

ASSOCIATION OF CORPORATE COUNSEL

TITLE: International Patent Prosecution – Best Practices and Updates on the Patent Prosecution Highway Program

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SPONSORED BY: Kilpatrick Stockton, LLP

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MODERATOR: John Hogan, Patent Counsel, Wyeth

Female: Welcome to this ACC Webcast. John Hogan, please go ahead.

John Hogan: Thank you. Hello. My name is John Hogan. I'm patent counsel in international group for Wyeth. I'll be your moderator today. This is the third Webinar of the IT committee, and I'd like to thank our IT committee sponsor, Kilpatrick Stockton, for their support.

Just a couple of housekeeping items first. If you have questions, you may type them into the chat box at any time during this presentation. We'll be taking questions at the end of the presentation, so certainly wait for the question-and-answer section.

Again, if you have technical issues, you can contact CommPartners directly or chat – or type it into the chat box and they'll respond.

With that, I'd like to introduce our two speakers. John McDonald is a partner at Kilpatrick Stockton. After 20 years in scientific research, John left Emory University School of Medicine to become a patent attorney. He is a partner in the intellectual property practice group and a member of the health and life sciences team. He assists clients in developing strategy for domestic and international patent protection in the biotechnical, pharmaceutical and chemical industries.

And our other speaker today will be Mr. Hazim Ansari who is the Director and Founder of Metrix Services. He graduated Magna Cum Laude from Loyola Law School of Los Angeles and received a B.S. in Chemical Engineering from Stanford University. And he's currently of counsel to the intellectual property department of Hennigan, Bennett & Dorman LLP.

John, you want to start?

John McDonald: Certainly. Thank you very much, John. Today's topic is strategic considerations in accelerating U.S. and foreign patent prosecution. And we would like to cover a few topics. The outline is generally presented here. We're going to be discussing new developments for accelerating U.S. and foreign patent prosecution and specifically mentioning a few items, the

patent prosecution highway program, a program that's been coming into existence for a few years and is now really picking up steam, some new developments and acceleration of U.S. applications, and then we'll say a few words about acceleration of exam outside the U.S., and, most importantly, we will look at all of that in terms of the impact on a global patent strategy for our company and why these things need to be carefully considered for a company as it plans its international patent strategy.

The patent prosecution highway, which will be abbreviated as PPH throughout this presentation, well, what is it? It's a new trial program with major implications for accelerating patent brands. And it is not enforced throughout all countries in the world but only a selective number of countries and organizations including the European patent office.

The goal of the patent prosecution highway is to try to address the tremendous backlog of patent applications, which is creating a log jam in the European patent office, the Japanese patent office, the U.S. patent office, and to try to decrease the amount of inefficiency in this system, especially with multiple searches and just multiple layers of examination, which renders the entire process quite costly and lengthy.

In a nutshell, in the first office in which you file, if you have a ruling from that office that at least one claim is allowable or patentable, you can then request accelerated exam in another country's patent office if that other country is part of the patent prosecution office – excuse me – that is related to that first country. So not all countries have this relationship, only a select few, and that's what we'll be talking about. And if there are more than one country that are all members of the PPH, then you can actually accelerate prosecution in several countries at the same time.

These are some of the countries which are participants. Between the U.S. and Japan, UK, Korea, Canada, Australia and the EPO, there are now relationships such that an allowance in any one of these jurisdictions can accelerate exam in the U.S., or an allowance in the U.S. could accelerate exam in these other countries.

Why is this important? In certain countries, such as Japan, you can wait, as many of you know three, four, five, maybe six years before you might get a definitive office action. Now that wait, after an allowance in the U.S., can be dramatically reduced, and we've experienced office actions coming down from the Japanese patent office, after once entering the PPH, in as little as 60 days, which is remarkable compared to five or six years.

The UK is particularly moving at a fast clip. And I just met with some European associates based in Nottingham from Potter Clarkson the other day, and they were telling me that they are getting allowances of some applications within seven to eight months after entering this program. Canada also has a tremendous backlog, and we're getting office actions now in part of the PPH within three or four months. So you can see that this program is really designed to accelerate things, and this will have a dramatic effect on the time to the first allowance in these different countries, of course, and it really speaks to the global harmonization that's occurring within the patent community.

There are cooperative agreements between other foreign countries, which are not all listed here, and Germany and Japan, for example, as well as the UK and Denmark and Korea have relationships with Japan. So there are a lot of different combinations which may be selected to really carefully, strategically decide how to accelerate your cases.

