Please stand by for real-time captions.

Moderator: Thank you for joining the NCATS Presents: Essential IP Advice for Small Business Commercialization. The webinar will begin momentarily. My name is Monique LaRocque and I want to go through some housekeeping items. We would like the webinar to be interactive and we know you may have many questions. At the end of the presentation, we will have a Q&A period to respond to your questions. However, you can chat us your questions throughout the entire webinar. To do that, use your chat window on the right or on the bottom. We will review the questions at the end of the session. We are offering closed-captioned today. You can get technical support as well. At the conclusion of the webinar, we hope you will provide us input and we will be chatting out the link. Please take a few moments to give us your feedback. With that said, I want to welcome you again to the webinar, Essential IP Advice for Small Business Commercialization, featuring our partner USPTO, on patent application and the examination process. We invite you to join the conversation on Twitter as well as to use our hashtag #NCATSsbir. With that, I want to introduce our featured speakers. Today we have Lili Portilla, the Director of Strategic Alliances from the Office of Strategic Alliances from NCATS NIH. We will also hear from Dr. Ram Shukla. He is the supervisory patent examiner at the USPTO. With that, I want to thank Dr. Shukla and the USPTO for joining us on the webinar today.

During our presentation, you will be learning a little bit more about NCATS SBIR/STTR and other small business resources to foster innovation and technology development. We will talk to how to protect your IP for small business owners and the role that USPTO plays and other resources that you should know about. With that, I will turn it over to my colleague, Lili Portilla from NCATS.

Lili Portilla: Thanks Monique. I appreciate everyone tuning in and listening to this webinar. I want to thank Ram Shukla from USPTO for participating and sharing information to our community. Very quickly, I wanted to give a brief overview of the NCATS SBIR/STTR program. The NIH SBIR/STTR program has several ways that individuals can apply to the program. The primary way that academic entrepreneurs as well as small businesses can participate is via the Omnibus Solicitation. It has standard deadlines of April 5, which is coming up, and September 5th and January 5th of every year. Those dates are pretty standard deadlines. On the NIH website and on the NCATS website, we have targeted grant solicitations, where we have listed or are participating in solicitations that that are of research interest to the organization. Due dates there may vary as well. Once a year, usually in the summertime, we release our contract solicitation and applications for that solicitation for small businesses to participate are typically due in the October-November timeframe.

The NIH SBIR/STTR program is one of the largest sources of early-stage financing for small businesses in the life science arena. This past year, the SBIR/STTR budget for the NIH was over $1 million, that is money that is set aside specifically for this program. We are not able to reprogram it for other initiatives. This is a program that has great bipartisan support in Congress, and it is a significant amount of money that is set aside for small businesses here at the NIH.

The benefits of the program are many, but we see it as a stable and predictable source of funding. As you can see the SBIR/STTR budget is tied to the NIH overall budget and it is not a loan and funds do not have to be repaid. It is not dilutive. All the IP rights that are developed under the grant and contracts are owned and retained by the small business. If you are able to get one of our SBIR/STTR awards, you are also eligible to participate in other technical assistance programs that the NIH has to help small businesses and training opportunities as well. And I think one of the other main benefits of the program is that our projects undergo a rigorous scientific peer review process. Many of our awardees are able to leverage that peer review in order to attract more funding and strategic partnerships for their companies.

Here we outline what the funding eligibility requirements are for SBIR and STTR. These requirements are set by the Small Business Administration, not the NIH. All federal agencies that participate in SBIR/STTR are all following these eligibility guidelines. A small businesses is considered one that has 500 or fewer employees. For a SBIR, the PI’s primary employment has to be with the small business. More than 50 percent of the company can be owned by individuals or independently operated. Or more than 50 percent can be owned and controlled by other business concerns. And you can also, if your small business has ownership by multiple VC or operating companies or hedge funds or private equity firms, you may be eligible also to participate in applying to the program. STTR is a little bit different. STTR requires that there be a research organization as a collaborator under the grant and here the PI can either be an employee of the research institution or an employee of the small business. If you are using intellectual property that belongs to the university and you need it in order for the company to have the freedom to operate with the intellectual property, we do require that there be some kind of IP agreement that at the time of award we would have to make sure it is in place that demonstrates that you have the ability to use that intellectual property, that may be owned by the research institution.

