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Tailoring Patent Policy to Specific Industries

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Dan L. Burk, *Tailoring Patent Policy to Specific Industries*, 7 *Intellectual Property L. Rev.* 1 (2003).

Available at: <http://scholarship.law.marquette.edu/iplr/vol7/iss1/1>

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THE SIXTH ANNUAL
HONORABLE HELEN WILSON NIES
MEMORIAL LECTURE
IN INTELLECTUAL PROPERTY LAW*

TAILORING PATENT POLICY TO
SPECIFIC INDUSTRIES

DAN L. BURK**

INTRODUCTION¹

Thank you for coming to the lecture today. Our guest speaker is Professor Dan Burk who is the Oppenheimer, Wolff & Donnelly Professor of Law from the University of Minnesota. Professor Burk holds a B.S. in Microbiology from Brigham Young University, he has a Masters in Molecular Biology in Chemistry from Northwestern University, he has a J.D. from Arizona State University and he has a J.S.M. from Stanford University. Among other places he has taught, he has taught previously at George Mason and Seton Hall, and he is here today to talk to us a little about Tailoring Patent Policy to Specific Industries and I hope you will help me give Dan Burk a warm welcome.

PROFESSOR BURK'S REMARKS

Thank you very much. I am happy to be here. This is my first visit to Marquette and I am particularly happy to be giving an address that honors and memorializes the work of Judge Nies and the work that she did on the United States Court of Appeals for the Federal Circuit. I

* Audiotape of The Sixth Annual Honorable Helen Wilson Nies Memorial Lecture in Intellectual Property Law, held by Marquette University Law School (April 10, 2003) (on file with the Marquette Intellectual Property Law Review). The lecture is delivered each spring semester by a nationally recognized scholar in the field of intellectual property law.

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1. Professor Eric Goldman provided introductory remarks.

think it is particularly appropriate given my subject matter today, as you will see, because I am going to talk a good deal about the Federal Circuit and about the role it has in tailoring patent policy and shaping patent law, and of course Judge Nies was an important part of that. I want to thank Professor Goldman and the faculty and the members of the IP Law Review, also [the] local practice community who I understand are supporting this important lecture series. And I particularly want to remember and thank someone who is absent, my friend and colleague, Professor Mark Lemley from the University of California-Berkley with whom I have collaborated in developing some of the ideas that we are going to discuss and I am going to present to you here today. The genesis of this project, which has been an ongoing series of investigations and publications in intellectual property law, really started a number of years ago when Professor Lemley and I were attending a meeting, which has been unkindly referred to as a boondoggle occasionally, in the Cayman Islands, but is a very important scholarly meeting, you have to understand. During the course of that we had an important scholarly conversation on a boat during a day long snorkeling expedition, sort of going out to swim with the fish and the rays and so on, and began discussing patent laws, of course you do on these trips to the Cayman Islands while you are snorkeling, and thinking about the way that particularly the law was developing in the areas of software and biotechnology which each of us have some expertise in. And, we perhaps got a little too much sun that day but we began to realize that the law in biotechnology and the law in software w[ere] sort of proceeding in different directions even though they were supposedly both part of the same uniform patent system that we have in the United States and that led us to begin to ask some questions about how we can take a generalized patent statute and apply it as an incentive to different industries when those different industries have such disparate requirements for innovation and for development of the inventions that we want to try and prompt in the various areas. And, so what I want to think with you about a little bit today is precisely that question because it has nominally some important implications for intellectual property law but really for law in general. How do we take a generalized system and try to apply it to different areas?

So, I am going to begin by talking to you a little bit about statutory choices. How do we design statutes? How do we make choices about the way that we are going to set up statutes to accomplish certain purposes? In this case, in intellectual property, to create the incentive for innovation that we think is important as a part of our industrial

policy, and I am going to ask you to think about that in terms of the literature on rules and standards. Rules of course being legal criteria that are very bright line and sharp and well defined. Standards being the classic sort of fuzzy balancing test on the laws and mix of each of those and we have to think a little bit about which approach we choose to accomplish a given goal. Then we are going to go through some industry profiles and think about different types of technologies in different industries where innovation takes place and ask what the best mix is in each of these industries to accomplish our goal of creating an incentive for innovation in that particular industry. I'm going to suggest to you that our patent law is designed with what we and some others have called policy levers that judges in particular can use to shape or tailor the law to meet the needs of particular industries and then think towards the end of the hour about how we actually do that kind of statutory tailoring in some examples of specific industries. And we'll focus where I began back on biotechnology and software as two good examples, although I'll allude to some other kinds of industries where we might do this kind of shaping and tailoring as well.