What's required to enter this program? Well, just using the U.S. in a Japanese case as an example, let's say there was an international application, a (PCT) application file, and from that there were Japanese and U.S. applications filed in the national stage. And if the Japanese application had a claim that was allowable and the U.S. case had not been examined yet, then an applicant can request entry into the patent prosecution highway. And that requires that the claims

in the pending U.S. application be amended to correspond very closely to the allowable claims in Japan.

Now this is not something that is you know devoid of problems. For example, there are certain things which are not patentable in certain jurisdictions. For example, methods of treatment claims, which are patentable in the U.S., are notorious for not be patentable subject matter in some other locations such as Japan and in the European patent office. And so there may be need to change claim format into medical use type claims, Swiss style type claims or pharmaceutical compositions with an intended use type claim. And our foreign associates well know which claim format might work, but it's something to keep in mind when you've got some subject matter which might not be patentable in another country. You may not want to use this patent prosecution highway because the claim formatting that will be required might be difficult to push through to an allowance.

So how does one do this? Well, an applicant files a request to enter the patent prosecution highway and a petition to make special in the U.S. You've got to give up all the Japanese office actions and all the art sided in Japan in addition to filing your own information disclosure statement like usual that would contain any art that might be patentable to the subject matter of a pending claim.

So once the request is filed, then the application can be fast-tracked in the U.S. or in other countries that have cooperative relationships. And this fast-tracking can speed things up dramatically.

This decreases the time to an allowance or an issuance in the U.S., but it's not guaranteed. Let's say the U.S. examiner does his or her own new search and comes up with new art – you still have to battle through that. But the fact that that case is going to get picked up within a few months instead of a few years in the U.S. is critical because it might have a tremendous impact on the time to reach exclusivity and the ability to basically exclude others from making, using or practicing your invention in the U.S. And, if your invention happens to be a time-sensitive technology, that could be critical because if you wait three to four years to get through the U.S. office or the Japanese office, perhaps even longer, your technology might not be worth the patent it's printed on by that point in time. So you have to very carefully consider the business interests of the company and whether it's really worth it to go down this path.

You can decrease the time to issuance, as I said, and you can possibly cut the cost of prosecuting an application in different countries by trying to reduce the numbers of office actions for example. But chances are you're going to have to have claims that are much narrower in scope than the kinds of broad claims you might fight for years, back and forth with a patent office, to obtain. The downside is you're going to incur a lot of these costs much earlier.

But let's now turn toward an example. Here, on this slide, you can see a scenario in which a provisional application is filed followed by a (PCT) application and then national phase in a variety of countries, all members of the PPH, by the way, Australia, U.S., Canada, Japan, South Korea. Now, in this particular slide, Australia has issued and South Korea has issued. What can we do here? Well this would be a situation where the Australian case could then be used to try to enter the U.S. because the U.S. has not yet been picked up for examination. And the Australian cases, many of which will accept you know claims to compositions of matter, methods of use, you know very broad claims, those claims could then be conformed to U.S. practice and filed with a request to accelerate. So, after that Australian issuance, you could go into the U.S. and try to accelerate. And once the allowance in the U.S. comes along, you could go to Canada and try to further accelerate in Canada, which typically has a very long lag.

Now in Japan you could not do that because the first office action had already occurred. So the cases can't have been picked up for exam at the time that you enter the patent prosecution highway.

So if we take a few minutes to talk about the pros and cons, let's talk about the advantages of traveling the patent prosecution highway. As I mentioned, it accelerates the time to the first office action by the patent office, a savings of many years in some cases. It will increase the speed to obtain the first patent, provided your application – your claims are patentable, of course. It enhances the ability to then quickly reduce or eliminate competition in certain jurisdictions, and that could be very important depending on where your competitors are located, where their manufacturing is, where your markets are, and all of that, of course, would be a very important business consideration.

It can increase the licensing value of your inventions of course. As soon as you have an allowance or an issued patent, you're going to be able to obtain a higher fee for the licensing rights. Choice of jurisdiction, you have to carefully consider what's the best jurisdiction for the types of claims you want to pursue. And maybe you should enter that one first in terms of accelerating exam.

In other points, well, the perceived value of a company, its stock for example could go way up if you had very important patents issuing and in the pipeline. And your ability to attract investment, which could be very critical especially in view of the events of the last few days, could be enhanced with the allowance of important claims.

