

FICPI/AIPLA Colloquium "A Comprehensive Approach to Patent Quality"  
Amsterdam, June 8–9, 2007

Session 6 "Problems Encountered by Applicants in Adequately Protecting Inventions"  
Speakers: M. Kirk, A. Kasper, M. Jewess, K. Finnilä, H. Sauer,  
Unidentified Questioner, M. Powell

KIRK	<p>Let us now begin the second day. The first person on our panel this morning is Mr. Alan Kasper. He is the Second Vice President of the American Intellectual Property Law Association, and he is going to address a topic that several people touched on yesterday—"Differing National Application Formats." Alan?</p>
KASPER	<p>Thank you very much, Mike. I'm speaking on this topic from the perspective of someone who at one point in his career was a patent examiner. I was in-house counsel for a large corporation for about 15 years and now I've been practicing in a law firm for 20 years, and a good part of my responsibilities includes patent prosecution.</p> <p>So one of the things that one could see from that very perspective is how simple format differences might make an important consideration when one is preparing a patent application. Things that are actually quite simple, such as the physical requirements for the documents—their sizes and so on, requirements that deal with numbering of paragraphs, or numbering of lines—they are all things that can have an impact on the cost and effort that goes into filing an application in several countries.</p> <p>The content of the application—the order and title of sections, sections that are required by different countries, that are mandated, the way tables or formulae are handled, and the claim style and content—these are all things that can vary from country to country and will have an impact on the way that an internal office, whether it's a law office or whether it's a corporate office, will handle the preparation of an application for a domestic filing and then ultimately an international filing. The impact of these differences, however, can be significant and varied.</p> <p>Certainly from an internal perspective, there's a significant cost impact because of the staff time that's required, because of the attorney time that's required; there are also operational and financial impacts on the patent offices themselves because, if there are differences in the format, the examiner and the staff of the office handling that application may have to send out correspondence saying that the format is improper or requires some measure of change. So, we see that these costs become cumulative and, to a great extent, unnecessary.</p> <p>There are also impediments to some of the more advanced approaches to patent application preparation and filing—electronic filing, for example. If you have differences in format, that same application may not be filed in different countries through an electronic filing system because those differences need to be rectified so that they can, in fact, be compatible with the filing systems in those countries. As we see today, there are machine translators that are available to translate from one language to another, and that translation mechanism also can be affected by the format of the application. And last but not least, particularly with respect to the United States, we see that there is a significant risk of substantive</p>