Now in order to start that process I think the place really to begin is with the opinion of the United States Supreme Court in *Diamond v. Chakrabarty*. Back in the early 80's we all knew and we have known for sometime that was a watershed decision in the law of intellectual property and in patent law. The specific issue you will recall that was put before the Supreme Court at that time was whether the United States patent statute extends to transgenic bacteria, to genetically engineered type of bacterium, specifically in that case one that was designed to digest and to break down petroleum. So it was useful for oil slicks for controlling oil spills. Since it was a living organism there was some question about the extent of the patent law of whether the statute could be used to cover living organisms and the Supreme Court came back and said well, the answer is yes, in fact the answer is more than yes, its not just that the patent statute extends to living organisms. Our patent statute in the United States, we were told by Justice Berger, it is intended to cover anything under the sun made by man, or to be a little less sexist, anything under the sun that has been made by human beings. And we have some statutory categories in the patent statute that talk about articles of manufacturing, compositions of matter and process and so on as being patentable subject matter. But those are really representative, they're not exhaustive. Those are the kinds of things that can be patentable and if it's been made or shaped or changed by humans it's potentially patentable subject matter. And the court in

looking at the statute looked at it as a general statute and said we don't see any indication that Congress didn't intend to extend this to everything under the sun made by humans. Its true we have some separate statutes for plant variety protection, we have a statute for any sexually reproducing plants—the plant patent statute, but those aren't indications the Court didn't think the utilities statute, the patent statute that we associate with most patents, that that couldn't extend not just to living organisms but to all kinds of subject matter. Now that is a roddershed statement for a variety of reasons, not just because it sort of led to the biotechnology industry as we know it and not because it involves all sorts of ethical and interesting issues regarding patenting living organisms and patenting life and so on. But because of the approach the Supreme Court took about a statute of general application that will apply to everything, all sorts of categories of invention and the implication is that the courts will really be responsible for making sure that it works with new kinds of technologies we have never seen before, with technologies that Congress hadn't fully thought about, couldn't have perhaps imagined when it passed the statute. Contrast that decision with the decision just a few weeks ago in Canada, the *Harvard College* decision, in which the Canadian Supreme Court essentially took exactly the opposite position. Looking at the question as to whether a (transgenically) altered mouse was patentable under the Canadian statute which looks very much, by the way, like the U.S. statute and is in fact drawn to a large extent from the U.S. statute, the Canadian Supreme Court said we don't think that our statute extends to complex organisms that have been altered by humans because those organisms raise all kinds of issues—moral issues and issues that they are self reproducing and they have characteristics that we think other kinds of inventions don't have and we see in our statute no specific provisions indicating that Parliament intended this subject matter to be included. We don't see any specific provisions dealing with the fact that a mouse is sort of self-reproducing and we infer from that that Parliament didn't consider mice in the complex organisms in passing the statute. So, it is not includ[ed] in the statute and if parliament wants it within the statute they need to tell us. They need to amend the statute or give us a new provision directed to that new technology. All right, then you see the contrast of the default of the United States decision that we have been living with for the past 20 years or so is that the statute covers everything unless Congress tells us it doesn't. The default in the Canadian decision—the statute doesn't cover everything, it only covers new technologies, unusual technologies, if Parliament specifically tells us