But, as I said, we have to be careful a little bit because some jurisdictions have different rules, method of treatment claims are not patentable everywhere, and business method patents are not patentable everywhere. So you have to carefully look at this with your patent counsel and coordinate strategy with the foreign associates as well.

What are some of the cons of traveling the PPH? Well, you definitely are going to incur significant costs up front. Why is that? Well, you're requesting exam earlier. You're going to have the U.S. attorney fees for doing that, the foreign associate fees for doing that, the filing fees themselves, and all the back and forth between the U.S. and foreign counsel in getting the claims in the right kind of shape for that jurisdiction and getting all the documents in proper order.

You also limit the claim scope in the office of first examination you know. That's the extent of claim scope, but you can then try for an allowance in another jurisdiction, see, going from Japan into the U.S. or vice-versa. You're not going to be able to suddenly start with broad claims as you might normally be expecting to do so.

So, in order to travel the highway effectively, you've got to accept the fact that your claim scope might be a little bit narrower. However, that could be very critical for a company if a company had, for example, a blockbuster compound, a lead pharmaceutical or a critical chemical or manufacturing method. If that company were willing to accept that claim scope, then they can move forward at a very rapid pace with that.

And if you accelerate exam in the U.S., which I've done a few times, you also incur a lot of fees up front. There are specific requirements we'll be talking about in a minute for accelerating exam in the U.S. such as conducting searches of the prior art, characterizing the searches on the written record, filing examination support documents that contain those statements, and so there are attorneys fees, search fees, and you've got to pay a lot more on the front end to try to accelerate the case in the U.S. before you really get moving. But hopefully you'll decrease the numbers of rounds of office actions back and forth and the requests for continued exams and appeals, et cetera. Hopefully it'll be faster and cheaper in the long run.

And another negative of traveling the PPH is that if you're not successful, you're going to need to file continuations or divisionals with different claim scope. And in the EPO for example, if you do have to file divisionals, that could be quite expensive.

Another potential negative is that you're going to be revealing prior art earlier to the competitors that watch your patent applications, either from your own search or from the searches conducted by foreign patent offices. So if the Japanese patent office picks up a piece of prior art, that could have quite a negative effective on your portfolio. While in one sense you're going to learn about it earlier, and that's not all bad, but, if it's a really tough piece of prior art, not only are you going to learn about it but you're going to have to reveal it to the U.S. patent office. And so there are pros and cons. Also such art could be used in an opposition for seating even after the allowance of the European application.

And, finally, examination support documents in the U.S. through the acceleration practice can be quite tricky because the statements that attorneys use to characterize prior art could be the fodder for litigation later on in trying to oppose the validity of that patent.

So a company might not want to travel the highway, especially if it needed lots of time for – lots of money and time for research and development. So you wouldn't want to necessarily go down the PPH highway if you had a very, say, marginally enabled invention that was extremely theoretical with very little data because then you might be skating on thin ice. And, if you ran into a very difficult enablement rejection, it might be hard to overcome that, and you'd be creating a record that could be viewed and might influence its prosecution – the prosecution of that application in other jurisdictions.

A lot of startup companies need more money to pursue these kinds of things, and the typical paradigm in the past for – well, especially biotech companies, was to delay prosecution costs and push things out in time until the last possible minute you would need to move forward as that company developed its you know lead drugs for example.

And, if you are successful with the PPH let's say in Europe, and you've moved faster, well, success could be difficult in the sense that suddenly you're going to be hit with grant and translation fees and you're going to incur earlier regional phase entry into the different countries within the EPO, and that could certainly cost quite a bit of money, 50 to \$100,000 depending on a number of countries. And so those are some of the considerations for not traveling the PPH.

And, Hazim, I think the next few slides are yours.

Hazim Ansari: Thanks, John. I – John requested that I talk a little bit about the patent prosecution highway from the standpoint of, frankly, some of the companies that I have – I have represented and continue to represent.

And so I want to discuss it really from the vantage point of where, historically, the patent prosecution highway has not been a good idea. And the reason why I approach it in that fashion is that, generally speaking, accelerated examination and leveraging success in an existing patent office is, as a default basis, a good idea. And so I usually begin at that point saying, "Look, I need to find a reason not to do it." And the reasons not to do it tend to be much more focused on business strategy and where the company is in development rather than any purely patent or legal basis. And let me describe a few of those considerations.