The SBIR/STTR program is a three-phase program. Not to be confused with clinical phases. Phase I is typically feasibility studies and those are budget guidelines for NIH around $225,000. It's always important to look at the specific funding announcement to see what the budget guidelines are there and to talk to respective Institutes that you are applying to, to see what the budget guidelines are, also. Some topics that NCATS has identified, we do allow applicants to go past these budget caps that NIH has, and you can go up to $325,000 for a Phase I and up to $2 million for a Phase II grant, which is typically more R&D that is going on. The project periods for a Phase I can last anywhere between six months to a year. For Phase II, it can be anywhere between two and three years. We also participate in what is called the Fast Track where you can apply for Phase I and the Phase II grant at the same time. And the Direct to Phase II is a program that we have here at the NIH, that if you have enough data, and you have feasibility data you would have gotten under Phase I and you have that data already, you can skip that Phase I and go directly to a Phase II. Some Institutes participate in Phase IIB Competing Renewal/R&D program. NCATS does. Our caveat is we must have funded your Phase II grant. All Institutes have different rules around this, and it is good to check with individual institutes that you are applying to. Phase III is what we categorize as the commercialization phase and you are pretty much graduating from the program. Keep in mind that NIH generally is not the customer of whatever you are developing. At Phase III, we are hoping the company is trying to figure out other strategic partnerships and other ways to leverage funding that they received through the grant through other private sources.

I will not go individually through these. But in the slide deck are some of the current funding opportunities that are open. The Omnibus Solicitation is the way that most of the grants come into the NIH. It lists all the research interests of all the participating 24 Institutes here at the NIH, as well as our sister agencies that participate, the CDC and FDA. There are other specialized and specific funding announcements here that you are also eligible, based on the topic that you may be interested in applying to as well.

In closing, if you are interested in learning more about what NCATS funds, we encourage you to go to the NCATS small business webpage to learn about our funding opportunities and research priorities under the program. You can also check out our FAQs and funding solicitations that are open. If you have any questions, you can contact us via our email box that is listed here. We are happy to talk to you about any ideas you have about applying to the program. If you are not a good fit for NCATS, we’re going to send you to the right Institute and refer you to one of our colleagues at one of the other Institutes here at NIH. I believe that completes my brief overview of the NCATS program. With that, I would like to hand over the presentation to Ram Shukla from USPTO. We are very excited about this opportunity for Ram to talk about some resources that the USPTO has for small businesses. And be looking in the future for other helpful webinars that NCATS will be organizing in this arena. So, with that, I will hand it over to Ram. Thank you.

Ram Shukla: Thank you, Lili, for the introduction and for the opportunity. I am a supervisory patent examiner at the U.S. Patent and Trademark office. Let's get started because I have a lot of material to cover.

The presentation has three parts. The first part, we will do an overview of intellectual property. In the second part, we are going to talk about patent process, patent application and how examination is done. And then finally, we will talk about some of the tools and resources that USPTO has got for inventors on its website and also in person.

USPTO has got headquarters in Alexandria and we also have got these regional offices in different parts of the country. Now, America Invents Act was signed in 2011 by President Obama. When this AIA, we call it, was signed, one of the requirements for the office was to open regional offices. The reason why the headquarters is in Alexandria and inventors and businesses being all over the country, if someone needed information or help, they had to travel to Alexandria. That is why these regional offices were opened. These regional offices are like mini-sized offices of the headquarters which they will have all the same facilities as the headquarters have.

Headquarters are in Old Town, Alexandria. And basically, it is the main campus which houses the administrative offices and it also has got a public search facility where inventors can come and search our patent databases and they can use the same tools as the examiners use. These tools are also available in all the regional offices. They also have small research facilities and there are also examiner interview rooms, where you can come and interview examiners. Sometimes if you have an exam and you are working in a different part of the country, you can come to either the headquarters or one of the regional offices and you can connect with the examiner through video and you are able to discuss your case with the examiner. We also have a hearing room for the board, what we call P tab. We also have some public meeting spaces where you can come and use this space for IP-related meetings. So those are some of the facilities available to inventors and everyone.

