

Update on U.S. Patent Reform Initiatives
Judge Pauline Newman, Ph.D., LL.B., M.A.

DR. EVANS: So I really do have a distinct pleasure and privilege at this point and that is to introduce Judge Pauline Newman. I've actually known Judge Newman now for almost 10 years. We've worked extensively on issues regarding the education of the judiciary in scientific matters. In all of my contacts with judges across the country and throughout the world, in the course of those projects, I've rarely met anyone who commands such respect and reverence as Judge Newman.

She not only is an extremely accomplished judge, but she has her Ph.D. in chemistry. She is a circuit judge with the U.S. Court of Appeals for the Federal Circuit, and she's here to give us an update on patent reform initiatives here in the U.S., namely the patent reform bills in the House and Senate and recently federal court decisions. So a big hand of gratitude for Judge Newman for taking time out to come today.

(Applause.)

JUDGE NEWMAN: Thank you. I was so fascinated by that introduction.

The materials that are being handed out -- do you all have a copy -- are an outline of this very complicated topic, of which there will be barely time to scratch the surface.

What I want to emphasize, to put what's happening in Congress in the context of the things that you may find that you need to discuss, is to remind us that the purpose of patent law is to bring science and technology to the public, not to withhold it, not to put artificial barriers in its utilization, just the opposite.

(Audio system failure.)

JUDGE NEWMAN: -- of the patent system as it's come to our attention and the particular issues that we understand that you are concerned with.

But I do want to stress patents are an instrument of commerce. They are also, however, an instrument of the development of science and technology. Again, that's why they're in the Constitution, to pull the development of science, the application of science, the applied technology to public benefit with the help of the law. So there are balances to be established, and that's what the law is supposed to do. That's what this law is trying to do.

The lawmakers, in turn, are advised, through the various political procedures, to know or at least to be told and to try and balance all of these concerns and particularly now here where there are new forms of science and technology. That's what's behind this present legislation, the evolution in what's called the knowledge economy, the digital advances, and the evolution in biotechnology and the enormous promise for public benefit that both of these technologies have brought, and to figure out whether the law does serve it adequately and whether it can serve it better, again, in the public interest.

So it's very timely, indeed, for you all to be looking at and to assure yourselves and to participate in this process.

But again, I stress that the overall purpose is to serve the public through the path of new science and technology in a capitalist economy where the role of the private sector, the profit motive is what drives, pulls, and pushes many of the scientific advances perhaps -- not only perhaps, but of course, much science evolves in the university without the intrusion of the public profit motive, but to bring it out broadly to public benefit. Unless we devise some governmental participation, we need to have very much in mind the role of the private sector, the risks involved in the realities of entrepreneurship, the complexities of the kinds of science that we're talking about, particularly in the biological sciences, and put it all together.

Well, Jim asked me about the pending legislative proposals. From the political viewpoint, a fair amount has happened in that the way things have evolved in the Congress have focused on some extremely controversial provisions that serve particular aspects of the economy. And I'm told primarily the software industry, again, what we all know as the knowledge economy, the digital procedures, have been fraught because of the potential for profit and the widespread national and international interests with commercial battles. And many of these are taking place in the courts through the patent system. To make sure that the balance is properly set is what the Congress is trying to do in reviewing this law.

I should also say, however, that the future of what I'm about to tell you about is uncertain. What I'm talking about and what's outlined in the material that I handed out is what's called a manager's amendment that was submitted by Senator Leahy on June 21st of this year as a substitute for the legislation, which had gone through the House and was languishing somewhat in the Senate because of the extreme difficulty of finding consensus and because of some of the more controversial provisions that it contained.

I also understand that two attempts at a quorum to process this amendment have failed thus far. If there are further attempts -- and I have no idea whether there will or won't be, but there are many people pressing this legislation -- I suspect that time would be very short, indeed, for further input and participation of this committee.

