with the U.S. Patent System as well, he is the Chief IP Counsel at Chiron, and we are really pleased to have him here. After that will be Joe Farrell, also from our Economics Department, who is presenting a paper that he and I are working on. I may have a few words to say on that in the Question and Answer period, but Joe is mostly going to handle it. Joe is also from the Competition Policy Center and they are a

co-sponsor of today's conference. After that will be Doug Norman from Eli Lilly, who also has extensive personal experience with the U.S. Patent System, obviously from the pharmaceutical and medical services and processes industry. And batting clean-up is Steve Kunin from the U.S. Patent and Trademark Office.

And so, in all the discussion of sort of what the Patent Office is doing, and how examiners are really sort of performing, Steve has got the day to day experience on that. So this is really a terrific panel and I am now going to do, I think, what is best advised which is get out of the way and let them go. So we start with Dietmar. Thank you. We will start with Bronwyn and then Dietmar.

MS. HALL: Okay, well, the bad news is that I do not have much of a voice and the good news is I do not have much of a voice – given the number of panelists! So I will try to be brief which is going to be a struggle, and serve as a warm-up act for my colleague, Dietmar Harhoff, who has the slides.

There were two things, having listened to the previous panel, one of which came up in the previous panel, that I wanted to emphasize just out of my experience with looking at patents. And the number one point to always keep in the back of your head is that

patents are extremely heterogenous in their value, and that means that figures like three percent of patents are not very meaningful, really. It is usually, you know, it could be that three percent is a completely uninteresting set of patents, or it could be that three percent is all of the value in the Patent System, and you just have to keep that in the back of your head. And I particularly mentioned this with respect to the concern for genome and software and business method patents. It is possible at least in the genome case that the reason we are focused on it is because those are valuable patents, even if they are a small number, okay? So you just have to keep that in your head when you are thinking about it. And the second thing, I won't say much about the second point, I want to say – repeat again, which economists are always repeating -- is that more patents are not necessarily better for innovation, you know, for a long number of reasons that I do not have time to list right now. Now, the previous panel did a really good job discussing the details of what I will call "patent quality" even though I know that is an over-used and misunderstood term, but, you know, inventive step, obviousness, the whole set of criteria like that, I wanted to do only one thing which is report on a couple of numbers which provide evidence on this question – statistical evidence, okay, on this

question with respect to the USPTO, keeping in mind that it is not the USPTO's fault that this is the case. I mean, the USPTO has been flooded with patent applications over the last 15 years. When you look at the aggregate numbers, you can easily identify a structural break that took place using the usual time series technique that took place in 1983-84 where there was just an enormous shift in the growth rate from zero percent a year to five percent a year in applications. And the budgets have not grown at the same pace, but nevertheless, here are the two facts – the first one is that if you look at U.S. originated patents and non-U.S. originated patents, and how they fare at the European Patent Office, what you find is that the grant rate at the European Patent Office, though it is the same – level playing field here – the difference in the grant rates for U.S. originated patents and non-U.S. originated patents has risen in the past 20 years from zero percent difference to 16 percent. So U.S. applications are being turned down more often. Now, this does not say anything about the USPTO, this says something about what the expectations of U.S. applicants are, and so that by itself suggests a decline in the standard of U.S. applications, but one cannot help but think that that is not because they are responding to something that is going on in the U.S. The second fact,

and this is directly related to what is going on at the USPTO, and it was discussed in the previous panel, but I just wanted to give you the fact, which is now, suppose you look at U.S. priority patents, equivalents at the EPO, okay? So we are comparing what the USPTO does with applications for an invention for which there is an equivalent at the EPO, so these are more valuable in principal patents because there are equivalents at the EPO. How do they fare at the EPO vs. the USPTO? And the answer is the difference in the grant rates – and this is Dominick Galeck's (phonetic) work, mostly – differences in the grant rates has grown from about 12 percent 20 years ago to 30 percent today. Okay? So I would argue that there has been some change in the standards being applied either at the EPO – they have raised the standards – or at the USPTO – they have lowered the standards. Could be either one, really, but that is just the overall fact. Alright, I can tell that I am going to lose my voice pretty fast and also that I am going to run out of time, so what I want to do at this point, I wanted to talk about the benefits and costs of post-grant patent review, something that we have suggested in the step report, something that was discussed in the FTC report, something I saw, in fact, in at least one of the position statements that were in the packet that we received. I

want to reinforce this idea that I think there is some value in having a post-grant review within the Patent Office, particularly for new technologies, okay? Because of the feedback effects you get from having a review, having prior art being brought in by outsiders, and this does in fact – this is going to – it is not that the Patent Office does not catch up on its searches, it is that it takes a while and it may speed it up a bit, you know, they may get the information more quickly. We are down, stop, okay. I am doing to stop. Dietmar is on.