Just to give you an overview of the office. We have about 12,000+ employees. Of those, we have got about 8,200 patent examiners. Now these numbers are from 2018, so the numbers may have changed a little bit. We also have 549 trademark attorneys and we have 383 judges and then we have got the Trademark Board where we have 73 judges. In 2018, we had 643 plus applications filed and we had 338,000 patents issued. On the trademark side we had 468,000+, almost 469,000 applications filed and 273,000 plus certificates of registration. These numbers, they change every year. Patent examiner numbers are kind of the same. We have almost 60 percent, 55 to 60 percent, the numbers may be plus or minus, examiners who work from home, we call the patent hoteling program; they telework from anywhere in the country. Similar programs are available in trademarks as well.

Let's talk about intellectual property. This is a brief one, our main focus will be on patents. There are three types of IP. One, patent, then the other one is copyright and we have trademark. Now, trade secret is another IP. There is a difference between trade secret and all others. Talking about the patents and IP in general, as the name says, the property of intellect, that is what is intellectual property. So, what can be patented? We have three types of patents. One is a utility patent, as the name indicates, utility means, it has use. Second one is design patent, which is a patent for the ornamental, just design, it has nothing to do with the function. Just the design of the article.

And you can also get a plant patent. Now, a plant patent could be two types. You could get a utility patent for a plant, too. The plant patent, we say it is for asexually produced plants. You can have recombinant plants, transgenic plants, and all those will be in the utility plant idea, and again the utility means use. Some of the examples you will see, for the utility patent, your iPhone, iPod and fertilizers and medicines, all of these are utility patents. They will be covered by utility patents. Sometimes you have transgenic mice which could be used for screening compounds, screening drugs. They would be for utility patent. Now for duration, you have 20 years from the date of filing for protection, that is what the protection is about. What happens when you file the patent application, sometimes it will take time to process, but your total number of years is 20 years from the date you filed your application. Design patent has 15 years and plant patent has 20 years from filing date. Copyright is another IP. Copyright is for books, art, images, films, videos. Again, you have all these different examples, like music, artwork and video. What is the protection? The life of the author plus 70 years. Some works are 95 years from publication and others 120 years from creation. For copyright, you really don't have to go and do anything. The moment you put on paper something you write, you have copyright. The idea of getting a copyright certificate is, that way if somebody has copied, you can go and sue that person and stop that person from copying your stuff.

Now we have trademarks. You get trademarks for words, symbols, logos, designs or slogans. The big thing about trademark is, that is how people know product. For example, a big one is Google. For coffee, you know if you buy coffee and somebody is not selling the coffee you want or what you thought it was, that is why the trademark is there, to get the protection. Same way if you see a bottle with Coca-Cola logo on it, you would expect that is what you get, not anything else.

Now trade secret is different. When I say different, questions comes, should I patent my invention—you know it’s a formula, for example, or should I get a trade secret? The idea if you patent it, you have to disclose what is in that formula, because the idea is that when you get a patent, others will see that and they can use it. So, you have to disclose how to make that and how to use it. If you want to have a trade secret, you cannot keep that secret [if you have a patent]. If you have to keep it secret, then you have [to pursue] a trade secret. There are protections where if you can show that somebody stole your trade secret, there is a process, you can go and sue that person. But if you cannot keep it a secret, you have to decide, what you want to do? Do you want to get a patent or keep it as a trade secret? As an example, Coca-Cola formula is something which people have tried. One thing about trade secrets is, if your product is out in the market, people will try to reverse engineer it. There is no protection against it.

What is the role of IP in the U.S. economy? Some numbers are here from 2016. As you can see, IP contributes usually to the U.S. economy. I’m not go through all these numbers. You will have a copy of the slides and you can look at it. They really impact the U.S. economy and the world economy. Now we have a global economy. So the question will come, again, when you have an IP in the U.S., because everything is global nowadays, you put something on the Internet, people will have it. What protection do you have? And how do you protect it?