However, there also are a number of areas of patent law which can have an impact on the interests that I've heard mentioned this morning that you may want to think about and perhaps should think about. Some are on your agenda for later today. I noticed that both Professor Gold and Professor Straus, two international leaders in the scholarly exploration of these complex issues, will be talking with you this afternoon -- and to think about what isn't included in this legislation, as well as what is.

Well, what I have here is a very brief outline of the pros and cons for each of the currently retained, in a manager's amendment, legislation. And I've mentioned here right at the front that this compilation was made by my law clerk, Chris Katopis, who is standing in the back. Chris, raise your hand. And if you have questions of procedure or how things are working or the materials that were compiled here, I've got Chris' phone number down here.

(Laughter.)

JUDGE NEWMAN: But I've also added my personal views as to each piece of legislation. I couldn't resist having my say.

But I only have, in this limited time, time to go through a few of these, and so I'm going to start at the top with the one or two areas which are perhaps of greatest significance for what I'll call the health of the patent system.

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Now, I'm not going to say the strength of the patent system because that is the foundation of this controversy. Again, I'm told that the lobbying effort -- there was enormous lobbying on all sides that's been going on here -- of the software industry has been generally overall to weaken the patent system, recognizing we've all seen some very heavy litigation, some very high stakes, some billion dollar judgments in this area, and concerns as to whether this in fact is how the system should work.

Lined up on the other side have been pretty much a combination -- a curious coalition perhaps -- of the university community, the pharmaceutical and biotech industries, and big industry in general concerned that, although there may be some developments that would move into public use, even without reliable patent support, there are many others that don't.

And one of the things for you to think about, of course, is how science and technology evolves, what are the motivations, what are the purposes, the incentives, and how will it work best to serve the public interest that we're all here to serve.

So what's considered to be the most significant change that remains in the bill or the two most significant changes have to do with fairly technical aspects of the patent law.

The first is what's called the move from the first-to-invent system to the first inventor-to-file. The current system in the United States, if there are competing patent applications because there have been authentic, concurrent inventions by different people, is for the Patent Office to run what they call an interference proceeding to find out who, in fact, was the first inventor. That person then is the one who gets the patent.

Well, this legislation would change so that the first person to reach the Patent Office, the first inventor to reach the Patent Office, would in fact get the patent. It would eliminate the patent interference procedure.

It would retain one safeguard and only one, and that is for the person who loses the race to the Patent Office to say that the guy who got there first really stole it from him or "derived" it from him is the word that's used. You don't have to show any felonious criminal activity. So that's in the system, but other than that, it is a first-to-file system.

Now, I've listed the various arguments that are presented in favor of the system. I, in fact, believe, suspect from what I see, that this may be one of the few points here which may be enacted in the current legislation.

Well, the first argument is that the rest of the world has a first-to-file system. So if we are realistic in our expectation or hope that some day there will be some kind of unified, one-patent-fits-all approach, that this current obstacle -- it's mentioned as an obstacle. I don't think it's the primary obstacle, but it's been put in that position. Anyway, this obstacle would be removed so that we'd be ready for this brave new world of one international, multinational patent.

Another argument is that today less than 1 percent, maybe one-half of 1 percent, of the patents in the Patent Office are found to have the kind of conflict which warrants the interference proceeding, and that in most of those cases, after a long, drawn-out, expensive process, the first side that filed more often than not, experience shows, prevails.

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Then another argument is that the first party to file has certainty that someone else isn't going to come along and say I really invented that first and take it away after 10 years of bureaucratic hassling in the Patent Office.

The interference proceedings are very long. They are handled in the way one might expect to make sure that there aren't any mistakes. There is a very heavily overloaded Patent Office at the moment and perhaps for the future, but these have always been notoriously long, drawn-out litigations. The polypropylene interference of some 10-20 years ago took 20 years to resolve. At that time, patents were measured from the grant date. So the patents that finally issued were dealing with old technologies and the fight continued. Even now we still see some of this litigation in our court. Now that patent life is measured from the filing date to start with, with some extension if there are internal proceedings, one might find a good deal of the patent life devoured by this bureaucratic proceeding.