that it does. So that has launched the Canadians perhaps on a very different trajectory than the one we have seen over the last 20 years in the United States. What we seen happen in the United States since the *Chakrabarty* decision; well we've seen the lower courts, in particular the federal circuit, really take that statement to heart that the patent statute covers anything under the sun made by humans and expand that not just to apply to biotechnology of all sorts but really as an answer to the question as to whether software was patentable and other kinds of technologies might be patentable. Most recently we have seen the courts say in the *State Street* case and some more recent cases that these are things under the sun made by humans, these business methods, these computer software inventions and so, yes, under the *Chakrabarty* decision they certainly come within the statute. Now, some people argue that this has gone to the point of absurdity where you find intellectual property being extended to all kinds of things that are perhaps counter intuitive to the general public, how to swing a golf club and other sorts of patents that have issued that you have seen. My personal favorite is the patent on the Socratic method, although my friend Eugene Balik reminds us that the real Socratic method is when you ask people hard questions and they kill you. But this patent is for the Socratic method implemented in some computer devises and people have said well that is sort of sill—we've gone too far. But, the point is that is sort of a logical endpoint if you take the *Diamond v. Chakrabarty* holding seriously. So whether the Canadians will go that direction or not is an open question. Canadian software patent law is not very well developed, but it may be that they are now on a different track with a different set of assumptions than the one that we have seen in the United States since the *Chakrabarty* decision. Now the fundamental premise in that *Chakrabarty* decision, and the one that differs between the Canadian *Harvard College* decision and the *Chakrabarty* decision, is how do you approach innovation? What kind of a statute do you need to prompt innovation? And there are essentially two strategies that you could adopt and the United States has adopted one, thanks to our Supreme Court, and the Canadians seem to have adopted another thanks to their Supreme Court. One way you could go is you could say well, we need a specific statute for specific technologies, you know transgenic mice are funny, unusual things and we need a statute tailored to transgenic mice, and computer software is a funny, unusual kind of thing, we need a statute tailored to computer software. In order to get the right amount of innovation in those industries we really need to think about the requirements of those industries and craft a specific

statute that does that, so that every time a new technology comes along the legislature in the Canadian case, Parliament, is going to have to give us an amendment or a new statute to accomplish that incentive. The other direction you can go is the *Chakrabarty* premise, the approach taken by the United States Supreme Court, to say well we'll have a general statute and it will tie to all kinds of technology, the fit may not be perfect because technologies are different and we may not have foreseen what they will require to encourage innovation, but we have courts and we have other sorts of institutions that can modulate that statute and shape it to the needs of specific industries. There may be some question then about what institution is the best institution to do that and I'll say a few words about that in a few minutes, but certainly the implication of the *Chakrabarty* decision is that the courts in the United States will be doing that. And, this is very much like the age old question in the law about should we have rules or should we have standards. Should we have sort of specific bright line, narrow sorts of legal criteria, or should we have broad more flexible kinds of approaches? Now, occasionally in the U.S. we have tried that first approach which the Canadians now seem to be adopting on a large scale. We have some examples of technology specific statutes that have been adopted in the United States, for example the infamous Semi-Conductorship Protection Act passed back in the 1980's when Congress was convinced that the U.S. semi-conductor industry was in real financial trouble and was going to be overtaken by foreign competitors, specifically the Japanese, and really need some help and so they created and crafted a statute that was supposedly specifically designed to meet the needs of the semi-conductor industry to protect the mask works that were the key to the chip production technology at that time. But it is a great example of what would happen if Congress wrote a statute and nobody came right. In the time since then we have one and looks like maybe now we are about to have a second litigated case trying to enforce rights under this statute. Now people register mask works but they don't ever seem to ever enforce the rights that they have been given and that is in large part we understand because the statute was obsolete the moment it was passed. Right, the semi-conductor industry had already begun to adopt different methods and so this is really more or less an irrelevancy for both business reasons and technological reasons in the semi-conductor production industrial sector. We also have an example of this in biotechnology where Congress was convinced that it was important to create a new provision of Section 103, the obviousness provision, in the patent law to specifically meet some