MR. HARHOFF: Well, thanks a lot. Thanks for inviting me to this panel. I feel I am honored and it is a great opportunity to say something about the European experience on post-grant review, which is called Opposition. And let me just hop directly into a summary of empirical facts so that we know how such an institution could look. This does not mean that I am advising anybody to assume exactly the design perimeters that are here, let us talk about design perimeters later. This is an inter-partes procedure, you can file an opposition within nine months after the patent grant. I will say a little bit about the costs. Typically what you find is that it is opponents, rivals, competitors that are opposing the patent-grant. Sometimes you also find that NGO's like the Animal Protection Society of

Vienna or GreenPeace or others are doing that, and I will argue that that is probably good that we have such an open process. How about the frequency? If you look at EPO Patent – I hope everybody can see that, but I will repeat it just by reading it off – the opposition rate, 7.9 percent of all patents are being opposed at the European Patent Office historically. It has gone down somewhat. And there is a second instance and an appeal against the outcome of opposition which is realized by 31.7 percent of all the opposition cases, so you can see that the patent holders, but as well the opponents are really going after – this is a battle for IP, very clearly, with a high frequency. Germany, by the way, has a similar opposition system and there the opposition rate is even higher, okay? And I will later argue that that has to do with the fact that in Germany you only have three months to file, and therefore you do not have time to settle with the possible counterpart you have. What is the duration? Each instance about two years, okay? So it is quite long, adding to the already relatively long grant period, examination period that the European Patent Office has which is on average 4.2 years for decision making. What are the outcomes? Now this is the really relevant part. About one-third of the patents are revoked. They disappear. Okay? And given the structure

of the system in Europe, there is no judicial appeal against that once the appeal chamber has said the patent is not there. One other third is amended, and that means narrowed – the claims are narrowed. And then, in 27 percent of the cases, the opposition is rejected. The opposition is closed in about seven percent of the cases which means that either the patent owner dropped the patent, they did not pay the renewal fees, or the opponent dropped the procedure and was never heard of again. What are the costs? Per party, per instance, between and $15 and $25,000 Euros, so if you go through both instances, it would be between $30 and 50,000 Euros. There is a very low potential for driving up your competitors' costs, and I think that is very important for not making this a harassment institution that can be abused strategically, although some strategic abuse may be going on. Which cases get to opposition? Now, again, this is very important because we have been talking about what we would like to see in this mechanism, and what you see is that in new technical fields, for example, biotechnology, nano – many patents are nano these days, in fields with uncertainty, with asymmetric information between the patent owner and the opponent, you see a lot of opposition. When it is high impact patents, like in cosmetics, for example, although it is not an R&D

intensive industry, you have high opposition rate, and typically we can show in empirical studies that it is the valuable patents, that typically opposition draws from the upper quarter of the value distribution. So let me simply summarize that and say that this is a mechanism which has in terms of economics both the quality of screening and of information revelation, because what is produced in the procedure here is knowledge about prior art, knowledge about the interpretation of prior art. Many cases do not reveal new prior art, but they deal with the interpretation of prior art, which may be contentious between the parties and, of course, this mechanism identifies high value patents. And now, my interpretation as an economist is very simple that, in a second round, once you have identified these patents, you can give them much more attention than you can in the standard examination process where maybe you have close to 40 hours in the European system, but errors happen nonetheless because not all the information is on the table, even if you have greater resources available than at the USPTO. So there will be errors, even if there are more resources, and you need some kind of mechanism of doing that. I have some slides here which I will skip through very quickly just to tell you what this would look like and how it peters out, and then in subsequent

national litigation in Germany. The European Patent Office examines and it grants a patent, and then these patents become national patents because something like a European patent is not really in existence, okay? And subsequent litigation is within the national systems of the judiciary and so forth. So in Germany, what you find is when you look at EP granted patents coming to Germany, there is a subsequent invalidity challenge that you can raise against the patent at any time – this is not time limited – and any party can do this, so this is a mechanism that the United States does not have. It is a quarter of a percent. Now, I can use these data to show you that the real welfare kick out of the system comes from striking down those 2.7, those 7,300 cases which do not proceed in the system. Their career has ended and they will not cause litigation either. Okay? There is also an effect from hardening legally the patents that were under opposition because they withstand validity challenges much better than other patents attacked in this procedure. Let me say something about the overall litigation rate in Germany. Again, if I did this for Europe as a whole, I would have to go into basements because we do not have electronic archives of litigation files up to now, unfortunately. The litigation rate in Europe, in Germany, that is my calculation, is 0.9

percent. Litigation is less costly in Germany, it is faster in many cases in Germany. Another member of this panel has come out very much in favor of this mechanism, so all of this is speaking against and sort of an inflationary number here, compare this to the 1.9 percent in the United States where litigation is more expensive, takes longer, and so forth, I think that this is partly an impact of the opposition system as a pre-screening mechanism that take out a number of these cases. Some issues – and I will just pick a few – I have picked out a few key design perimeters. At the European Patent Office, the case is heard by a special board. There is an issue whether you want the original examiner in there or not. I hear from the EPO that the revocation rate is higher when the original examiner is not part of that board, and that might just be human nature. Which time period should you allow for filing the case? I would argue make it short. The USPTO strategic plan set 12 months. These are 12 months during which there can be settlement between two parties where society at large would not like to see settlement because you do not want to have collusion at this level. The last point I want to make, I do not think that discovery is very helpful here. You want to make this a lost cost mechanism, keep it simple, so that you have the screening function and

not sort of an imitation of litigation. Thank you.

MR. BLACKBURN: Good morning everybody. Did the clock start? What have I got here? Now, is this pathetic? Guess how many times I have been deposed? Let's move on.