And another strong argument is that in fact most entities now think internationally. Since other countries have a first-to-file system, we too, small or large business, are pretty much obliged to rush into the Patent Office before any publication in order to obtain valid patents in other countries.

Well, this sounds good, doesn't it? It sounds straightforward. How could anyone object to all this?

Well, those who object perhaps have at least as strong arguments. First, they say the overall culture would change. There would be a race to the Patent Office. It would be premature. People will file, race to the Patent Office just as soon as they reach a certain stage, not develop their science or technology a bit further as they might otherwise. One aspect is that the content of the patent application would contain less useful disclosure of the science and technology just because it hadn't yet been developed. And there are very strict rules about what's called "new matter." You can't add. You can refile perhaps, but then you lose your first date and it's very complicated. So the idea of the quality of the filings might be affected.

Then patent applications are very expensive. Figures that I heard a few years ago where that fairly simple applications were somewhere between \$10,000 to \$50,000 in legal fees and then the filing fees keep going up as well. This is a diversion, I think, no matter how deep a pocket you're dealing with, to have to spend this resource that you might better spend on your R&D when you aren't yet really so sure what you have, but because of the race to the Patent Office, the risks of delay are enormous, especially if you think you're onto something or maybe if you aren't sure whether you're onto something.

Then there's the question of secrecy. The first-to-file legislation proposal would also broaden. There is now recently enacted an 18-month publication rule. So your patent applications are made public after 18 months. But there used to be an exception for small inventors, or anyway, those who announced that they were interested in international filing could keep their patent application secret. Now, as part of this overall structure, whatever your invention is -- and some inventions are very hard to police, process improvements and so on, minor improvements that might give you a competitive edge -- once they're out, whether they're patentable or not, they're known to the public.

And just as a digression, we know or expect that it's going to be harder to get patents, harder to preserve patents than it has been in the past based on some judicial decisions. Those decisions

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seem to be attuned to the current state of science. It's too soon really to know what they're going to mean. It is an uncertainty that maybe should be factored into the larger picture.

In any event, after 18 months, if you do find that someone else has gotten there first, you have no hope, even though you were the first inventor, of salvaging your own work.

Then there's the question of the grace period, a grace period which would tolerate, authorize publication. This is something that is pressed particularly by what's called the Big 10 universities. That was the letterhead of a letter recently filed that seems to reflect the academic viewpoint quite well, that publication is, indeed, very important. There are publication days, timing, all sorts of complexities that go into the balance of the need and interest in publication and the need and interest in filing that requires a grace period. Well, the current proposed legislation does include a one-year grace period.

Now, another argument, however, which has as a result come to the fore, has been that since the first-to-invent system of the United States has been raised by the rest of the world, particularly the European and the Asian countries, as a major obstacle to harmonization of our laws, maybe we shouldn't just give it away. Maybe we should trade it for insisting that the other laws accept a grace period, and there has been a certain movement towards acceptance of a grace period. That is, is it premature to make this unilateral concession?

Well, I go into this detail for this first issue on first-to-file/first-to-invent to stress that it's not simple, and the others are worse. So if in fact you, as I hope you will, weigh all of this and take a position reflecting the public interests, that you reflect to understand that it's not going to be easy, but to me, that's all the more reason why there should be input reflecting the public interest, as well as the various private interests which have already been brought to bear.

I should point out that small business groups that at one time powerfully opposed this change have dropped that opposition. They announced it at the meeting of the National Academy of Sciences -- I think Jim was there -- whose report has been referred to -- I assume because even small business is interested in international activities.

