HUSEIN PANJU:. On today's show, I'm very happy to welcome my guest Geoff Mowatt. Geoff is a partner with Dimock Stratton LLP in Toronto and is a certified specialist in patent law. His practice includes all areas of intellectual property law, with a focus on patent and trademark litigation—including pharmaceutical litigation Geoff has experience in all aspects of intellectual property litigation, ranging from pre-litigation opinions to appearing before the Ontario Court, Federal Court, and Federal Court of Appeal. He has worked with counsel from all around the world to coordinate the Canadian part of multi-jurisdictional lawsuits. Geoff is also co-author of a chapter for the *IP Benchbook for Patents*, which is an electronic textbook for the judiciary for the Federal Court and Federal Court of Appeal. He currently sits on the Ontario Bar Association Professional Development Committee and the Civil Litigation Executive and is the chair of The CBA Biotechnology committee. Geoff, thank you for joining me on the show today.

GM: Thank you, Husein.

HP: The first topic we're going to talk about is e-cigarettes. E-cigarettes have become very popular in the last few years, and there have been some new legislative attempts to regulate this market. Now many companies in this industry have already started getting their trademarks and patents, so there'll be plenty of IP issues to address in the near future. So, Geoff, to start out with, why don't we start what e-cigarettes are and why they're so contentious.

GM: Yes, so an e-cigarette is a handheld device that is sometimes the size of a conventional cigarette or sometimes made to resemble a conventional cigarette. Otherwise, they can be in flashier packages, more appealing to today's youth. Basically, with an e-cigarette, the user inhales a vaporized liquid known as e-juice. The e-juice is vaporized within the device itself using what's called an atomizer which is typically battery powered.

The e-juice is often available in various flavors and may contain various amounts of nicotine. It's the nicotine content that sometimes raises some concerns. There's also a concern with respect to health issues, many of which are unknown because the e-juice contains excipients like propylene glycol, which once vaporized, inhale deep into the lungs. And so, there are some concerns about that.

HP: And so why are e-cigarettes so popular nowadays?

GM: As the decline in the use of conventional cigarettes increases, e-cigarettes are certainly a smoking secession aid. That's one factor. It seems vaping, as it's called, vapors, as opposed to smokers, it does seem to be something that's trending in the younger population.

HP: Okay, and is it clear right now whether the e-cigarettes are healthier or not?

GM: To my knowledge, it's not clear one way or the other. E-cigarettes on the grand scheme of things are somewhat in their infancy. Their long term health impacts of ingesting an excipient like propylene glycol or even the flavoring chemicals deep into your lungs may be something that may cause health concerns we may not see for years and years, much like has happened with conventional cigarettes over the years.

HP: All right. I know recently the Ontario government has tried to regulate this field. Can you talk a bit about the Bill C-45?

GM: As of May 26th, the Making Healthier Choices Act came into force in Ontario, following suit with Nova Scotia that I believe has adopted similar legislation. Ontario considers itself to be on the forefront of protecting today's youth from the dangers of tobacco and the potential harm of e-cigarettes. As of late May, it was passed, it's now legislation, and as the new legislation, some of the things that are now illegal to do include the use of e-cigarettes in designated non smoking areas, selling e-cigarettes in certain places where the sale of tobacco is prohibited, displaying e-cigarettes in places where e-cigarettes are sold or offered for sale, much like the restrictions on displaying cigarettes. Promoting e-cigarettes in places where e-cigarettes or tobacco products are sold or offered for sale. There are a number of practices that are now illegal with respect to e-cigarettes much how we've seen over the years with cigarettes themselves.

HP: So how did this affect the IP landscape?

GM: So with respect to IP, when anything starts to become more and more popular, you would expect to see IP issues surrounding it. And so, we expect to see developments both on the patent front as well as the trademark front. If you look at the Canadian patent database already, there's more than 30 either granted patents or pending applications. We would expect to see more as the market for e-cigarettes continues to grow. As those patents become granted, in all likelihood, you'll start to see infringement actions based on those Canadian patent rights to pop up in the federal courts and provincial courts as well.