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	<p>limitation on rights, and I'll touch upon that in just a couple of minutes.</p> <p>Now here I titled this slide, "Saving Users \$300M Annually: One Goal of the Industry Trilateral Single Format Project." The Industry Trilateral, as many of you may know, is a group of users including IPO, AIPLA, BusinessEurope and JIPA in Japan who undertook an investigation of what could possibly be done to prepare a single format application that could be filed in a number of countries.</p> <p>Some of the motivating factors that we looked at were that about 300,000 original applications are prepared annually, but that there are significant differences in format among the offices. These differences often are historical and non-substantive simply because offices have generated their requirements based upon their local domestic needs at that particular point in time. They necessarily require some rework and post-filing amendment so that those differences among countries could be rectified.</p> <p>We estimated that, as part of this Industry Trilateral Project, significant costs of approximately \$300 million annually could be saved by having some of these differences rectified. This is only the cost to users and is not reflective of the costs to the offices as well. So perhaps a rough estimate might be about double that amount for the total cost to offices and users with respect to these differences in format. And of course, as I mentioned before, these differences do interfere with both universal electronic filing and machine translation.</p> <p>So the Industry Trilateral undertook a project to identify what could possibly be changed to provide single format guidance—something that was uniform and would allow filing of a single application throughout the world without any significant change. The assumption was that PCT and PLT did not solve the problem, but that there would be a preference for international formats. The goal was not to have a minimum requirement, but to have a uniform requirement so that anyone who wanted to file internationally could use the single format and satisfy the requirements in any country. The goal was to avoid substantive costs and prosecution issues at this first step because these are very controversial and perhaps too difficult for offices to handle at this point in time.</p> <p>So, the focus was on things that were simple and easily accomplished. We recognized, however, that there would be amendments to the law and regulations that could be required, so, in short, we tried to have a simple and doable first step followed by some second steps that could deal with some more complicated issues.</p> <p>Some of the things that were recommended by the Industry Trilateral include: No required national legends. For example, in the United States, there is a requirement for the CREATE Act legends, federal funding legends, and family lineage of divisional and continuation application notations at the beginning of the application. No required</p>
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	<p>statement of industrial applicability, as found in Japan. No required citation or discussion of prior art in the specification. Again, these are things required in Japan by statute and in Europe by practice, and the belief was that the elimination of some of these requirements or handling them in different ways that didn't require additions to the specification would save significant costs.</p> <p>Having an abstract with standard size, specific section titles and order. Here I note that the United States does have certain legal issues with respect to the titles that might be used. For example, the requirement to have a title read summary of the invention could have legal impact in the United States, so the idea was to have titles that were plain vanilla and did not have any substantive impact.</p> <p>Numbering of paragraphs is another area where uniformity could be achieved globally. This one is very significant for the United States because in the U.S. the use of numbers in the abstract and claims, which are very convenient tools for understanding what the invention is, raises a problem with interpretation and potentially narrowing of the scope of the claims in an issued patent. Use of scientific measurements, units of measurements, uniform drawing standards, standards for formulae and tables, and optional parts lists were all considered important elements of a single format application by the Industry Trilateral.</p> <p>This gives you an idea of the flow that has taken place over the past year of decision making and undertakings by the Industry Trilateral. Beginning in November 2006, there was an Industry Trilateral report which was submitted to the trilateral governments. The Trilateral has also established a Working Group based upon that report to try to come up with recommendations that they could adopt for achieving a standard format. That was followed by meetings in February 2007 with the users and the Working Group. In March, there was a pilot plan drafted and a drafted prior art form that was going to be used as a basis for identifying prior art in a uniform manner to satisfy both the U.S.-type requirements for an IDS and the Japanese-type requirements for identifying prior art in the application.</p> <p>In April, we completed the set of hypothetical applications, and, in May, they were submitted for evaluation. These applications were modifications of actually published applications that were voluntarily submitted to a Working Group, modified consistent with the standard format, and then subject to evaluation, as I mentioned, to see if in fact these can be acceptable to the Offices.</p> <p>During the period of June through September 2007, they will all be evaluated and a report ultimately prepared with the proposed modifications of the plan as necessary. As you see from the footnote, there is also a tagging exercise that was proposed to identify the sections with specific tags, actually curly brackets, which could be machine readable and usable down the road for identifying specific portions of applications for machine filing purposes, for access</p>
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	<p>purposes, and for translation purposes.</p> <p>One of the things that was deferred in this recommendation, on the basis of consultation with the Working Group and the IT, was the requirement for national legends. This requires a change in U.S. law, and so this has been deferred to a subsequent working group that will consider this issue.</p> <p>Similarly, the requirement for industrial applicability, which is optional with the offices, may be addressed by the JPO. Regarding the requirement for citation of prior art in the disclosure of the application, we're working on a standard form that may be acceptable to the JPO and the USPTO—something that could be used to identify the prior art and still satisfy the statutory requirements. In Japan the addition of reference numbers in claims, and, again, a requirement for U.S. law to be changed so that if someone did put reference numbers in the claims, it could be useful for the examiners, for the applicants, for third parties reading the patent, and there would be no legal impact on the listing of those numbers in the claim. And specific section titles would also be something that would be addressed.</p> <p>Thank you very much.</p>
KIRK	<p>Thank you, Alan. Next we have Dr. Michael Jewess, who is the representative of the Trade Marks, Patents &amp; Designs Federation of the UK (TMPDF). Mike is going to talk to us about "Timely, Comprehensive Search." Mike?</p>
JEWESS	<p>I am the head of the Intellectual Property Department of a large multinational company which files a substantial number of patent applications internationally every year. I also am an officer of the Trade Marks, Patents, &amp; Designs Federation which represents my company and many other similar companies like this in the United Kingdom.</p> <p>The present system does not, in my view, provide "timely, comprehensive search" of patent applications. I will begin by describing the worst case that one could imagine.</p> <p>Suppose one is a British company. One files a British Priority Application and shortly thereafter gets a search from the British Patent Office. Encouraged by the results of that search at year one, one files a PCT application. One then gets a search and an international preliminary examination report from the European Patent Office. If this is favorable at year 2½ from the beginning, one goes into the Regional Phase in Europe and into the National Phases in the US and Japan. At this point one has spent about £20,000 (€30,000 or \$40,000)—this would be a lot more, of course, if one had also filed in Australia, Canada, Korea, China, and Norway.</p> <p>Because the International Preliminary Examination report was so favourable, the European Examiner allows the patent application to</p>