One reason not to do it is when you're working with a young company, particularly a – at least in the case of myself and John, a biotechnology company that, perhaps, did a reverse merger and is public, depends a lot on public sentiment and perception, but doesn't necessarily have the mature operations in R&D yet, perception is extremely important for that type of company. And the possibility of getting a broad patent coverage is actually more important than getting patent coverage at any cost. More specifically, there are certainly clients and cases that both John and I have worked on in which it was much more important to hold out for broad coverage than to achieve patent coverage, actual patent coverage, across many jurisdictions in a relatively short period of time.

And it's very important, I think, for counsel to truly appreciate the financial impact that getting certain patents issued or not issued may actually have on the company and its ability to raise financing, particularly in this kind of market. Currently, I'm – for example, am dealing with two or three small biotechnology – actually three bio – small biotechnology companies that have pending applications that are actually not hoping – hoping for no office actions that will actually indicate the likelihood of claim coverage available to them. And the reason why is because, again, the ambiguity plays in their favor as opposed to having a very clear indication of what the patent office will and will not allow. So that's an example in which you know we tend to go against the default position of accelerating examination and getting issue patent unless, of course, the patent claim that you get is sufficiently broad.

But, as John mentioned – and at least in my personal experience – you tend not to get terribly broad claims relatively early on in prosecution that would allow you to actually go through and do this type of accelerated examination before first office actions and these other jurisdictions. It happens. And it's happened to us a few times, but generally you might take to actually get the broad claims a lot longer in fighting with the patent office.

Going to the next slide, the – this is another point that John raised, and I just sort of wanted to touch on it again. Another reason for going against the default of entering the patent prosecution highway is whether your company really understands exactly what its core products and services are and exactly what type of patent coverage we want to get. And, again, this tends to be the younger companies as opposed to the more mature companies. In younger companies, I promise you that in every single one I've ever dealt with there is a cycle, a cycle in which they think they're going to be making money in one way and then, over the course of frankly a relatively short period of time, they realize they're going to be making money in a completely different way. And in that transition process, in that cycling process, resources get wasted. Resources get expended. And then people discover, of course, that that's not where they should have put their money.

As John mentioned, the – one of the downsides of the patent prosecution highway is that you expend more money earlier. And, for young companies, that can be very dangerous actually because you are expending valuable resources pursuing patent claims that may, in fact, not end up being as important to the company as, for example, filing more patents in the United States covering different aspects of what they now realize is their business. So looking at the patent legal fee or patent prosecution fee world as a zero sum game, the issue is are you sufficiently clear on your client – on your company's business, and is the company sufficiently confident in its business plan to warrant making that kind of investment that quickly if – at the expense of other patents that could be filed in the United States or markets that they're sure they're going to be in and operating in a particular way?

Next slide, John. And this next slide is really – goes to that issue that I had just discussed which is how realistic are the clients or, for in house counsel, your own company's international plans.

I would like to add one additional point. John mentioned this with respect to accelerating examination in the United States. And I cannot over emphasize the legal ramifications of not presenting a – or presenting a search and essentially a set of search results to the patent office in a petition that is incomplete or that has any degree of perhaps hyperbole, exaggeration, a misreading of the patents, any mistakes whatsoever in that situation getting amplified because the patent office is directly relying upon you and your representations in a fairly in depth analysis of the search to examine and potentially issue a patent.

In litigation, as, again, John has touched on, courts tend to be very stringent and relatively strict about even the slightest misrepresentations, even if arguably unintentional, in these types of search documents and petitions. So I cannot emphasize enough that this is not just a search document that will go into the patent office files and is an administration matter. On the contrary, it will be and most likely be the center of litigation at some point in the future, and I've already

seen that, at least in two cases, where the statements of patent prosecutors were viewed to be, frankly, misrepresenting the art. And even though the art was before the examiner, the court did not take too kindly to those statements. And it skews the litigation thereon.

I think that's all my slides, John.

John McDonald: Say, Hazim, on that legal resource allocation point, if companies are operating under fixed budgets, do you think perhaps that there should be a very strategic meeting between the business people and the IP people the year before the next budget is submitted because, once the patent prosecution highway is entered, it seems like things are going to take off pretty fast?