So, actually, lately when I am giving talks, if it is a mixed group, I say how many people are lawyers, how many people are scientists, now I say, "How many people are planning to depose me next week?" Anyway, hi George. Anyway, so, why replace validity litigation? Well, for you litigators out there, I hate to tell you, it is not about you. I know you are saying, "What about me and my needs," but it is about industry. Aim it at the prosecutors and the academics, it is not about you either, it is about industry being able to make, as Ron Laurie put it, make rational capital allocations. So what does industry want first? More than anything out of the Patent System, they want predictability, because if it is predictable, the outcome, they can negotiate, a deal can be struck. In those cases where it is not predictable, what they want is fast, cheap dispute resolution because that gets you back to predictability. So why do you want predictability? So you can formulate a rational strategic business plan for what you are trying to do and allocate your capital correctly, whether you license, you go into another area, you do add-on research, whatever. You need a predictable

system. But, you know, hey, wait a minute. Isn't the American litigation system the best? You are either for it or against it.

So, well, building on Dietmar's talk, I have sort of pulled out a not actually hypothetical example, although I was trying to remember what the numbers were in the middle of the night, so I am not holding these up as precise, but they are pretty close.

So, same patent, same issues, litigated three different places, here is what it cost and the time: Germany -- $400,000, 18 months; the UK -- $2 Million, 18 months, there is discovery in the UK, alright? The U.S. – $6-8 million, 30 months, and just got to the Markman hearing. Okay. Compare the outcomes. They were identical. The substantive outcome from the business' perspective of all this litigation was the same. So how much justice can you afford? The dollars you spend on this dispute resolution system do not go into R&D, do not benefit society in another way. I know, what about me and my needs? But if you – you can maybe sell this level of litigation and cost if we were in a different market like perfume or scotch, high price tends to work there, but for the same price, for a lower price to get the same results, it should not be selling. Okay, so let's see, can we move to an opposition system? Can the PTO actually deal with

the validity issues? We have heard some concerns about their ability to deal with things. Usually that comes up with the things like best mode, or inequitable conduct, how would you deal with those? Well, if you have a system where you have different defenses available in an opposition system than you do – or you have more additional defenses available in District Court litigation than you do in an opposition system, somebody in each dispute is going to want to try to get to District Court. But now let us look at other countries like Japan and the EPO countries where they do not have these type of defenses. Sky is not falling, their opposition systems tend to work pretty well, and are a substitute for things like the duty of disclosure, etc. It works pretty well. So the simple solution is get rid of these areas of substantive requirements for patentability in the U.S. like most other industrialized countries who do not seem to require it. So do we eliminate litigation altogether? Well, I do not think anybody is seriously suggesting you eliminate litigation for the liability aspects of an infringement. But perhaps you could eliminate it altogether for validity and adopt something akin to the German model. Or you could make it an option out of litigation where, say, the District Court litigation has stayed and pending resolution, the District Court will accept the resolution

on validity, and that could include a PTO opposition and a direct appeal to the Federal Circuit, but not – you gain nothing if you then have a de novo review of that process in the District Court. So the question is how does that option get exercised, is it up to the judge, can either party opt for it? Does it take both parties to agree to it? But the key thing to get the advantage of an overall cost reduction and time saving in the overall dispute resolution process is that one party in a particular case cannot frustrate access to the opposition system. Because what we can agree to ahead of time is that those of us who are in the marketplace of IP is that we end up on both sides of this, and we can see a net savings, but when we are in a particular dispute, somebody says, you know, "We will have a five percent better advantage, we think," and I will tell you, I think most of those calculuses are wrong in this form vs. that form, then you will have a breakdown and there will not be resort to an opposition system and you won't get the advantage of it.

Okay, big concern, it has been raised, will patentees be harassed in an opposition system? Well, there are lots of ways to deal with this. The first is adopt the time limit like EPO does. Proposals are one year out there. A concern here is, though, what do you do about the invention, in particularly you will see this in biotech,

its commercial relevance to you, it does not come about for five or ten years, and you never bother to look at this thing to see whether it was truly something worth spending the money in opposition, I guess. Well, you know, maybe the way to do it is that you award costs. That would, I think, go a long way to eliminating harassment and you could say it is in any opposition filed more than a year after the patent is granted, so it truly has to be a rational business decision to bring the opposition and you have to have – you would as a business person think you have some pretty good grounds to do it. An alternative is to look at some sort of standing requirement, again, perhaps maybe after one year passes. I am a little concerned that it will be anything close to the case or controversy which prevents people getting access to the courts for DJ actions, as they do today, because that has been a real problem in the Biopharma industry. You do not have infringement during the Hatch Waxman Exemption which goes on for years, so there is no reasonable apprehension of suit, yet you are supposed to be investing hundreds of millions of dollars in bringing a product to market, and you cannot test a third party patent that might be in the way.

So, finally, maybe some form of res judicata is something to think about. That is, it really would depend

very much on what the rest of the system looked like and what the other options were for doing validity in District Court. And I beat the clock.

PROFESSOR FARRELL: Thank you. As Rob mentioned at the beginning, this is a presentation of parts of what will be a joint paper between myself and Rob. To give you the bottom line in a sentence, there are sound systematic economic reasons to believe that the incentives to challenge and defend patents in litigation are often, not always, but often wildly skewed, and the result of that is, if you are tempted to think that you can repair rational ignorance or any other kind of ignorance or inevitable imperfection at the Patent Office through the litigation backstop, you are badly mistaken.