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go to grant very rapidly, and then one incurs the costs of translating into German, Spanish, French, Italian, and Swedish and possibly other languages if one goes for a wider group of European countries.

Unfortunately, after the grant has occurred in Europe, the US Examiner finds pieces of Prior Art that are far more relevant than those which the British and the European Examiners have themselves found. Under the present system, this might require one to start proceedings in each of the European countries to amend the claims. This will be easier under EPC 2000 but still not trivial.

Anyway, the US Patent then goes to grant with claims that are novel and non-obvious over all the Prior Art that has been cited by the British, European, and US Patent Offices. Then the Japanese search is performed. The Japanese Examiner cites Prior Art which is different from that which has been cited in the previous offices and which is highly relevant. Perhaps it is so relevant that one abandons all the patents, writing off an expenditure of about £35,000 (€50,000 or \$70,000) at this point, even on my rather modest foreign filing programme. Alternatively, one may need to amend the claims in the US through a re-examination, while in Europe the proceedings for amending the National Patents has to be modified somehow or restarted.

The first of these possibilities, where the Japanese Patent Office cites something which is so relevant that the Patents in all the other countries are useless, has happened to me personally. The Japanese Prior Art was so close to the specific embodiment of the Patent that there was no possibility at all of having a valid claim in any country.

Now this slide may present the worst case, but in my Department we do experience problems of this sort even though they don't all occur on one case as in my "worst case" example here.

Of course, there would be no problem if the Patent Offices all did very similar searches so that there were no surprises at later stages. Yesterday, we heard that searches by Patent Offices had 98% correlation. This, however, is not my experience.

Some research has been done to compare Patent Office searches. Six (6) inventions, randomly chosen, were investigated, each of which had been searched by the British, European, US and Japanese Patent Offices. In the case of Invention No. 2 only was some correlation found between the searches of these four offices. In the cases of Inventions 5 & 6, the correlation was weak.

In the case of Inventions 1, 3, & 4, i.e., in half the cases researched, there was no correlation at all between the searches; and, in each case, two or three of the Patent Offices—not the same ones in each case—did poor searches, failing to find relevant Prior Art. Of course, in doing this research, the citation of equivalents was treated as a