supposedly unusual and idiosyncratic kinds of requirements of biotechnology process inventions, but again no one seems to use this very much in part because it requires certain election under Section 103 and the common law has caught up with the needs of the industry and so the provision that was passed by Congress is again really an irrelevancy. So this is the danger in the specific narrowly tailored statute approach, which is that you may get a statute that fits that industry really well at the time as sort of a snapshot or cross-section of that industry but technology is dynamic—it moves forward—and if the statute is not dynamic it gets left behind. So someone is going to have to come back and change that statute, the question is who is going to do it. Is the legislature going to come back and do it, or can you ask someone else like an administrative agency or like the courts to do it. If you don't you end up with a narrow well-crafted, well-tailored statute that quickly becomes irrelevant. Some people suspect that the *sui generis* form of database protection that we now see in the European Union may suffer the same fate. There is some work by (Hugenholtz) and his colleagues at the University of Amsterdam suggesting that that narrowly crafted specifically tailored database incentive statute is going to become an irrelevancy as well. So, again the danger of the specific approach and as I said this reflects the old discussion about rules versus standards. It is nice to have rules, these clear bright line hard-edged legal criteria. Carol Rose at Yale calls them (crystala). Because you can tell where the border is very easily. It is easy to apply rules, courts know what is expected, there is a lot of notice involved, people know what behavior is expected of them. The drawback of course with these very rigid and predictable kinds of approaches is that you get type one and type two error in large amounts, right. That narrow situation doesn't adapt itself well to the broad variety of facts that are out there. So if we say the rule is you must drive 55 miles an hour, everyone knows what is expected, it is easy to tell if you are violating that statute or not, it is easy to enforce because all you have to do it whip out your radar gun and you can tell what the speed was, but if there are reasons why you should be driving faster or should be driving slower they may not be taken into account in that narrowly crafted rule. So, sometimes we enact standards. These sort of flexible balancing test like the fair use rule in copyright, all of the rules in torts as far as I can tell as to what a reasonably prudent person is, and you know these are not easy to tell where the border is. It's not easy to tell before hand whether you are engaging in prohibited conduct or not. But it is very flexible and it can accommodate lots of different situations and lots of different variations. The drawback of course being

that I can't tell you if you are making a fair use of something or tell you if you are engaging in reasonably prudent conduct before the fact, only after a judge looks at it do we know. So it is hard to put people on notice and sort of unclear and sometimes frustrating. So that is the trade off that we have and it's the trade off that we have in crafting innovation incentives as well. If you think about the Canadian approach, it looks more like a rule-based approach. If you think about the American approach, it looks much more like a standards-based approach. Which is better in promoting innovation? Think about the profiles of some discrete perhaps idiosyncratic different sectors of technology. Think about for example the chemical and pharmaceutical area. What do we know about chemical and pharmaceutical innovation? What kinds of things should be necessary to promote innovation in that sector? One thing we know is that the technology lends itself to very rapid discovery of new inventions. You sort or take some molecules—and playing with them, putting different (cite) chains on them, fiddling around with their structure—and you can very rapidly generate a large batch of new discoveries, new molecules that didn't exist before using (chematorial) chemistry techniques and so on because structural variation is very simple to come by. However getting those inventions to market is very resource intensive. You have very long development times and maybe log new inventions but you know what they do and how well they work for their intended purpose. There is a lot of regulatory oversight. If it is a pharmaceutical we have very strange FDA requirements for testing. We may have EPA requirements for environmental safety and so this becomes a very, very (expensive) process. Not to develop the new invention, but to get the thing to market. So, chemical and pharmaceutical innovation is characterized by sort of rapid discovery, but very slow innovation when we define innovation as actually getting the thing to the market place. How about biotechnology, which I mentioned at the beginning of the talk. We have small DBCs or so called dedicated biotechnology companies in the United States where again the discovery process is not only routine, but automated. You put your sample into the machine and the machine comes back at with you with a protein sequence or a DNA sequence or whatever. So the product development time is very short, but these are inventions that change complex organisms. Some of them are pharmaceutical; some of them are agricultural products. They interact with ecosystems. They interact with the physiology of humans or other living organisms and so there are a lot of variations. A lot of permutation of how they can behave that creates uncertainty. Whether