Briefly talking about what is the role of the patent system. The first one is, it protects inventions. Well how does it protect? It gives the inventor an exclusive right for a certain period of time. That’s what the protection is. Remember that, you get exclusive right. You have to enforce your patent. It is not automatic. It encourages inventions. How does it encourage inventions? Well, when people see your patent, they may go and add to it, modify it, and do more research to make it better, or something new and promote commercialization and application of invention. When you have a patent, you can go and raise money and change it to a product. Finally, accelerate commercialization of invention to the whole society. The part being that people will have this new product you created and they will benefit from it and then more commercialization, they will buy and people will make money. That is part of the entirety of the patent system and how it helps.

Talking about the office, about the organization, USPTO is an agency under the Department of Commerce and the Under Secretary of Commerce is our boss, our head of the USPTO and under the Under Secretary, we also have a Deputy Secretary. The Deputy Secretary is also called Director of USPTO. Now the Director of USPTO advises the Secretary of Commerce on domestic and international IP issues. Under the Under Secretary's office we have two commissioners. One commissioner is for patent and the other commissioner is for trademarks. The patents operation is under the Commissioner for patents. The patents are divided into what we call Technology Centers. They deal with different technology. For example, I am from Technology Center 1600 which is Biotechnology and Organic Chemistry. The other Technology Centers which are listed here, they all examine different types of technologies. You have to think in the sense that if an application is filed at the office, somebody has to examine that. One of these technology centers it will be assigned to. It is based on a classification system. When I say classification system, it is not a classification in terms of classified information, but rather as you see in a library where the books are listed and by subject and all that. Using that, the application will be assigned to a Technology Center, which will have expertise to examine that subject matter. For biotechnology, we have what we call working groups. These are like departments you could say. For example, we have a work group which deals with nucleases, proteins and a work group that works with antibodies and treatments and we have one which deals with pharmaceuticals. In each workgroup we have a group of examiners, smaller groups of anywhere from 10-18 or 20 examiners, who would specialize in a particular technology, within that group. For example, my own arch unit, I am supervisor of an arch unit, we examine applications on anti-sense, siRNA, micro-RNA and methods of treatment-related technology. This is how the office is organized and this is how we can distribute the applications to where they should be examined.

What is a patent? It is a property right. It is a right to exclude others from making, using, selling, offering for sale, or importing a claimed invention. That exclusion is for a certain term. As a mentioned before, it is 20 years from the date of filing. And it’s territorial. So, what that means, and I think that’s the most important, if you start a business and if you want protection in multiple countries, then you have to apply for a patent in those countries. Now think about it, if you have a market for your product, whatever it is, in different countries and you put it on the Internet, you have only protection in the U.S. You have a U.S. patent. People will see the product and they can go in that country and they can copy and make it. You really cannot do anything. There are certain ways you could try to, but you do not have much protection. Same way if you were to produce that product in another country, then the company or the factory that is producing it, they could copy and sell fake items, a copy of your product. You do not have protection just with a U.S. patent. You have to get a patent from that country. There is a mechanism, there is a platform which is called Patent Cooperation Treaty [PCT]. I think as of 2015, 150 countries have signed the treaty and under that you can file an international application, you can choose the countries where you are going to prosecute or apply for a patent and they all can be managed under one platform. The filing date will be the same. The documents could be moved between offices. There are different programs and initiatives which can be used. There is such a platform which will help you to file in multiple countries. The application you file under PCT, it gives you support which can be used by multiple offices. It also does some preliminary report and examination. These are optional things you can get. Different countries can share that information. Your application can be prosecuted in those countries. You have to remember that different countries may have different patent laws. You cannot assume that if you got a patent in the U.S., you can get a patent in another country. The laws are not the same. Each country will prosecute your application based on their own laws. The resources are available for other countries. That is available to you.

We have three types of patents. A utility patent, where you have a new and useful process. A machine, article of manufacture, or composition of matter, or any new and useful improvement thereof. This is basically the list of things which you can patent. The design patent is another one. Any new, original or ornamental design; it protects the way an object appears. And the plant patent where it invents or discovers and asexually producing any distinct and new variety of plant. The rest of the discussion will be on the utility patent.