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	<p>positive correlation between the Patent Offices.</p> <p>Let's have a close look at the three cases in which there was <u>no</u> correlation between the work of the three Patent Offices.</p> <p>Invention No. 1. The British Patent Office found no citations. The European Patent Office found only A citations, but the US and the Japanese Patent Offices each found an X citation, although the two X citations differed.</p> <p>Invention No. 2. Here the Japanese Patent Office failed to find a citation. The EPO had only one citation, a mere A, whereas the British and the US Patent Offices both found X citations, but again they were different.</p> <p>On to Invention No. 4. Here the British Patent Office and the Japanese Patent Office failed to cite anything and only the US Patent Office found any X citations.</p> <p>What was the conclusion we drew from the research on these six inventions?</p> <p>(a) The identity of the best-performing Patent Office on searching varies from one invention to another. The only systematic difference, unsurprisingly, is that the Japanese Patent Office is best able to find Japanese-language citations.</p> <p>(b) To avoid wasting money on securing invalid patents, applicants need the results of the European, US, and Japanese Patent Offices searches <u>as soon as possible</u>—sooner than the present system provides them.</p> <p>In 2005, there was a proposal before the seventh session of the Working Group for the Reform of the PCT that one could request on the PCT application searches from all three of the major Patent Offices—the European, the US and the Japanese. Translation into Japanese would not be necessary under this proposal.</p> <p>The effect of this would be (going back to my second slide) that all of the searches would be available at year 2½ before I had spent £20,000. In cases where the Prior Art was fatal, one would decide not to spend any money at year 2½, and in more favourable cases, one could file claims drafted so as not to require costly further amendment.</p> <p>However, and this is my final conclusion, it is a matter of great regret to me that this proposal for supplementary searches of PCT applications has <u>not</u> been implemented, and, as I speak, it doesn't seem likely to be implemented.</p> <p>Indeed, the desire of Patent Offices seems to be to do <u>less</u> searching rather than more and for each Office to accept without question the</p>
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	<p>results of the other Patent Offices as being comprehensive. This is understandable; we heard yesterday of increasing backlogs at the JPO and that the USPTO was now outsourcing searching of its ISA work. However, I think it is wrong; the research that I have reported in this presentation shows that, without the <u>independent</u> searches of at least the three major Patent Offices, one cannot assume that one has a comprehensive view of the Prior Art.</p> <p>Thank you Ladies and Gentlemen.</p>
KIRK	<p>Our next speaker this morning will be Mr. Kim Finnilä, the President of the Finnish Association for Corporate Patent Agents. He will address the "Claim Set Necessary To Cover Infringements." Mr. Finnilä?</p>
FINNILÄ	<p>Good morning ladies and gentlemen. As was said, my name is Kim Finnilä, and our association now has a very interesting abbreviation—FACPA. We're joining the big club with all these FICPI, AIPLA, whatever. Thank you.</p> <p>I feel somewhat shaken, perhaps not stirred. The reason is the excellent arrangements of this conference. Mrs. Saffer, perhaps you as a lady could appropriately symbolize the ship, which Mr. Huntington, the captain, has run tight. We have been well cared for by our first officer, Mr. Kirk. Thank you for the excellent arrangements, and also thank you for the candlelight dinner at which you, I believe, were assisted somewhat by the weather gods as well. So let's go on.</p> <p>This topic is "Claim Set Necessary To Cover Infringements." I think everybody would like to have a good solution for this one. It brought to mind tactics and strategy, divisionals, continuations, continuation in parts, cashing in or hiding interesting possibilities. But I shall try to, or have decided to, remain very simple.</p> <p>This is still the basic thing we do. When we decide to file an application and draft it, we can say the quality of the invention is determined at that point. There is no return. That's the quality of the application, incoming work as the offices like to discuss. The quality of the patent depends on the final wording of the claims and they give the scope of protection.</p> <p>As you see, I'm speaking from a European point of view. We have Article 69 EPC and its Protocol of Interpretation with regard to the scope of the patent. We will have something new in December—we will at least have equivalents mentioned; they are not defined. Neither is prosecution history to be accounted for.</p> <p>We spoke yesterday about these two articles. I decided to write them out since a number of you are not from Europe and perhaps you're not confronted day to day with them. They say that the invention should be disclosed in a sufficiently clear and complete manner so that it can be carried out by the man skilled in the art. This is a thing</p>