it be (using) these complex systems, again you have a lot of regulatory oversight. So, once again you've got a very long development time from discovery to market. Frequently in the order of decades to get a product to market and the financing and capitalization of those companies is frequently quite problematic. How about the semi-conductor industry? We said Congress had passed a law intended to help the semi-conductor industry a couple of decades back, it didn't seem to work very well. What is the current profile of the industry? How do they do innovation? Well it is extremely resource intensive, we know that from the economics literature. You have relatively short development cycles, you know the famous Moore's law that the processing power keeps increasing and the number of circuits on the chip keeps getting larger as the (administrasation) progresses. But you are putting a lot of stuff on that ship and so the coordination of all the designers and engineers who are giving input into that product and actually the number of separate inventions in the final product, on that particular chip, is very large so you have big coordination costs and for each chip you come up with you basically have to build a new factory. There are very expensive fabrication costs. All right so this is very, very resource intensive. Hundreds of millions of dollars for each new product that is created. And one size doesn't fit all because as I said you've got lots of different inventions in the same final product. It's not like a chemical structure where the structure is the invention and the product and the invention are sort of coterminous. It's a situation where the product embodies lots of different inventions. How about computer software? Which again I mentioned previously. In contrast to some of these others, the development we know from studying the software industry tends to be incremental. Each developer builds on the previous one because inner operability is important. And the product cycle times are again quite short, like semi-conductors. The shelf life of your new version of the software is maybe six months or so and then you need to upgrade it or change it. So you've got to have a lot of different things that work together and there [are] continually new things coming into the market. But unlike semi-conductors, unlike biotechnology or chemical (forum) not only do you have these very short market cycles, but the resource requirements are relatively modest. The classic software developer is the teenager in the garage or the basement but we do things a little bit more sophisticated than that in the software industry. But again we are not talking in the hundreds of millions of dollars range, were talking about a much smaller and much more modest investment in some equipment, some skilled people and then a fair amount of debugging.

But nothing on the order of what we were talking about in the other industries. So each of these industries is clearly quite different with regard to that. Now how can we make, as the *Chakrabarty* decision wants us to, a one size fits all patent statute meet the requirements of each of these different industries? All of these industries have patentable innovation that takes place in the industries, but if we are going to create an incentive for biotechnology it would seem from the industry profile that is a very different proposition than creating an incentive in software or creating an incentive in semi-conductor chip process innovation. Well, what I suggest to you is we have this general statute, *Chakrabarty* suggests to us that it needs to be adjusted by the judiciary to meet the requirements of each of those different industries, and there are doctrines or policy levers within the patent statute that allows the judiciary to do that. We have identified two different types of policy levers or two different types of modulating doctrines in the patent statute. Macro levers, we call them, are doctrines that shape the patent law specifically to a given industry. So they say this industry is different. Biotechnology is going to be treated differently. Software is going to be treated differently than other kinds of technologies. There are also micro levers which don't operate in industry wide or sector wide levels, but instead treat each invention on a case-by-case basis; but nonetheless because inventions in a particular sector will have certain characteristics, the end result is that all of the inventions in a particular industry end up being treated differently than inventions in some other industry. And I'll give you some concrete examples of each of those. I said we would have to think a little bit about the institutional competence question because *Chakrabarty* suggests that the judiciary is going to do this and Professor Lemley and I would argue that the judiciary is probably best suited to do this. The Canadian approach seems to be, based on what the Canadian Supreme court has said, that the legislature has to come back each time there is a new technology developed, or each time there is a new development in technology, and give us a new statute or an amendment to the statute to accommodate that. For a variety of reasons we can see why that may not be desirable. Congress or the Canadian Parliament or pretty much any other legislat[ure] you care to talk about doesn't return to statutes that often. It takes a lot of political capital and political will to come back and do that kind of work. They are busy doing other stuff that may be more politically interesting to them. And most importantly there are very, very serious public choice effects in (rent) seeking. And we can see that from the examples I gave you earlier in the United States of technology specific statutes. Why