How do we get a patent? You see the first block as, new idea. Just a word of caution. You cannot patent an idea. It is a utility patent: how to make and use. Right? Your idea has to be converted into a utility product. What you have seen listed before. Once you have that, you can file a provisional application, which is optional, you don't have to file, and you have one year, in which you have to file a non-provisional application, which will get examined. If it gets approved, then you get a patent on that.

Just going back further and talking more about these two types of applications. Provisional and non-provisional. Provisional application, it has a one-year time period. It expires after one year. You use it for getting priority, file for priority date filing. The idea is that you have one year. Within that one year, you can decide what you want to do. Do you want to file a non-provisional patent? When I say, do you want to, that means you will decide based on your business, what you want to do further, and if you get a patent, do you want to get a product developed? All of those things, you have a year to decide. You don't have to put any claims in there. It will not be examined. Nobody will look at it, unless you file a non-provisional and then the examiner will come back and look at it for what you have put in that provisional. And then there is no provisional application for design of patent. Provisional is not allowed there. Non-provisional application is the one which gets you the patent. It is what will be examined. You need to have claims filed. I said, when should you file a provisional application and when should you not? One thing you have to think is that, if you are thinking about talking to people and sharing with them your invention, while you can have an NDA, it would be a good idea to file provisional, because with a provisional from the date you filed you are covered. It means, when you file your non-provisional, your filing date will start from the date of the provisional application. When it is examined, you are covered for that time period.

How much does it cost and how much time does it take? As of 2019, April 2019, an average pendency for a patent application was 24 months, and its similar, maybe a little bit less nowadays. It could be longer depending on a lot of factors. When you file an application, is it complete? Is it complete in all the senses before goes to the examiner? If the examiner looks at it, if he finds something else is missing - one good example, for biotech people: A lot of times people file an application and they put some sequence in the listing, not all. When an examiner sees it, it will be sent back to you, you have to put all the sequences, sometimes there are not sequences. All of those things add to the time of processing the application and getting the patent.

There are fees. You have to pay. There is a general filing fee and there is also a search fee and an examination fee. There could be some additional fees and the link here, if you go to the link, it will provide different kinds of fees you have to pay. What about small businesses? For small businesses, there are initiatives and in fact, there is a reduced fee for a small entity and micro-entity. Both of these have certain requirements you have to meet to be categorized as one. So, the fees will be reduced for these two. And then, after an application is examined and it is determined that it is patentable, you have to pay an issue fee. After that, you have to pay a maintenance fee at different time periods, which are listed here: 3.5 years, 7.5 years and 11.5 years after the patent issue. One question you can ask again, are patents affordable? These are the fees we are talking about is what you have to pay to the Office. On top of that, [you may] have attorney fees, which could be big. And then you could get professional duplication, size, complexity, they all add to the cost. On top of that when you are working with the examiners and there are extensions and all this, they could also add to the fee. It is a relative thing. It is hard to say how much it would be, but there are different types of fees and some of them are listed here.

Just to give you an idea of what is an application, what do you have in any patent application? What do you have to provide? The parts of the application are title, abstract, drawings, if you need, to show your invention, background of the invention, a brief summary of the invention and a brief description of the drawings, a detailed description, and claims. Claims are the real deal, because that is what is examined and that is what you get a patent for. In court, if you have to defend it, that is what you would need. The invention is the claim. Other parts of the patent application, they really support the claims.

What should a claim be, and when we say scope of the claim, what does it cover? You cannot be too general. If your invention, if you go too broad, it may not be patentable and will be too general. If it becomes too specific, it may not be as valuable to you as a patent owner. When you are working and when we are examining, we have to determine what is the proper scope of the claim. I’ll just use a simple example here: if you have a single-family house, where are your boundaries? How do you determine that? You cannot claim the entire street. You cannot claim the entire development where your house is. Where are your property rights? Basically, that is what the claim scope is, in simple terms. During the examination, that is what the examiner will work on. Examine and determine.

What is the process? When you file an application, your application is assigned and then it goes to our office. It’s called a pre-exam where they will look for all the formalities. After that, they will decide based on classification, where should it go. You saw the list of Technology Centers. It will be sent to one of the units and be a signed to an examiner. The examiner is going to examine and go through your application. They will have back and forth with you. For each application, when you file, you have what we call two bites of an Apple. Which means the examiner will send you an office action, you respond, and the examiner will take a look at how you responded and make a final determination, whether you get a patent or not. That really closes the prosecution, the two bites. If you get a notice of allowance, you get a patent. If it was rejected, then it gets abandoned. That is the simple form of the patent examination.