Hazim Ansari: I completely agree with that. I think the hardest thing – well, first of all, that meeting has to occur. But the hardest thing you have to do as counsel is to actually be a skeptic. And that I found to be politically and diplomatically the most difficult thing in the world because what ends up happening is the decisions of other people drive your allocation of resources. But, when those allocations of resources get questioned, unfortunately the decisions of others may not come to light and be used as a reason for why you did it.

So being a skeptic is probably the hardest thing to do when your VP of Business Development and your product guy are saying that you're going to be knocking in and breaking through a market within 18 months. So...

John McDonald: All right, thank you. Well now turning a little bit toward acceleration of exam in the U.S., which is something that can occur on its own, completely aside from the patent prosecution highway or ...

Male: I'm sorry John ...

John McDonald: ... in conjunction with it, I'd like to say a few words about acceleration in the U.S. before moving on to Europe. And then try to wrap up with showing how a lot of these different things we've talked about today can interact and affect the global strategy.

Male: John, I just wanted to raise a quick point. I wasn't sure if you saw that the – there were a bunch of chat questions being posed, and when you wanted to address those, but I just wanted to draw your attention to it.

John McDonald: OK, thank you. I believe we'll be addressing them, John Hogan, at the end right?

Male: OK.

John McDonald: The U.S. acceleration of examination, this is something that is different from the old petition to make special, which used to be used for specific circumstances whether its an aged inventor, bioterrorism, environmental concerns, biotechnology. This new program allows a decision on patentability within 12 months. The thought is that within 12 months you're going to either have a final office action where things are not looking so great or you're going to have a notice of allowance.

And it was created to try to cut down on the very long pendency of applications that can pretty much wipe out the commercial viability of the patent. You know software applications or business methods, some of those you don't want pending for five years. Software will be extinct. If you've got a blockbuster drug, you might want to push that through pretty quickly. Faster to market exclusivity, and you'll be able to block others from making, using or selling that drug. So you might be willing to accept a narrower claim to cover your lead compound.

So this accelerated exam program allows earlier interactions with examiners by focusing on the specific issues and claims under consideration. But there are some pretty stringent requirements

for entering accelerated exam. You've got to file a petition that has a lot of different elements to it. You've got to conduct your own patentability search, which must address the independent claim and the dependent claims. So that search must be found to be adequate for claim coverage as well as covering adequate databases in the U.S. and internationally.

You have to characterize the search results. We've mentioned this before. And Hazim made the very important point about the potential danger in litigation. You've got to make statements about how the claims are patentable over the prior art and address the claim elements that the prior art is most close to. And that can be a very difficult tightrope to walk because that document it will be public and can be used in litigation at a later time.

You've got to have limited claims, no more than 20, no more than three independent. And you file all of this electronically.

Again, in terms of cost considerations, you're incurring a lot on the front end. You're doing a search, so you've got your search costs. You've got the legal fees in characterizing that search, and you're running a risk on later charges of perhaps inequitable conduct if you mischaracterize references. It could be an attack toward validity.

I mentioned about the number of claims. In terms of speed, I said within 12 months you're going to have a lot of resolution, favorable or not. But the cases I've currently got pending under this program we've been able to come to a first office action within three months now of filing the request and having it accepted. I do recommend that you have co-pending applications that have broader claims scope in case your current application with narrower claim scope runs into some roadblocks. And, in fact, you have to agree to restrict your claims and to elect specific species very quickly, and you cannot fight that.

So going into accelerated exam, you're giving up your ability to get broad claims. You're going for narrow claims. And, again, if that makes business sense to a company, if they really know its business, as Hazim said, and they are willing to accept a limited claim, say a blockbuster drug, then it might be worth it. But if you can get an acceleration and get an allowance within 12 months, then you've got some real success.

Now, in the EPO, the PACE program has existed for quite some time. And here you don't have the same burdens as you do in the U.S. The foreign associate, the European attorney fills out a form, pays another 150 or 200 Euros – I don't know how much it is at the moment – and then the EPO, the European patent office, will pick that up and get you an exam pretty quickly. Downside, you can't sit around. You've got to reply quickly when there's an office action or you forfeit the special status and you go back in the queue of all the other applications.

Now I understand from my friends in Europe that this program is so heavily subscribed that it's almost losing meaning now in the same way that the old petitions to make special were sometimes just outrightly ignored in the U.S. patent office.

But the accelerated exam in the U.S. is a different animal now than the petitions to make special, and there's no downside in at least applying for the rapid exam through PACE in Europe.