I do want to point out also I think this aspect is of particular relevance when the science is evolving rapidly. Rapidly evolving science can have advantages and disadvantages on both sides of this equation, but since the proposal is in the hopper and enactment may or may not take place, the delicate balance as to how it might affect, in particular, the evolution and the utilization and the practical application of genetic advances is something that ought to be considered perhaps more deeply, more profoundly than is already on the record.

Then just as another aspect of the complexities, at one time there was a proposal that a secret prior user was protected, that such a person wouldn't be forced into the patent system in order to protect a first-to-file right. The present law is sort of ambiguous as to such protection. That was initially in the legislative proposal, but that adds so many additional complexities that it was dropped. However, by dropping this proposal, it leaves unknown and uncertain where things are. Again, people always used to say that an advantage of the patent system is that if you practice the invention in secret, someone else comes along, patent -- "patent" means public -- makes it public through the disclosure in a patent application. The person who was keeping it to himself and practicing it might very well be found to be an infringer. Nobody really knew because it was secret. And so there's been very little judge-made law in this area. But it's very hard to keep secrets such as that today.

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So where does it fit? Well, the Senate -- this proposal -- requests a thorough study of the practices in other countries on prior user, and I think you'll hear something about that this afternoon. Whether this legislation should be moved forward without considering that aspect is another question that would just go into the balance. There are many advantages. There are disadvantages. And how you come out -- again, I encourage you not to say it's too complicated. That just leaves the decision in other hands.

How much longer should I talk?

DR. EVANS: We want to have some time for discussion.

JUDGE NEWMAN: Let me just mention one more issue then, and then let's talk about it. And that was really why I tried to put everything that's active in here because I knew we wouldn't get to it.

It's the issue of the public participation in the patent system and particularly what I've called here the second window. It provides, in some fairly complicated ways, for the public more formally to bring to the patent examination process information that the examiners haven't had or perhaps haven't adequately considered. That's the pre-grant submission procedure of published information that I mentioned. This is generally uncontroversial. I myself think it's a fine idea.

I think we need to be realistic about the difficulties of providing enough rapid, speedy, and qualified patent examiners to handle all of the changes in technology, not that the agency has not shown that it's capable of handling a good deal of complexity very rapidly, but because the whole patent field has gotten to be such a hot employment area, that there are far fewer career examiners and many more less experienced in the Patent Office, again leading to mistakes.

A very important aspect of the patent as a commercial aspect is that the people who are investing, whether it's an entrepreneur or your banker or some relative or just an industry's R&D activities, include weighing the various risks, the risks in a research project that it will succeed or won't succeed, how much it will cost, the risk that your investment will be recovered through market forces, the role of the patent, how well will the patent protect your market, or will it really teach your would-be competitors how to do something else, your having opened the door. What are the risks of litigation? A number of the other areas here do talk about the risks of litigation, the return, the licensing issues, particularly are of interest to university inventors who aren't going into the business themselves. They don't want to protect their business, but they need to provide enough protection for some industry to take the idea, commercialize it, and market it and return to the university whatever is fair from the product.

So the pre-grant provision of information seems to be noncontroversial. It requires, of course, the early publication that I mentioned, and that is the more difficult aspect of that, rather than just opening the door to additional information.

The debate is in what's called the second window. The first window, after the patent granted, is that for a year after the patent is granted, the legislation introduces something that corresponds roughly to what in other countries is called an opposition proceeding. Here it's called a cancellation proceeding.

But the second window would allow anytime that someone is accused of infringement to go back to the Patent Office and essentially litigate the aspects of whether the patent should have been granted or not.

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Well, as with everything else, there are arguments, powerful arguments, on both sides of this, and I have mentioned some of them.

The strongest argument is that litigation is so expensive and burdensome and punitive, win or lose, and if in fact there is something wrong with the patent, whether it's too broad or shouldn't have been granted in the first place or if revised or narrowed would remove the risk for your product, there ought to be an easy, cheap, alternative way to do that. And this legislation puts a lot of rapid reaction restraints on the Patent Office. It requires them to set up another administrative tribunal to handle this. There are time limits, and it's really unobjectionable that an alternative would be helpful.