Just to give you another quick review of the process. When the examiner does the first examination and gives you an opportunity to look at it, now you can amend the claims and send it to an examiner to take a look at it for a second examination and then the examiner will decide whether they meet the requirement and decide to allow or not allow. Your options are that you can let the application go, or you can go to the next process, appeal to the Board, called P Tab. And they can decide if the examiner made an error or not and there you can get a notice of allowance.

What does the examiner do? The basis of the U.S. Patent System is, unless the office can show that you don't have a patent, your claim is not patentable because they do not meet the requirements, you have a patent. That is the initial burden of the office of the examiner to show that you do not have one. That is what you will get in the correspondence.

Next slide, please. That is what an examiner does. He or she will read and understand the invention and determine what is the scope of the claim. They will search what has been done and then determine based on this the patentability of the invention.

Next slide, please. There are several statutes. That’s what we check your invention for. The first one is [35 U.S.C.] 101. Let’s go to the next slide, please.

What can you apply a patent for? A process, machine, article of manufacture, composition of matter, an improvement of any of the above. Those are the five things that you can apply for a patent. They need to be new, nonobvious and useful. Those are part of the statute. For a biotech, what is a process? If you synthesize a new compound or new drug, that is a process of making a compound. You treat the disease, that is the method of treating, that’s a process. Machines could be your PCR machine or sequencer. Article of manufacture could be the same. You create a new vector for transecting a cell; that would be composition of matter, protein, peptide, compound and then you are improving any of the above. These are some of the examples of things you can apply for a patent in biotech.

Next slide, please. What are the requirements? You get only one patent for each invention. You cannot have a double patent. That’s what we call double patent rejections. There is overlap. It has to be useful. That’s utility. This is the list we told you: process, machine, article of manufacture, composition of matter. And then, whoever invents or discovers. A patent may only be obtained by the person engaged in inventing. You can’t get a patent on somebody else’s behalf.

Next slide, please. In addition to the 101 we talked about, it needs to be novel, and nonobvious. Novel means nobody has done it. Exactly the same thing - nobody has done it. Nonobvious means, if all the information is available related to that technology or invention, it would be obvious for another person who works in the same field to do it. And then we need that it should be adequately described and enabled. Enabled means, how to make and use, means the person who reads the application should be able to make and use it. That is described in clear and definite terms. Those are the requirements for an application. Next slide, please.

So this is going on more into the statute, so let’s move on to the next slide, please.

We have some of the things to share. This is another part of the statute when we talk about indefiniteness and distinctly claiming the subject matter. Next slide, please.

When we talk about nonobvious, something is not obvious, the idea being that would it have been obvious for a person to use the information available and make that invention. These are the determinations which an examiner has to make to say whether a claim is patentable or not. Next slide, please.

This is an example of a claim that has been issued. A method of treating [giardiasis in] a patient having said condition, comprising administering to the patient a compound. Or pharmaceutically acceptable salt form thereof. So, think about it. You have the disease and you have the compound. Can you make it broader? Can you make it less breadth for the claim? Next slide, please.

So, what resources do we have? A lot of resources in fact. This is a good collection of the web pages. You can learn about the patent process, how to search. There’s an IP awareness assessment tool. Inventor and entrepreneur resources are there where you could reach out with specific questions. The pro se assistance means, if you are preparing your own application and not using an attorney, there is a resource for that. All of the resources are available and much more on our website. Please do visit and take a look at them. Next slide, please.

This is the most important tool that examiners use: our “Bible,” MPEP. This is what is used for examining. It has all the laws and rule and regulations. Next slide, please.

This is an example, just a snapshot of the patent process. Next slide, please.

These are some initiatives about applications at different stages of application you can use. We don't have time to go through that. Next slide, please.

This is the dashboard. We provide information, if you want to know what is the pendency or a iknow statistical information, you can get on the website. Next slide, please.

You can have an interview with an examiner. This is one way. Next slide, please.