So, why do the incentives to challenge and defend patents matter? Well, we have a cheap, secretive error prone, according to many people, PTO process, and the question is is there a well functioning backstop for this. Okay? Well, there are other backstops, there are other processes, which Rob can talk more about if he wants to, he knows about that, I do not really, the main one of those, as I understand it, is litigation. Litigation is costly and I will say in a minute why I think that is important for the analysis. It is not for the obvious reason that we end up spending a lot of

money. There is relatively little in between, and the real topic of this panel, which is not actually the topic of this talk, is what could we put in between. I will say a bit about that at the end, but it is not my main point. Okay? So rational ignorance and its cognates may be fine if litigation works well. Whether litigation works well depends on the parties' absolute and relative incentives to fight in litigation. Now let me explain why that is true. In order to get the right answer, you want two things, one is both parties have enough incentives to bring forward a reasonable and adequate amount of evidence, and the other is you want the incentives to be broadly balanced so that, loosely speaking, the decisions are apt to follow the merits rather than being biased in the direction of whichever party has stronger incentives to bring forth all the available evidence. Okay? Suppose you have a lawsuit between two parties, one of whom very much wants to win it and the other of whom, for some reason, does not really care very much? Well, even if the latter is in the right, he will probably lose because he will not spend the resources to bring forward all the evidence and put on the best case. Now you might hope if you are a real optimist, that the court system is good enough that, even if one litigant does not care as much as the other

litigant, the fact that he is right will make him win. If you think that, and I am probably pushing on an open door here, if you think that, then you will predict and expect that people won't spend very much money in litigation, and that the amount of money they spend in litigation will not vary according to the stakes. Those predictions would be false. Therefore, you have to believe that the incentives do matter for the average outcome. And therefore, if as they claimed on the title slide, the incentives are wildly skewed, you will tend to get the wrong answer, on average, coming out of litigation. That is a problem if you are thinking of litigation as any kind of good back-up for an imperfect administrative system.

So, what do I claim are the relative incentives? Well, of course, they vary. But what I want to say is that in a widespread class of cases, I would venture to guess in the average case, the patentee cares much more than the alleged infringers. And I claim that this is apt to be true for two reasons, one of which I learned yesterday, is actually in the literature, and the other of which, as far as I know, is not. So the first one that is fundamentally in the literature in Joan Miller from Lewis & Clark has been at the forefront of discussing this, is that when there are multiple alleged

infringers, a validity challenge is a public good among them. Okay? That follows from the Supreme Court's Blonder-Tongue decision, which basically said that if one alleged infringer gets a patent overturned or ruled invalid, that becomes truth which the others can call upon. And what that says is suppose you have five alleged infringers, each of them only have one-fifth of the incentive to challenge the patent, that the patentee has to defend it. Okay? Well, five is probably a modest number, but let us take five because it actually fits with the numbers that I have messed around with. A factor of five is a big deal, given that the evidence on litigation costs suggests that spending 50 percent more than your opponent is going to make a significant difference. What is that evidence? Well, if that were not true, then people would not end up spending a significant fraction of the amounts at issue in litigation, and they do. Okay? So a factor of five, or whatever it is from the public good component, is a big deal. Now, by the way, the public good issue is reinforced to the extent that the patent holder can, as my understanding is they quite often do, put it about that they will discriminate based on challenges, or based on how quickly and tamely an alleged infringer takes a license. So it is quite cheap for a patent holder to

charge somewhat less than the otherwise profit maximizing price for a license to tame alleged infringers, and somewhat more to feisty ones. It is quite cheap because the profit maximization curve is flat on top, and therefore departing in either direction costs relatively little. Three minutes, okay. I am going to have to speed up. The second point, the one that as far as I know is not in the literature, is when these multiple alleged infringers are not just independent multiple alleged infringers, but compete in some product market downstream, things are worse, and the reason things are worse is, if one of them successfully challenges a patent, not only does it reduce its own costs, but it reduces the costs of its rivals. And that pass-through, it turns out, has a huge effect on the incentives to challenge. The alleged infringers may bear little of the excess costs of a questionable patent, even collectively. Who bears the costs? Downstream consumers.

So, for example, suppose you have a billion dollar industry, suppose a five percent royalty is being demanded on a questionable patent, suppose there are five equal-sized firms in an industry that is using this technology, and suppose that the demand elasticity in that downstream industry is 2. Okay? Then the patentee’s stake in defending the patent is $50 million,

the downstream industry's total stake in challenging the patent is not $50 million, it is approximately $6 million, okay? In other words, this pass-through thing in this particular case is a factor of more than eight, and then there is the further factor of five from the public good phenomenon. So what?