Now, at present, there is what's called an interparties reexamination proceeding that had the same goal. However, it's not being used.

People for whom the stakes are high, those who want to challenge the patent, would rather go to court on the theory that the Patent Office perhaps would be more likely to understand the issues, understand the science, and proceed to reinforce what they did before, whereas there might be a better chance at eliminating a patent in court.

But they also say to limit the unlimited challenge to one year is really too short. People have other things to do than watch every patent that comes out and see if there are flaws in it that would render it vulnerable to attack.

They also point out that no one really objected to being able to push a patent into reexamination at any time during its life. So what's all the fuss about for a cancellation proceeding?

They also say that because of all of the complaints, a good number of safeguards have been built into the law, including the safeguard that if the patent survived such a proceeding, you can't again challenge it in court. Now, that is not the present law with the reexamination. So it would, indeed, have a strengthening effect on the patent. Critics say, therefore, people who aren't so sure how it's going to come out are not going to run the risk of reducing their chances of eliminating the patent that's in their way by using the proceeding.

The arguments on the other side are different. They say that the only patents that are ever challenged anywhere at any time are the successful ones where the inventor has made the invention or acquired it, has invested in its development, brought it to market, shown that it's profitable, and then along comes the other guy who says, oh, I'm entitled to a piece of that because there are some flaws in the first place. So they say that this would tempt such opportunistic attack. It would also tempt burdensome attack perhaps on people who are least able to afford it. They say that the possibility that I can always challenge the patent -- and remember the recent Medimmune case says that a licensee can always challenge the patent.

So the opportunity to do that can change the entire landscape of licensing negotiations because the patentee is, by definition, in a weaker position generally as a matter of law even though the specifics of that invention haven't been investigated. So they say that it's ripe for abuse and that the abuses may outweigh the advantages.

They talk about the need for a reliable asset to acquire risk capital, as well as other capital investment. They say that it's uncertain enough to have judicial review of patent validity. I suppose I'm part of that problem. Therefore, adding another area of uncertainty can shift the negotiating balance in unknown and unpredictable ways.

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The Big 10 universities took a very strong position on this. What they said is if patents are to have any value, there must be some finality to the process, and that's what they were talking about. Litigation, of course, is not final. But finality to the administrative process, which was designed for benevolent reasons to be easier and cheaper to manage, they say to allow investors to develop with confidence. Well, it's complicated. It's very complicated. So I commend it to you.

I also mentioned that in foreign countries, as I understand it, the opposition period is limited to a certain amount of time after the grant of the patent. And I do know that we've all seen some horror stories of tying up such patents for their entire life. Again, the life is being measured from the filing date rather than anything else.

The absence of this second window, it said, doesn't prevent the challenge of a patent in court. If you're charged with infringement, you can bring your challenge to the court and resolve it that way. So, the opposers say, there's no need for an additional bureaucratic proceeding unless we show that it's just not working the way things are now. Well, of course, there are a lot of reasons to criticize the way things are now.

Later on -- we may not get to it. Perhaps there are technicalities of the patent law, the so-called interlocutory appeal at various stages of the patent litigation so as to try and simplify and clarify the issues as the litigation proceeds is something else that's being proposed in this legislation. Again, there's as much or more to be said against that procedure as in favor of it. But again, the interests need to be balanced, but they need to be balanced from your viewpoint, not mine as trying to settle litigation, not the viewpoint of any particular industry because the viewpoints all vary, but as far as that which you know about the development and the evolution of science and technology and its public availability, just to think about how that affects and is affected by legislative changes and whether there's anything that you should be doing.

All right. Well, then this is a good place to stop. Is it, Jim?

DR. EVANS: Yes.

JUDGE NEWMAN: Okay.

(Applause.)