was there Semi-Conductorship Protection Act—because of lobbying and (rent) seeking by special interest groups at the legislature. Why do we have a special 103 Section for biotechnology? Again, because of (rent) seeking activity, lobbying by special interest groups. And it may not be conducive to good and innovation policy to have the statute crafted or tweaked by special interest groups. They may or may not have the big picture in mind. So there [are] some fairly serious questions with having the legislature do that. Now some people can collect a lot of data, can collect a lot facts, get a lot of information, and perhaps courts are not as well suited to do that. Courts certainly can collect some facts. Particularly at the trial court level, but all advantages are comparative. And we have suggested in our work that the judiciary is best suited to do this, number one because they seem to be doing it anyway. You recall I said at the beginning of this talk that we first began to think about this because it was clear that the Federal Circuit was crafting a different kind of patent law for software then they were for biotechnology. And there is a lot of standing tradition of having crafted different patent requirements for small molecule chemistry than for other areas and other technologies than patent law. So if the judiciary is going to be doing this anyway it seems to make sense to have the judiciary do it purposefully and in a calculated and rational manner, rather than haphazardly which is what we suspect has happened up to this point in using these levers that are available to them in the patent statute. We are still big believers in judicial minimalism. We think the judiciary ought to be restrained, but they can and do engage in this kind of tailoring to specific industries and so it seems to make more sense to have them do it in a rational fashion. Let me give you some examples of the kinds of doctrines that the judiciary uses to do this. There is a fellow who shows up at various points in patent law known as the person having ordinary skill in the art or it shows up in the obviousness standard, shows up in the enablement standard, and in some other places as well. Clearly that standard, standard looked at from the standpoint of the person having ordinary skill in art, is fact specific and is going to tailor those doctrines to specific industries because of the characteristics of those industries. So if the person having ordinary skill in the art would know a certain thing or would do a certain thing in biotechnology that is going to make obviousness or enablement in biotechnology look different than obviousness or enablement is going to look like in software or semi-conductors or some other sector. So that is very clearly a lever that the judiciary can use to tailor the law to those specific industries. The written description requirement which is a

disclosure requirement from the patent statute can be used and has been used and is being used by the Federal Circuit to specifically tailor patent protection to certain industries. Most notably in the biotechnology area, that we clearly have a different written description requirement in biotechnology than we have in any other industrial sector or technology. That lever can be used to tailor the statute to the needs of that industry. We suspect actually that it hasn't been used very well to do that, but it would be good if it were used in a calculated fashion. The doctrine of equivalents, that we have heard about a great deal from the Supreme Court and from the Federal Circuit recently, again has fact specific questions in it as to what is substitutable and what is not and that factual determination and that factual inquiry is again going to determine the scope of equivalents for different industries making the equivalents in one industry look different than it might in another industry. Reverse doctrine of equivalent—same thing. It doesn't get employed very often, but when it does again it is going to be tailored to specific industries. So there are quite a number of these. The utility doctrine, which again in chemistry and pharmaceuticals and biotechnology, has explicitly been tailored in such a way that it is different in those industries than for other industries, because of some peculiarities of invention in those industries, can make patent protection look the way it needs to or be tailored the way it needs to to promote innovation in those industries. There's actually several others that we don't have time to go into today although I'm happy to talk about it during the question and answer period. Levers are tools that the courts can use to tailor what looks like a general patent statute to meet the needs of specific sectors. We've talked a little bit already about the advantages and disadvantages of having the legislature try and do this—as I said Congress or Parliament is not going to come back and fix this very often. One possibility we could think about is whether an administrative agency could do this. That is certainly done in other areas like environmental law and occupational safety and so on. We're just beginning to discover what the rule really is for the Patent Office in tailoring the statute to specific industries. But let me note for example that the utility guidelines that the patent office has come up with, for biotechnology in particular, tailor utility in a way for biotechnology that we don't tend to see in other industries. So maybe if the Patent Office has a role and as we understand the implications of the (Zirco) decision and how the Patent Office's degree of deference might play out—we'll learn more about that, but they may well have a role. But as I've said the judiciary seems to be to us the best place for this to happen. Technology is dynamic.