Well, so, based on the evidence from litigation costs, this is going to mean that the patentee is going to tend to win if the merits are broadly equal, challengers can only be expected to win what should be really quite easy cases. Among the likely results? Too few challenges, inadequately pursued, too few bad patents overturned, and downstream final consumers bear the brunt. It is worth noticing that the role of litigation costs here is not so much that these challenges are costly when undertaken, it is that they may be more costly when they deter litigation. What to do. One thing you could do is to have cheaper post-issue challenges. That will help if what is going on is that the general expensiveness of litigation makes the ratio of incentives matter more, in other words, if a cheaper process makes the ratio of incentives matter less. It could well be true, although it is not analytically obvious. Another thing you can do is have a bounty system proposed to strengthen the private incentives to

challenge, you could allow multiple challengers to get together. A third thing you could do is to accept that the adversarial approach is deeply flawed and say that pushes us, despite what you might otherwise hope, to try to improve the PTO. And a fourth thing you could do is to have these competition agencies, who should be in the business of defending final consumers, do so. Thank you.

MR. NORMAN: I want to say thank you to the folks at Boalt Hall and from the FTC for inviting me here to speak, and at least pass on some information related to how some in the industry, not all, feel such a post-grant opposition procedure should be established. I would say that, coming from the pharmaceutical industry where we live on a daily basis with the Hatch Waxman Act, such that we are absolutely unequivocally guaranteed that four years post-product launch, we will be involved in a patent challenge from a generic competitor, which carries with it a bounty of the ability to obtain a 180-day co-exclusivity, that we are talking about a system which is tried and true for eternal litigation. And my life is little more anymore than litigating patents in Federal District Court. However, I have had some experience over the years in dealing with re-examinations and re-issues in the United States, oppositions in Japan, and

oppositions in Europe. And I would be here today to advocate for a United States opposition system that is not as tightly wound as the Japanese, but perhaps a little more tightly wound that the European system. The elements that I believe would be most desired in a U.S. post-grant opposition system is one that has a set period of time in which to request an opposition. In Europe, we have nine months, others have proposed here in the United States 12, yet other commentators have come forward and said, above and beyond the 12 months, there ought to be some period during the entire pendency, the life of the patent in which a challenger can come forward and request an opposition much along the lines that you could get declaratory judgment jurisdiction in the Federal District Court to bring everything back to the Patent Office and run one of these sort of cheap validity – supposedly cheap validity challenges, before the USPTO. I would be less in favor of something like that because of some questions that I will raise later, much of it dependent upon the diceyness of declaratory judgment jurisdiction as it is currently being interpreted within the Federal District Court System. I would say that, of course, all evidence needs to be brought forward at the beginning of the opposition, the patentee ought to have the right, of course, to be able to respond in kind. Discovery should

be allowed, but ought to be limited to some reasonable manner. The vast, vast, vast majority of expense that arises from Federal District Court litigation in the United States arises from discovery. For instance, now that everything is finished, I can tell you that I ran a lawsuit for Eli Lilly & Co. a couple of years ago where the Federal District Court Magistrate ordered us to produce to the opposing party every document within Eli Lilly & Co. that had the name of the chemical compound on it, okay? And try as we might, we could not get the Magistrate to back off that, and so we ended up producing 1.9 million documents to the opponent, less than 5,000 of which were ever found to be relevant and introduced into the court record. And so it is the outrageous expense of the way the United States Federal District Court System wants to run its discovery that is causing all of the problems that we all admit to now in litigations. However, before the Patent Office, we do need to have some sort of limited discovery, the Patent Office has experience in interference proceedings whereby the Administrative Patent Judges at the Interference Board certainly know how to run appropriate discovery within the confines and the bounds of what would be truly relevant to the issues at hand. It is quite important that the Administrative Patent Judge be legally trained

to the extent that, if we are going to follow the Federal Rules of Evidence and, as most people say, we ought to get to some level of estoppel, whether it be issue or claim preclusion, but some sort of estoppel arising out of a post-issuance opposition, then it is quite important that we actually follow the Federal Rules of Evidence and have a Judge that is willing to enforce those. Have a time limit – everyone is saying a year; that would be wonderful. J.R.R. Tolken says "the tale grows in the telling," so do the expenses in litigation and, therefore, a time limit that would be extendable only for cause would be most important. Key elements – the time period, I have already spoken quite a bit – or a little bit – about the fact that we ought to probably have a 12-month period in which to bring the opposition, and then be limited thereafter to such an extent that, once a patent is past this 12-month period, there ought to be some level of certainty, as Bob raised, in the patentee's life, in the patentee's business, to be able to determine whether or not you want to draw up an additional $100-150 million building, a pharmaceutical plant, to make this chemical compound. It would be nice to actually have a little bit of assurance that there are going to be very, very limited opportunities for those coming in to make a challenge to actually pull you back into the Patent