Now, if you're successful in moving the case through in Europe, you are going to incur costs earlier, once again, your foreign associate costs, response to office actions, maybe even oral proceedings at an earlier point in time in the European patent office to resolve issues over the prior art. But then again, that might be worthwhile to get that allowance. If you get the allowance, as I mentioned earlier, then you're going to have other fees for registration in individual countries, translation, et cetera. So, again, it has to be thought through, the global strategy, and especially if you're going to move things fast in Europe.

So overall, in terms of business, is it important to accelerate and coordinate a global strategy? Well, I think it goes without saying that it's important to consider that and to consider the ramifications of acceleration, especially on a country-by-country basis, the fact that it's going to cost more money, and you've got to budget for that as well. You've got to know your business, as Hazim said, in order to really take full advantage of this. You've got to think about the claim coverage you're willing to accept and the importance of the invention in certain markets. Where are your competitors? Where are the sales? Where is the manufacturing? And where are the big markets?

And, finally, to really coordinate your strategy and take advantage of different options such as accelerated exam in the U.S., in Europe, elsewhere – there are accelerated exam programs in Japan and other countries as well. In order to really do that effectively, you've got to think of the global picture here. You've got to have good ties with your foreign associates and know them well. We believe in really working closely with our associates and visiting them because, when you've got to pick up that phone late at night and if they're going to respond to you, then you're going to be a lot better off than someone who responds to you a week later. Speed and communication and responsiveness are just critical if you're accelerating exam.

I thought it might be useful to look at a couple examples here at the end of the talk on coordination of global strategy. So, on this slide, we can see another case where we've got our provisional, a (PCT) application and several national phase applications that have been filed and are pending, none of which has been examined. Then, in the U.S., let's say we accelerate exam, and we've got a narrow claim scope, and then we are also filing a broader U.S. case. Or we could have the broad case filed first and then a narrower U.S. case filed with accelerated exam meeting all the requirements that we've already talked about, narrower claims, et cetera.

Well let's say that U.S. case issues or even we get a notice of allowance, what can we do with that? Well, as we've talked about, we can then accelerate, or we could accelerate in Europe. But once we have that U.S. case allowed, we can then move things along faster in any of these other jurisdictions, Australia, Canada, Europe, Japan or South Korea where it has not been picked up for examination yet, we could do all of them or selectively do them.

Let's say in Europe you've accelerated with PACE and you have a positive result. You could then move things along in other countries if examination has not yet been picked up.

So, by accelerating exam in the U.S. perhaps and in Europe and having an issuance, you could then access the other countries that are part of this program and the special relationships they have with each other in order to move things faster in other jurisdictions.

And so, knowing the Web, knowing the interconnections of these different countries and their relationships is critical in order to develop a strategy that's going to get you to allowed claims as fast as you desire. What is the impact on your business? Faster to the ability to exclude others from the market. You will be able to charge a higher premium. You're going to cut down on competition in selected jurisdictions, enhance licensing value and add value to the company.

So all of these things need to be considered before you enter prosecution highway or accelerate exam. And, most importantly, will it serve your business needs? And so in house counsel needs to work closely with either in house patent counsel or out house patent counsel and their foreign associates and know that those relationships are solid to really maximize the potential of this program.

And, John Hogan, that's all I've got right now. Hazim, do you have anything else you would like to add?

Hazim Ansari: No, I do not John.

John Hogan: Yes, we do have a few questions. So the first one is, “Could a U.S. application using the patent prosecution highway in Japan rely on a patent prosecution highway allowance in Japan to accelerate examination in, for example, Denmark or Germany?”

John McDonald: I believe that Germany and Japan have now established that relationship if I’m not mistaken, although I’m not sure if it’s completely formalized as of yet. Denmark – let’s see, I’m trying to find out about Denmark. I think Denmark was on the board for one of those special relationships as well with Japan because Japan has relations with Korea, the UK, Germany, the U.S. – yes – and Denmark. So that could be done.

John Hogan: Thank you. The – another question is, “Can you enter the U.S. and Canada simultaneously in the scenario that you had outlined on page 10?” And that was the case where you had gotten an Australian allowance or an issue patent, and then you were going to enter the U.S. Could you enter the U.S. and Canada simultaneously?”

John McDonald: I think Australia – unless things have changed – only has the relation with the U.S. now. I don’t know if there’s one between Canada and Australia. Things are moving so fast, frankly, I’m going to need a chart to keep up with it. But I’m not sure that that is set up between Australia and Canada yet.