You have to try some of these. This is a tool to learn about IP. Next slide.

If you have a problem, you are not working with the examiner and there are issues, you can use the Ombudsman program to help you. Next.

That was the last slide. I am sorry I had to rush the last few slides. I will be glad to answer any questions. Thank you for your attention.

Moderator: Thank you. We have received many questions. We will go through as many as we can. I will give the first one to Lili and then we will move over to the USPTO-specific questions. Lili, is there a difference between the NCATS SBIR/STTR programs and NIH SBIR/STTR?

Lili Portilla: The NIH, being a federal government agency has a SBIR program. Each of the Institutes also have them. The various institutes have specific research missions and initiatives that may track directly with the types of topics they are looking for. As I mention in the Omnibus Solicitation, that is the best way to figure out what is going on across the NIH. There is a document and a hotlink in the Solicitation that allows you to see what all the different Institutes are looking for as well as the FDA and CDC. You could do a keyword search in the PDF and see which Institutes would be interested in the type of proposal that you would like to submit to the NIH. We are part of the NIH and we have our own budget line that we manage, as do the other 24 participating Institutes.

Moderator: Thank you. I wanted to note, I sent out a link via chat to everyone with the link to NCATS-specific research priorities for the SBIR/STTR program as well as the funding opportunities page. The next question is for Dr. Shukla. Can we patent artificial intelligence algorithms specifically designed for certain clinical applications?

Ram Shukla: Great question. You cannot patent the algorithm itself, but you can patent a process for doing something, using the algorithm. That would be my short answer. We have had a lot of case laws about 101 subject matter eligibility. Is AI eligible for patenting? That is where I will say, you can use it for a method of doing something, using the algorithm. Natural laws of abstract ideas, you cannot patent, so you have to be careful in there.

Moderator: We have two other specific types of what is patentable questions. One is, can we patent the antibody sequence of an antibody produced by a mouse due to the mouse being invoked by an immunogenic stimulus or does this fall under naturally occurring?

It depends. A hypothetical question, hard to say. If you used a recombinant peptide to produce an antibody and the recombinant peptide it is unique, then the antibody would be unique. You might be able to patent that. I hope that answers the question. It all depends. If the antibody you produce in the mouse is naturally occurring, meaning it is produced against a known peptide or known protein, then most probably you cannot patent it. If you use a unique peptide, recombinant peptide which is not present in nature to produce the antibody, you might be able to.

Thank you. During the presentation you mentioned nonobvious. Some folks would like to get more details on that. If a utility patent was abandoned and a new application is filed with similar target/process, but with different molecules, can a patent be granted?

Let me understand the question. The application was abandoned. And a new application was filed using the same information.

Moderator: Similar process.

Ram Shukla: Since 2000, all the patent applications filed at the office are published. They are called pre-grant publications and that means it would be available as prior art. Also, it means that if you use the prior art, even though it is abandoned, it is published. It will be used in obviousness rejection. Is your application or your invention obvious over what was published in the abandoned application? When we talk about obviousness, you have to think if all the information is available what you have in your application, will a person working in the same field be able to use all that information and make your invention? That is what is considered as being obvious or nonobvious. I hope that helps.

Moderator: Thank you. The next few questions relate to timelines and some more specifics. So, I’ll begin.

If you file a provisional patent but someone else files a provisional patent with a similar idea before you, however, you have substantive data backing your claim and they do not, which one is awarded?

Ram Shukla: Okay. First thing is, who filed first? That is the test. First to file is the one who gets the patent. Second, when you file a provisional application, how much did you describe? And the other party, how much did they describe? Remember the statutes I talked about, we will be looking at, can one make and use based on the information you have given? You are not required to reduce to practice, as we say. It could be profit, but at the same time, it should be enabled, meaning using the technology available at the time that the invention can be made and used. Let's take an example of treating a particular type of cancer. And treating that particular type of cancer is unpredictable because of various reasons. When I say unpredictable, I mean when you are using known drugs and you cannot treat them, you have to use a specific drug to treat. You come back and you put in an application where you describe that I have this drug and it can treat it and you put all the inferences, but you have not done anything. Based on what is already known, can that cancer be treated? In that case, the examiner will ask. It cannot be done. You have to now show the data that it can be done. Going back to your question, it depends on what the invention is. You may describe and may be able to get a patent, or not get a patent. It is all based on what the invention is**.**

Moderator: Thank you. If the patent application is abandoned, is there an option to revive it a few years have passed?