Office. Another huge question is, in the event that we end up going towards a scheme whereby you can be brought back to the Patent Office, how do we deal with the status quo arising from the fact that many times, if someone is going to be infringing your patent and you want to bring suit against them, the first thing you need in order to maintain your business model is a preliminary injunction. If you get a preliminary injunction, then you are sent back to the Patent Office for post-grant review at any time during the life of the patent. We need some more rules and regulations and some more law around what needs to be done, how we are going to handle maintaining the status quo during the pendency of that if the Federal District Court Judge gives up the jurisdiction of the case and sends it back to the Patent Office. Again, we like to see our Federal Rules of Evidence followed, we want to see the appropriate procedures followed. I have been involved in European oppositions, unfortunately, where I showed up for the day of the opposition and my opponent walked in and actually had a whole new stack of prior art and a whole new set of briefs, and handed them over in absolute violation of all the rules and regulations set down by the EPO, nevertheless, the Opposition Division accepted it, and I spent the remainder of two days arguing against something that was

nothing more than an ambush. Along the same lines, too, we need to be concerned about how we are going to deal with expert testimony and whether or not you are going to have the opportunity to cross examine an expert who might give an expert's report because, again, before the EPO, I have walked in before and seen a PhD sitting across the table from me when I did not bring anyone at all, and found that the opposition was quite interested in hearing what the PhD scientist from my opponent's side had to say about the relevant level of ordinary skill in the art. I say this prevents reliance on the Astrology Factor because I was actually in litigation in the UK one time and mentioned from the witness stand that my client had taken advice before going into an opposition in the European Patent Office, and the good judge in the UK said, "From whom did you seek that advice? An Astrologer?" Sort of laying out how the UK court system, at least, feels about the European patent opposition.

A very key element that we ought to discuss is the right to amendment and whether or not this ought to be a right from the immediacy, how it ought to be dealt with, whether or not broadening amendments ought to be allowed. My stance on this would be that, from the time that you get out of the examination and you are in the opposition, you ought not be allowed to have a broadening

claim as you are going forward so that the public can have some right of reliance upon exactly what has been going on in the Patent Office and whether or not the public can in any way make its decisions based upon the scope or the breadth of the claim. To guarantee a speedy resolution of the opposition, the patentee should be allowed to amend the claims only once. I say this, again, because I was in Europe one time when we spent two days going back and forth with – I think we got up to 12 auxiliary requests and it became apparent to me that the Opposition Division was not really so much looking out for the public interest, but instead was hearing from me, hearing from the other party, seeing whether the other party could come up with an auxiliary request that I might be happy with, and vice versa, and actually the Opposition Division was acting as a mediator, which I think, if we want to use this as administrative action, may not be something that we would want to see occurring here in the United States.

Now, I set forth here what is intentionally a bad claim and, because it is a bad claim, I had some prior art instances that I was going to bring up to all of you, but I am out of time, so I will not – so no one gets to examine my intentionally bad claim. Thank you.

MR. KUNIN: Well, I, too, as the other

speakers have indicated, appreciate being given the opportunity to speak at this conference today. What I would like to do initially is say that I think the Office is doing a pretty good job of examining patent applications. I want to thank Ron and Todd for defending us at the earlier panel, but nevertheless, as you can see from the Office's 21st Century Strategic Plan, we have a number of quality initiatives underway so that we can go an even better job, and in our Strategic Plan we have shown support for establishing a post-grant review system in the United States. We have done some comparative studies with the EPO and the JPO, and I would tell you that we also find art they do not find, so consequently I think you need to understand that it really is sort of a distribution, if you will, in terms of relative examination. I think the important thing with respect to any opposition or post-grant review is that it be a process which is predictable, reliable, and timely. I do not think it ought to be an examination system, it ought to be a low cost administrative proceeding conducted at a re-named Board of Patent adjudication, done with special dispatch by a skilled Administrative Patent Judge, namely the people of legal and scientific competence as set forth in Section 6A of the statute. One of the things that I think we need to do to make it attractive is to

remove the provisions that currently exist in 315 and 317 on issue preclusion as to issues that could have been raised during the proceeding, at least during the first period, whether that be nine months or 12 months after the patent was granted, or re-issued. I think the one thing that we do need to recognize is that it is probably desirable for us to have a system that avoids patent owner harassment, but at the same time truly incentivizes people to challenge patents which they feel are weak, and this issue preclusion, an estoppel feature, is one that really needs to be given serious consideration. Maybe after the first year, if you can challenge after one year, you should have perhaps a substantial economic interest and maybe this higher level of issue preclusion would be applicable. I think we also need to make sure that these proceedings are ones that avoid some of the merger problems with other proceedings such as re-issue and re-examination, and they need to provide a sufficient period of time for the challenger to reply to patent owners' responses.

Unlike re-examination, I think it is very important for us to permit the challenger to challenge claims based on all conditions of patentability. This will get a complete resolution of validity issues. Also, to increase reliability, these proceedings ought to be

conducted using E-processing tools and techniques. The best approach, we feel, is one where we establish a proceeding that, once it is initiated, could be completed within 12 months. We do agree with the premise that, at least one narrowing amendment should be permitted by the patent owner, perhaps a further amendment only on a showing of a good cause, and this would be entirely controlled by the three-judge panel, the Administrative Patent Judges.