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	<p>you will run into when you look at infringements as well. I'll come back to that. The claims, they shall also be clear and concise and supported by the description. I think we can agree—we heard it yesterday a number of times—clarity is the key issue.</p> <p>Can I say some general words about drafting an application? At least consider giving only a short description of the background technology and avoid direct references to prior art. We know in a number of jurisdictions this is not possible—you're obliged to include this—but try to be very, let's say, careful with this. I'll get back to this, because when claims are interpreted, you might have inadvertently related to prior art disclosing a feature, and suddenly you find that you have cut out this embodiment. It happens very easily. Also the object of the invention—we have the problem and solution approach in Europe. It looks of course very nice when you have a very distinct problem, a very clear solution, and when the object is defined as clearly as possible. This again might show up as a limitation when you start interpreting the claims.</p> <p>Why is this? Because in Europe we have quite a variety of methods of studying claims. Some rely on the description, some remain with the claims. We have differing approaches, so already at draft stage you should prepare for litigation—draft the application so that it holds in the different jurisdictions. Then you can turn to U.S. attorneys and Japanese attorneys and so on in other countries. I would also advise to define the objects of the invention in connection with the advantages. They give you a bit more leeway when you start interpretation. Now some words about the description. The description is the essential part. If you discuss the claims, discuss the function of the features or combinations in general terms, and then, again, when you speak about advantages be very cautious. This is all something you can do.</p> <p>My experience is that, when it comes to interpretation of the claims and relying on description, everything you have there will be used against you. And don't emphasize irrelevant advantages. This is something you might easily do when you think you have a weak invention and you try to bring forward matters that convince the examiner. But then you must remember that the examiner is only an intermediate stage in the process you're in. Dependent claims should be carefully analyzed and then discussed, including alternatives as far as you can. When you come to the description of the drawings, be exact. Include everything, be clear, don't think anything is obvious. In the claims, well, as we know, it's a balance between wide scope and prior art. This is the quality assessment work done by an examiner; this is what Colin Philpott, for example, has talked about quite a lot. It's an assessment of inventive step and novelty to see if there is a difference, to see if there's an invention.</p> <p>It was mentioned also yesterday that you should draft your claims in view of the business strategy. I think it's very easy—well, not very easy—it's much more easy to draft a claim that takes a distance to</p>
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prior art, defines the invention very eloquently. But, is this the claim that your competitor will infringe? That's another matter. You have to know what your direction is, where you're going; it's difficult, but consider it very strongly. In defining and writing the claim, look at the claim. Have you written it so that the invention can be carried out by a low-skilled person? Judges are—I think Judge Yeakel said that yesterday. We must or should consider that we have different skilled persons in the game. In the beginning we have somebody who is a bit more skilled; when we go into interpretation in court, we do not have an expert, a man skilled in the art in which it was created. We have a person who has to understand something that's clearly defined; but said in a positive sense, he is low-skilled in the art.

You should also, as I said with regard to the business strategy, put yourself in the position of a competitor that you want to outmaneuver or to hinder. How would he look at the claim? How would he seek ways to come around it? And to basics—check that there are no undefined terms. This was clearly emphasized yesterday as well.

Also avoid any, or take out any, unnecessary features. This is something we do when we draft the application, but it's something that you should bear in mind all the way through prosecution. After a long fight with an examiner, or let's rather say match, you might give in to something that you get allowed. If you are in private practice, it might be the pressure of the client who says, "Can't you get it. I can't wait all the time?" But be very prudent about it. And then a small thing: avoid a combination of features in independent claims. This might then lead to that when you write the description; they're always presented in combination; they have an advantage coupled to both of them—and later on you might find you can't separate them, although it wouldn't be necessary to have the features combined.

Then you come to the situation where you actually—which is the topic—have a claim set necessary for infringement. You find that the competitor is acting. Well, you have to start to see if all features of the independent claim are realized. Then how about the object of the invention? Here again, this was what I said in the beginning—if you have a very clear, defined, strict object, this might lead to a restricted interpretation in one court in Europe. German courts look very hard at the description, and suddenly you might find that your competitor might go free. I think a typical example in this sense is the pipe clamp case in Europe in which there were nine different positions or judgments in three jurisdictions in separate instances.