Ram Shukla: That is a great question. What is a few years? If you abandon an application, you should try to revive as soon as possible. Yes, it can be revived.

Moderator: Someone is looking at the two bites of the apple. What about when the initial exam has questions, you respond (1st bite). Then they decide they need more information, so you reply back a second time (2nd bite). Then they respond saying that initial issues are resolved, but now there is a new issue. Do you get two more chances to respond?

Ram Shukla: It is not a request for information. You have to be careful. What the examiner does is, they write the reason why the claim was not presentable, what statutory requirements are not made. And what you do is you go back and amend the claims and say, here are my arguments and why they meet the requirements. Then, the examiner will make it final. There is no additional bites. You can file what we call the request for continued examination, RC. There is a filing fee. And you can go further and go through another cycle. That is the option. The other option is you can let that abandon, and before it gets abandoned, you can file a continuing application and you may want to add new information if you think that will help and that is called a type of continuing examination. It is in part, because you have added new subject matter to it, which is called CIP, continuation in part. Those are some options you can use to get for more rounds of examination.

Moderator: We have a few more questions. We will respond until 2:15 PM. I will go through a few questions on global patents. What is the timeline from filing a patent in the U.S. to the PCT application?

Ram Shukla. I don't have the specific time on that. You have to check the PCT site. It is on our website. I believe it is 30 months, but I don't want to give you wrong information.

Moderator: Since there is no worldwide patent, is there any advantage to biotechnology as a trade secret? Does that keep your invention or innovation hidden?

Ram Shukla: It’s all you, if you can hide your invention. Coca-Cola formula has been a trade secret for hundreds of years. If you can do it, yes. People have tried to reverse engineer it and they have not been able to copy it. The trade secret, that is where the challenge is. If you can keep it secret, then you can. If not, with the patent, at least, you will have control and you can go after those who tried to copy it. And if the product will be so good and make so much money for you, you may want to go to multiple markets in multiple countries and protect there.

Monique: When filing a patent in a foreign country, does the researcher need to translate and incorporate the provisional patent or only the permanent application?

Ram Shukla: If you are going by PCT route and, once you file a PCT application, the application gets fixed. Now you could file a first provisional and then file a PCT and you can get a benefit that way. People use multiple provisional applications. If you are filing through PCT, you have a fixed application. If you are filing in each country, independently without going through PCT, I guess it would depend on what you want to file and what is the filing date.

Moderator: Thank you. A simple question. If you have a challenge with your examiner, is a possible to request another examiner? What is the process for that?

Ram Shukla: Good question. I don't think you can get a change of examiner, but there are ways to resolve it. First thing would be to talk to the supervisor of the examiner. The Ombudsman program is there if it doesn’t work out with the supervisor. You can reach out to the Director of that Technology Center. They will mediate. There are several options available. Like I said, the Ombudsman program is there. So they all will be available to help.

Moderator: This is the last question. This person has a 20-year patent. The formulation of a previously unapproved FDA medication is being marketed illegally by a generic manufacturer. If he/she gets approved by FDA as a new chemical entity, does my 20-year patent override any market exclusivity that the FDA will issue?

Ram Shukla: I am not really sure I am equipped to answer that question. I am a patent examiner. Sorry. I do not have the answer to that question.

Moderator: Thank you. We will chat out the resource link and include some of the links in our follow-up note to all of the registrants on this webinar so that you can dig deeper and know where to get more information.

I want to thank you Dr. Shukla for all of the information you provided today as well as the resources. I would like to thank Lili Portilla of NCATS, as well as everyone who listened into the webinar. We appreciate your time. We appreciate your feedback. We sent you a link to a feedback form. If you could fill that out. If you have additional questions or want to schedule a one-on-one with Lili about the NCATS SBIR/STTR program, please reach out to us. Thank you for your time and have a wonderful day.

Thank you. >> [Event concluded]