Also, probably, there should be an opportunity for settlement in a situation where maybe there is a proposed narrowing amendment that could be handled by way of re-issue and, if such an amendment were provided in a re-issue, that the parties may choose to settle the inter-partes proceeding. Probably the single best feature of our current re-examination system is an ex-parte re-examination where the owner, him or herself, can come back to the Office of Administrative Proceeding to correct or strengthen the patent. Even with respect to an inter-parte re-examination, it gives the opportunity for the examiner to hear both sides of an issue, to make a better informed decision and, of course, the appeal process is much faster than getting to the Federal Circuit in litigation. Re-examination really is nice where there is what we call “killer” 102B-type prior art

that can be introduced and have a significant impact on the proceedings. Probably one of the worst features that we have heard is that there is no opportunity for the third party requester to obtain any discovery or cross-examination in affiants or declarants when evidence is presented by the patent owner in support of patentability. I think, finally, what I would like to indicate is that we are currently looking at how to put together a legislative package that would indeed establish a post-grant system that has all the various benefits of those who advocate some of the best features from systems around the world, and to avoid those things which have been already mentioned by other members of the panel which make it somewhat unattractive in other parts of the world. I think we can do this right. It is possible that this can be something that will either metamorphosize the existing inter-parte and re-examine into a more workable system, or stand as an additional aspect of the U.S. Patent System as a way to administratively correct patents in a way that can be substantially at lower cost and quicker, and truly address some of the issues that really led in the thought processes that went into some of the early President's Advisory Commissions on Patent Law Reform, one in the early 1990's by the then Secretary of Commerce, and see

that perhaps this could provide us a good opportunity to further reform the system to sort of make good balance between what can be done in the examination of some 350,000 applications a year, and then for those that really will have a commercial impact, they could go through a second level of review in order to get the kind of scrutiny that ought to be provided, that just cannot be provided by any Patent Office in the limited amount of time you have when most people want the timely issuance of valid patents. I think the aspect of having high pendency is also a problem in relationship to good quality. So we have to have a system where at least the initial examination is very thorough, but also in a timely manner to help provide greater certainty to those who are innovating and seeking protection, as well as their competitors. Thank you.

PROFESSOR MERGES: I am going to ask the panelists, if the question is directed to you, just try to re-state the question quickly so our transcription service can pick it up and follow it.

MR. GILBERT: [Rich Gilbert -- off mike]

PROFESSOR FARRELL: So the question is, is there an additional problem caused by the fact that in some sense a bunch of claims can be made and an alleged infringer has to prevail on all of them, and in a context

with error, that makes it almost impossible to expect to prevail. I am not sure what I think about that. I mean, if all the claims were correctly patented, then you ought to have to prevail on all of them, and I think you pointed that out, Rich. So is there an increased probability of an incorrect finding of validity based on the fact that there are multiple things? I am not sure. It does make some intuitive sense, but I do not have a very firm intellectual grasp on that question.

PROFESSOR MERGES: Yeah, Rich, it is an interesting question. If you sort of set it up as an introductory probability problem and you say, "Well, gosh, there are eight patents and they each average, you know, 20 claims," it looks pretty hopeless. But it is interesting that, you know, here is one where the cognitive scientists have really predicted reality pretty well. What District Courts actually do is they usually boil it down and they say, "Okay, guys – folks," you know, patent litigators, they say "Which of these eight patents are you really putting your money on?" And which claims within them are you really putting your money on?" In other words, you know, people are kind of boundedly rational, and District Court Judges have only so much patience and time, and so what they tend to do is kind of boil it down and say, you know," kind of the key patent

and what are the key claims because I just do not have, you know, nine years to kind of process the case." One way to kind of transpose your question is to say, "How would we handle that distillation process, you know, in an opposition setting? Is there a way to focus the inquiry in a similar way?" And it is a good question. I mean, I think it is something that would have to be thought through; if we could do the same thing because there are just sort of inherent limits on how much people can process and it shows up in the system, even when you are spending $8 million, because it comes down to one or two decision makers and they are just not unlimited. You know, it is not the Cray 1 (phonetic), it is a certain judge. That is just the way it goes.

PROFESSOR FARRELL: Can I just jump in again on that? I have come across cases where a patent holder has announced that it had multiple patents and that it was not going to litigate all of them in any one case, and perhaps that is a response to this distillation process. And that, I think, puts Rich's question back on the table in a more forceful way – but I still do not know the answer.

MS. : [Audience -- off mike]

PROFESSOR FARRELL: So the question was what are the relative incentives if you have basically a

patent thicket with multiple patent holders, and I think the spirit of the question was these multiple patents are all blocking on the things that the alleged infringers want to do. I do not know the answer to that, it is a good question. I think one observation would be that, as to any one patent, if you do not have the public goods and pass-through issues in strong degree, then there is a certain symmetry because the two are potentially fighting over the same amount of money if you are just dealing with royalties. If you are dealing with injunctions, then, for the alleged infringer, to win one battle is only to be put into another battle and I think there will be circumstances in which that is a rather weak incentive. So I think that might lead to some results parallel to the ones that I was talking about, but I do not know.

PROFESSOR MERGES: I think we should – we have got to hear from the biotech and pharmaceutical people on that question because that is kind of something that you guys face all the time, multiple inputs in the product development stream and lots of claims. There has been a lot of writing about it, so it is time to –

MR. BLACKBURN: Well, for the subject matter of the panel, you would want an opposition system, a cheaper faster opposition system to deal with those. And

it would be that simple.

MR. NORMAN: Right. And Bob and I could get even chummier spending time before the Opposition Division. But there is sort of a dichotomy if you look at it just from the biopharma issue, from the biotechnology side where we do have thickets, if you look at the pharmaceutical side, often you find savannahs and that is not my quote, Bob Armitage said that a while ago, but in the straight pharmaceutical industry, you end up having – because of Hatch Waxman – having to list your patents in the Orange Book, and if you open up the Orange Book and look at any given drug product, you will find very often only one or two patents that have been listed. Now, admittedly, you will find some that have 12, or 13, or 14, but, again, usually the biotechnology and the pharmaceutical industries are peculiar in that, because of the horrendous expense of bringing a product to the market, very often people are not willing to license a piece of their technology because you need that total market exclusivity in order to make back your investment on doing all the research and development on the pharmaceutical product itself. But, again, an opposition would be quite nice to take care of these things one or two years out.