Then the question of advantages and, of course, is the patent valid? I think Mike Jewess put the cards on the table. During prosecution, due to untimeliness, you might run into prior art that has not been considered. Some courts, some jurisdictions allow for limitations; now we'll have the EPC 2000, which allows for a central limitation. It might be wise to reconsider and go this way before you start acting. Another matter is that you might find that you yourself have made something public at some conference. There's always a chance that

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	<p>somebody gets hold of it.</p> <p>So I say, thank you very much for your attention, and I have three final comments: I think we know what quality is. I think we know how to achieve it. But, ladies and gentlemen, to get there we need commitment from all parties.</p> <p>Thank you very much.</p>
KIRK	<p>Our next speaker on this panel will be Mr. Hans Sauer. He is the Associate General Counsel for Intellectual Property of the Biotechnology Industry Association. He will approach the topic of claim sets from the biotechnology perspective, and I know that he has some pressing interests back in the United States on some other issues, as do several of us. Hans?</p>
SAUER	<p>Thank you, Mike. The reference to pressing interests back in the United States was appropriate, and, of course, I can't refrain from exposing you to those toward the end of the talk I'm going to give today. I'm Hans Sauer. I work for the Biotechnology Industry Organization—BIO—another of the many abbreviations represented at this conference. We're an industry trade organization—1,300 members, many corporate members, biotech businesses, large and small, but also universities staked by technology centers and academic institutions in the United States mainly, but also worldwide. Our companies work in the area of therapeutic products predominantly, but also in industrial biotechnology, industrial and agricultural biotechnology, and environmental remediation.</p> <p>The perspective I want to show you this morning and very briefly in the form of a couple of vignettes, if you will, is a biopharmaceutical perspective on difficulties that patent applicants and patentees from the biotech sector can encounter mainly under U.S. practice in trying to obtain appropriate protection for the full scope of what they regard as their invention.</p> <p>A basic problem that presents itself from the perspective of a biotechnology applicant is perhaps based on the premise that molecules can be structurally different but functionally equivalent. So, picture, if you will, a protein that has a couple of amino acid substitutions in its amino acid chain. You know that's a new and structurally different molecule, and yet these substitutions may not be sufficient to change the underlying function of the molecule. It works the same way.</p> <p>Or picture a cDNA sequence setting codes for a certain protein and that sequence has a couple of base substitutions which by virtue of the degeneracy of the genetic code and code for the very same underlying protein which performs the same function, so that cDNA sequence again would be a structural analog that works the same way.</p>