The common law process that we are familiar with in this country is equally dynamic. There is some fact finding ability in the judiciary and again we think it would be to deal with in a calculated way rather than in a haphazard way. Now, let's think about some specific examples of how this might play out, or how it is playing out, in modern patent law. We've talked about biotechnology and the industry profile, the sorts of things that go on in biotechnology, and how does that match up to what is happening in biotechnology with regard to patent law. Right now the Federal Circuit has tweaked the statute in such a way, used policy levers like the obviousness doctrine, like the written description doctrine, and other disclosure doctrines, so that the setting of the statute for biotechnology is that we have very high disclosure standards. You must give us the DNA sequence if you want to claim a DNA sequence. You can't tell us the function and have that be the adequate disclosure. You can't tell us just how to get that DNA sequence, even if you have really an assurance that method will work you've got to give us the structure. So very, very high disclosure standards. The flip side of that is that the Federal Circuit has said that we have very low obviousness standards. If we can't find that exact sequence in the prior art, in the literature, it's not obvious and you are welcome to claim it. So the outcome of this is that right now the setting of the statute for biotechnology is that everybody gets a patent, but nobody gets a very broad one. So we are going having numerous probably overlapping patents or numerous adjacent patents. All of which are very, very narrow. What about software? What do things look like in software right now? As I mentioned at the beginning of the talk, the Federal Circuit has tweaked the policy levers for patent law in software in such a way that we have almost the opposite that exist in biotechnology. Very low disclosure standards. You don't have to disclose code to us. You don't even have to give us a flow chart because the Federal Circuit has told us is that all you have to do is give us the function of the software. And once you give us the function the court has said it is "a mere clerical operation," a mere clerical function for any skilled programmer to write code that will do that function. Now if you have ever written any software you may have questions about the factual basis of that. But notice that it's exact opposite of biotechnology. The way you can interpret that is that the Federal Circuit thinks that the person of ordinary skill in the art of biotechnology is not very bright and needs a lot of guidance so we must disclose the exact sequence, whereas the person of ordinary skill in the art in software is a sort of (oogamich) who always needs to be told what should be done or what the function should be and that person will be

able to write code with very little guidance from the patent. So the disclosure standards are quite different between the two technologies. The obviousness standards are equally different. The court has told us that the obviousness standards in software are probably going to be quite high because of course if the person of ordinary skill can easily write an algorithm or code that will accomplish a certain function, you don't need much of a suggestion to prior art in order to make that code obvious. So it is in essence the flip side of what we have in biotechnology. And so rather than lots of little narrow patents stacked up on one another such as we are seeing begin to accumulate in biotechnology, in software, this setting of the policy levers would lead us to have very few and very broad patents. Now, I say valid because there are a lot of software patents issuing, we suspect that most of those are going to be invalid under this standard, and when the smoke clears and the dust settles you end up with a relatively small number of quite broad patents because of the standards for disclosure and obviousness. If you think about what I told you with regard to the industry profiles though that's probably exactly backwards from what we would want in each of those industries. In biotechnology because of those long development times that I talked about and taking a very, very great deal of effort to bring something to the market you'd want to have a big reward. A broad patent and a strong patent that you dangle in front of those investors to get them to invest in that. Were concerned that what we're developing in biotechnology is what some people call the anti-commons. The anti-commons being where you have divided property rights so small that you have to negotiate with too many people to do anything meaningful and the transaction cost prevents you from doing important or large projects. So, the industry profile suggests that we ought to have fewer and broader patents in biotechnology. We need to tweak or change those policy levers to accommodate that. And how would you do that? Well, the disclosure standard is the right lever to begin with. The federal circuits got that right. But we think that they need to relax those disclosure standards so that you can have broader patents and potentially raise the obviousness standard, which has (not been) done to date. How about in software? Since we said in our profile that software innovation is cumulative, that software innovation builds on itself. It makes sense to have more and narrower patents, right, because the life cycle of the software is very short. I need to build on what the person did before me. So maybe that will look more like biotechnology looks like now. How would you do that? Lower the obviousness standard. That is the right lever to use again and raise the

disclosure standard. And that would produce that outcome, which would be optimal we think for innovation incentives in that industry. So hopefully I have given you some sense of the different approaches we can take to creating incentives for innovation—some examples of the different industries that we might want to worry about or think about as examples of how to prompt or promote innovation and the doctrines or policy levers that might be used, we think optimally by the courts, and that means by the Federal Circuit in particular to create and craft and tailor patent law to the needs of each of those industries. I'm happy to take questions and discuss those matters with you. Thanks.