PROFESSOR MERGES: Todd, it looks like you

have got a question?

MR. DICKENSON: [off mike]

MR. BLACKBURN: Well, I was actually interested in that number, too, and not so much as relative to re-examine. I think the explanation for the re-examine system being under-utilized in the U.S. is because it is such a stacked deck for a challenger. And you have an option of keeping your counter dry for District Court litigation where you have more defenses and perhaps a better chance of bringing it about, so that is why, when you give people an alternative on an individual case, they are going to make that kind of decision. But I am certain that, in part, the reason there is more or vigorous opposition practice in Europe is, in part, because of the lack of some other reasonable alternatives at some level and also a perception of a fair process – or fair enough. The thing that always sort of strikes American lawyers who go over there, who have been trained in American concepts of due process, it is almost like the cultural equivalent in some countries of somebody trying to shake hands with their left hand. It is just really odd what they consider – like Doug's story – is a fair process. And I actually take, for example, Steve's proposal that, you know, there would be one opportunity to amend the claims. And I am a little

bit concerned about discussions of the opposition system that we are thinking about implementing, or might adopt here, to start immediately dropping to that level of detail because I think there is a lot of other issues that have to be decided about whether that is a fair rule. For example, I do not know how you can say you only have one opportunity to amend if the other side can bring in new arguments, for example. And they say, "Well, if you don't, we will make it where the other side can't bring in new arguments at a certain time," but is that actually the best result to a quality output? Or is a fair iterative process something that we ought to look at that keeps within time lines? But, anyway, that is kind of a long answer.

PROFESSOR MERGES: We probably only have time for one more question, so if you have a really good one. Yeah, go ahead.

MR.: [Audience – off mike]

PROFESSOR MERGES: That is actually a plug in the form of a question, but we will take it. Well done. But it is a good plug, we like it, thank you. Well, I mean, the obvious answer is that, you know, a lower cost system is going to encourage more participation and include more public interest components than a high cost system. The one issue that you might consider in terms

of design is whether or not the public agency can step into the shoes, maybe the PTO or somebody can step into the shoes of a private agency in the face of a settlement. And the settlement question is a really tricky one, you know, when you look at this. And so interesting problem. Dietmar wants to address it.

MR. HARHOFF: Of course, the cost issue is there. Let me tell you that in Europe there is an institution, Article 115, European Patent Convention, which allows third party observations, some ex partes procedure, and you come out with exactly or very very close to the same participation rate as with U.S. re-examinations. So it is really the ex-partes vs. inter-partes issue that is driving that. The other thing is, of course, and that addresses some of Joes' concerns, Factor 5 is fine, but if you make it Factor 5 on a low cost figure, it has considerably less bite, and that makes it even possible for organizations like in Europe, NGO's, Greenpeace, some animal protection agency, the Free Software Institution in Europe, to oppose certain software patents. And they have been successful to some extent. Now, the settlement issue is, I think, something that one should worry about, and one needs to go away from the classical interpretation of settlements as something that is strictly benevolent because in this

case it is not. It is at the cost and the expense of society. Okay? If Rollet (phonetic) has a patent and I have the information to shoot it down in opposition, and you give us enough time to figure out how to deal with this, and he gives me a license and I shut-up, okay? That is a wonderful case of dual monopoly and we do not want that. Okay? So be careful about the settlement issue. Within nine months at the European Patent Office, the averages that I hear from the patent lawyers when I talk to them after two beers or so is that there is a settlement rate of about 20-25 percent of the cases that do not even hit opposition. Now, that is low by U.S. standards in litigation, but I think it is an issue that you really should watch, and my proposal would be to make it a short time for filing – that is why my three months came up – give the parties some more time to develop the evidence, then, but allow the U.S. Patent Office to pursue the case in and of itself if it wants to, because it is the Patent Office's task to make sure that patents that should not be there should not be there.

PROFESSOR MERGES: Joe, last word.

PROFESSOR FARRELL: Yeah. I would just like to reiterate what Dietmar said about settlements. The most affected, or often the most affected people, are not at the settlement table, and the excessive incentive for

cozy settlements is fundamentally the same as the incentive that I was talking about to not bring a challenge in the first place.

PROFESSOR MERGES: We will take a break of about seven minutes, give or take, and then get back so we can be almost, sort of, close to, on schedule for lunch time. Thank you.

Certificate of Reporter

MATTER Patent Reform Workshop

Date: April 16, 2004

I HEREBY CERTIFY that the transcript contained herein is a full and accurate transcript of the notes taken by me at the hearing on the above cause before the FEDERAL TRADE COMMISSION to the best of my knowledge and belief.

DATED: April 28, 2004

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ADRIAN T. EDLER

certification of Proofreader

I HEREBY CERTIFY that I proofread the transcript for accuracy in spelling, hyphenation, punctuation and format.

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