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	<p>Biotech patent applicants unsurprisingly often, maybe most often, regard such analogs as part of the invention that they've made and that they've disclosed to the public at the time they file. Also unsurprisingly, biotech patent applicants, as any applicant would, want to find a way to carve out some kind of protection for such analogs which after all they feel they've invented along with their same basic invention.</p> <p>Two disclosure requirements: the written description and the enablement requirement, however, do tend to work, particularly in biotech and in other unpredictable arts, so that patent applicants sometimes have a bit of a problem carving out what they view as an appropriate penumbra, if you will, around their invention so as to crowd out competitors from coming too close as they proceed into product development—meaning that a patent disclosure may be sufficient to satisfy both the written description and the enablement requirement. We would hope it is. Yet, such a disclosure can be sufficient to allow others to design around your claims but insufficient to support you, the patentee, or the applicant, support you sufficiently in getting your own things that cover such designed around alternatives.</p> <p>In other words, the patent disclosure may allow others to derive a substantial benefit from the invention that you've disclosed but that you cannot cover by your claims. So that as a patentee, you may be forced to disclose more than you have a right to claim. Now, many would say that's just life, you know—it's part of the basic patent deal that you strike as a patentee with society. You disclose, you get a limited monopoly in return, and society gets a good deal because you always disclose a little more than you have a right to claim.</p> <p>Of course, some patentees try to get a good deal, too. So, what sometimes happens in claim drafting? There's pressure on claim drafting in the sense that you would try and dominate future developments and inventions that rely on your own earlier inventions with your claim language. Your claims may try to reach through to future developments that were never contemplated, that you couldn't have known, nor could anyone have at the time you got your patent application.</p> <p>The way to do that is to try and use functional claim limitations. Again, such functional limitations are based on the assumption that compounds with a common function will share a common structure and vice versa. The risk of such reach-through claims that use functional language and biotechnology and that the chemical arts have, however, is that they will cover and are, in fact, designed to cover alternative designs that were never contemplated, or that could not have been known, and that such claims can dominate the whole developing technology field, creating a disincentive for other innovative businesses in your field for developing improvements.</p> <p>The written description and enablement requirements are not the only</p>
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limitations that our applicants encounter, of course, when trying to seek a broader scope of protection for inventions in biotechnology and elsewhere. In the United States, the Doctrine of Equivalence has undergone significant constriction, if you will, over the past years. Claim construction, if the case ever goes to litigation, can have surprises, where applicants, to their astonishment, will find that things that they sent to the examiner, explanations they provided during patent prosecution give rise to a clear and unambiguous disavowal and claim scope, or one that you never intended or were never aware that you made, so that you find yourself with a claim that has a much narrower scope than the scope under which it was examined because, after all, the patent office uses the broadest reasonable construction.

Judges may see it differently; so do your adversaries. Remedies for infringement, in light of very recent legislative developments in the United States, may very well not be what they are today and I'll jump to that towards the end of my talk.

Briefly let me give you just one or two examples—one maybe from the written description here and how that works. So picture this: Your disclosure teaches a cDNA and encoding protein X, and you also teach two complimentary sequences that hybridize to that, but your claim is directed *generally* to all nucleic acid molecules that hybridize to that cDNA that you described. Can you claim all, even though you've disclosed only two? Is that sufficient to show a person skilled in the art that you have possession of that invention at the time you filed? I don't know.

In practice, the way it works is that such functional claim limitations which are aimed at covering variances of the disclosed structures can meet the written description requirement, but such functional claim limitations must be known to be sufficiently correlated to a particular known structure. This is one application of what's become known as the Lilly Doctrine under U.S. patent law, which is perhaps the most mysterious doctrine under U.S. patent law and one that I'm not particularly comfortable with. I don't know anybody who really is.

But, if you want to use functional claim language to create such reach-through claims and put a number around your invention in biotech, it's going to be the known correlation to a known structure that you've disclosed that's going to save your bacon at the end of the day. It works the same way for all technology fields. Of course, if you are in an unpredictable art like biotechnology, often you don't really have the same reliable correlations that you can apply to known structures that you've disclosed, so, without the written description requirement it is a lot harder in practice if you are from the biotech sector. The outcome is that often you find yourself enabling a lot more than you're able to describe sufficiently to support a broad claim scope.

Finally—and I'm skipping over the enablement requirement—

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"Reasonable Royalty Damages." The base remedy, monetary remedy for patent infringement in the United States by statute is the reasonable royalty. Today, when all is said and done and an infringement has been found, or if you violate patent, judges go and juries, too, into a very fact-intensive inquiry. They use a lot of factors because patent infringement is commercially complex. It's a specialty art, and judges can consider amongst many other factors 15 factors that are laid out in the landmark *Georgia-Pacific* case and others.

Judges can also base damages on the value of the entire infringing product (even if the claimed invention is only a component of the infringing product) if your invention—the piece that's built into the larger product—is "functionally related" to the rest of the product, and forms the "basis for its market demand." Judges can also award damages for derivative or convoyed sales—things that are sold together with the infringing product whose sales are driven by the infringing product.