John Hogan: OK. But, as you said, before you could enter the U.S., and then once you have your U.S. you could go through Canada because the U.S. and Canada have ...

John McDonald: Yes.

John Hogan: Can you speak to the claim scope in view of differing approaches to claim construction and the use or non-use of file histories among the countries? I think you touched on claim scope a little.

John McDonald: Yes. Claim scope, in your first office to give you a patent, that will then determine your claim scope if you’re going to use that to go into other countries through the patent prosecution highway.

In terms of accessing file histories, you’ve got to give up, when you go into these different countries, if they have a requirement for it, all relevant art except, in some jurisdictions, you don’t have the duty of disclosure except for what was revealed in the U.S. So, for example, in Japan, you’ve got to give up all the U.S. office actions and side art. In terms of file histories, the back and forth between the applicant and the patent office is given up, and a lot of that is publicly accessible now. So it seems like that can be viewed. Hazim, do you have any thoughts on that?

Hazim Ansari: Yes. I think the issue is you know how exactly do you define the claim scope coming out of Japan given the fact that their approach to defining the construction claims is different in some regards than the United States. And what it really comes down to is, frankly, well the same issue you always have with foreign applications and the United States construction translation of that. And that is what would a fair reading and translation of the claim and a fair understanding of what the Japanese examiner was attempting to do in creating whatever restrictions were required, what would be a fair reading of that by one of ordinary skill in the art in the United States? So you know as a fair measure, if I were doing a search report in the United States and I were relying on actions that occurred in Japan, I would be translating what the Japanese examiner has said with respect to particular pieces of art and presenting that, as well, without embellishment.

John Hogan: Thanks. Can you provide a U.S. published application and/or patent in which you successfully used the patent prosecution highway or accelerated examination? So I guess they’re not asking for any confidential information, but ...

John McDonald: Well, I think in a few months I could, but at the moment I cannot.

John Hogan: OK. There's another question about whether two different options are being discussed. Can you use allowance issuance in one country to get expedited exam in the U.S.? And, second, can you simply request expedited U.S. exam with your own search and analysis without an allowance or an issuance in another country?

That's correct. You can do both. There are two options. And, if the two countries in the first part of the question are part of the patent prosecution highway and have that relationship with each other, you can use an allowance or issuance in Japan for example to get – to enter the patent prosecution highway in the U.S., which does speed examination. Apart from that completely, you could simply request expedited exam in the U.S. with your own search and analysis. And you could also request expedited exam in other countries. They have their own program. So they are separate, but, as we've tried to make the point in this presentation, if you're successful in one place with expedited exam and the patent prosecution highway relationships exist, then you can use that to move even faster.

John Hogan: A slight variation on that, someone is requesting, "Can you expedite exam in the U.S. only for national U.S. filings, or can you also do it for the national phase of a (PCT) application in the U.S.?"

John McDonald: You could do both. You could do either one. And realize that once you did the national phase you'd have to meet certain requirements to accelerate exam in the U.S. And that would have to be an electronic filing. So you might do it as a continuation off the national phase filing in the U.S. from the (PCT), take that continuation, do your search, narrower claims, e-file the whole thing with your examination support document and keep the parent case pending with broader claims.

John Hogan: How does one match claim scope versus merely claim language when countries will construe the same language claims differently? Will differing language prompt a rejection despite the patent prosecution highway?

John McDonald: That can definitely occur, especially with some of the differences in language and translation that I've experienced between Asia and the U.S. And words have to be very carefully defined in the specifications and in the claims. And, yes, sometimes you can run into trouble with that kind of situation.

John Hogan: And both Canada and Japan had their own systems for accelerating examination. Have you done a study of the pros and cons of the patent prosecution highway versus a national system of acceleration?

John McDonald: I certainly have not because this is so new. Much of this has just come into effect within the last 12 months in terms of the PPH, and so it is difficult to know if there's even adequate data to mine to determine you know the relative effectiveness of one thing over the other.

Hazim Ansari: Yes, I have not done a study either.

John Hogan: Well, I think we're just about out of time. So I thank everyone for – I thank, first of all, the presenters for their presentation and the listeners for their questions. I would ask that everyone fill out the Webcast evaluation. You'll see a link on the – in the box that's on the screen. That's very helpful to us as we go forward. And I appreciate your attention. Thank you.

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