So there's a lot going on when you get to the damages stage of a patent infringement trial in the United States. It's a very flexible inquiry today, and it might not be tomorrow. Five weeks ago or maybe six, when we saw the current Patent Reform Bill introduced in Congress in both houses, what we saw was entirely new language that would mandate a new way for calculating monetary damages in patent infringement litigation. Infringement damages in the future—according to the bill that's being discussed in the House today, and this is perhaps the central issue in patent reform today in the United States and the legislative debate—would be based on the patent's specific contribution over the prior art, and that is not the invention as it's claimed; it's something else. Judges would also be required to subtract from the infringing product and from the claim the value attributable to prior art and other features that add value to the infringing product.

So when we saw this language and I started to talk to my colleagues, the first reaction was something like what?—what does that mean? I have no idea. I still don't. However, as you look at this, one thing is fairly clear. What is being determined is a royalty base and there's a lot of subtraction going on. We believe the way it's going to work is that judges who are required to base the royalty and patent damages on the patent's specific contribution over the prior art will take the patent claim, they will look at what's in the claim and subtract from the claim all things that existed independently in the prior art, whether or not they ever existed in the claim configuration, and they will subtract from the infringing product all things that independently existed in the prior art.

In the end, they will apply what's left of the claim to what's left of the product, and they will calculate residual royalties, which will be much inferior and much lower than the reasonable royalties that are required under existing law. The net effect, other than just being very difficult to implement, is that infringement will become cheaper. We

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	<p>think infringement will become just another business decision. And, in the end, if infringement becomes cheaper, commercial licensing will become cheaper as well. After all, who, when thinking about taking out a license to a patent, will not ask themselves, "Will it just be cheaper to infringe?" If you make infringement cheaper, of course, they're not going to pay more for an up-front royalty with their normal commercial licensing transaction. I want to leave you with that.</p> <p>I thank you very much for your attention. Mike, you have the floor.</p>
KIRK	<p>Thank you, Hans. The topic of the ongoing Patent Law Reform in the United States could keep us here for several days. We are a little behind schedule, and I would like to open the floor, however, to one or two questions. Please repeat your name.</p>
UNIDENTIFIED SPEAKER	<p>I had a question for you in terms of these references that were found. Did you do anything to go back and find out why your searchers didn't find those references?</p>
JEWESS	<p>Are you referring to searchers within my own company, rather than the Patent Office searchers?</p>
UNIDENTIFIED SPEAKER	<p>Your own internal searchers. At least the English language ones—at least the ones that were found by the EPO or the US Patent Office.</p>
JEWESS	<p>Ideally, one does searches internally, as Marc Adler of the IPO urged yesterday. My company has no internal searching department at all—a situation that is probably becoming more common. However, our inventors know the prior art quite well, and our standard practice is to file patent applications with claims initially based on what the inventors know of the prior art so that it gets searched by the Patent Offices. This is not a particularly inefficient procedure, because, without claims, it is hard to do novelty searches, and the Patent Offices do have very good databases. The big pity is that the application procedure does not give us the results of searches performed with those databases as early as would be really helpful.</p> <p>The British Patent Office did look at the data on the six patent cases for which I presented results in my talk (we confidentially advised them of the application numbers) and was able to work out what its searchers had done wrong in those cases where other Offices had found more relevant prior art.</p>
KIRK	<p>Thank you. A question in the back?</p>
POWELL	<p>Thanks, Mike. Mark Powell from the USPTO.</p> <p>I just wanted to set the record straight. The United States fully supports the supplemental international search, and it's not really relevant as to whether a competent government employee or a competent government contractor carries out the search of the U.S.</p>

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	documentation. I just wanted to set that straight. Thank you.
KIRK	Thank you very much.
JEWESS	I'm very glad to hear that.
KIRK	Thank you very much. At this stage, I would like to ask the audience to show its appreciation for this panel so we can move on to our next panel.