The market for e-cigarettes is definitely a growing market, globally, as of 2013. It was estimated to be 3 billion, and it's expected to grow 10 to 20 fold over the next few—by 2030. That's the patent issues. With respect to trademark rights. Similarly as something becomes more popular in the mainstream media, you would expect a lot more trademark applications related to such products and then the litigation as well.

Now, with trademarks there's going to be issues surrounding—you would assume restrictions on marketing and advertising you could put on the packaging much like you

would see on cigarettes. When considering trademark rights, you'll have to consider those restrictions as well.

HP: Can we talk a bit more about that? How does litigation in the IP sphere differ in the cigarette world as opposed to other products, given there are such strong restrictions for the advertising? Are there things IP lawyers would be doing differently in this realm rather than another?

GM: Yes. If a client approaches a trademark lawyer for example and seeks to register a trademark, it's not necessarily our job per se to tell them they can or cannot use that trademark from a regulatory perspective. When our clients come in, we want to provide them with full consideration of all the issues and so I think it would incumbent on a trademark lawyer or an IP lawyer in general really to raise any concerns that marking, that trademark use or packaging, marking on a packaging, might have from a regulatory perspective as well because you don't want your client to be stung either from putting a product out there that runs a foul from regulatory issues or trademark rights of others. That's how those two things are going to interplay from my perspective.

HP: Are there other lessons that IP lawyers can take away from the cigarette industry that can be applicable to the e-cigarette industry?

GM: Recently we have seen litigation around the trademark use on actual cigarette packaging. There's been some Marlboro disputes, etc. so once you're into a trademark action, the issues are very similar to any other case.

HP: Do you think legislation will get across the goals that are intended?

GM: Well, it will certainly restrict access to minors, so those under the age of 19 to have access to e-cigarettes much in the effectiveness will probably similar to the effectiveness you would see with cigarettes, whether that means it's effective or not is a different story I suppose. So I think it will restrict it in that sense and then you'll also see less use of e-cigarettes in places where using actually cigarettes was previously prohibited because now they're going to have to be used in the same place.

HP: Okay, so Geoff, thanks so much for your time for talking about this issue. Looking forward to following this as it develops.

GM: Thank you.

HP: One of those most contentious issues in pharmaceutical IP law is the issue of biologics. Biologics are drugs developed from living organisms with the capacity to treat afflictions ranging from cancer to HIV. The legal issues have become fairly complex with instruction of biosimilars, which are drugs that have many similarities to biologics. To start off with, Geoff, what are biologics?

GM: Biologics are basically drugs that are derived through the metabolic activity of living organisms. Things like blood products, cells and tissues, gene therapies, vaccines, things of that nature; the big difference between a biologic, or one of the most notable differences between a biologic and a small molecule drug which is what we typically see a lot of patent litigation around in Canada, is that the small molecule drug—and the reason it's called a small molecule drug is it may have 15 to 30 atoms. Aspirins, for example, have as many as 21 atoms. Compared to a biologic, that has over 3000 or even over 20000.

They're much more complex molecules, much larger, much more complex, and show a lot more variability. What that means is that because they are derived from living organisms is any small change from the manufacturing process or various other—any small changes throughout the process at all can have a very significant impact on the molecule that is generated.

HP: Can you give an example of that?

GM: One example I've heard about it is where a company was manufacturing its biologic in Denver, Colorado, and they decided to move their facility to the east coast of the U.S, and the change in altitude resulted in variability within manufacturing processes such that they had to get new regulatory approval.

HP: Let's move to biosimilars—I know they're also called SEBs. Can you tell us more about that?

GM: Yeah, so a biosimilar is basically a biologic drug that is made to be similar or comparable to an originator biologic drug. In Canada, in March 2010, Canada provided guidance for companies that wanted to manufacture biosimilars in Canada, and they call them Subsequent Entry Biologics. The SEB is actually an acronym for subsequent entry biologics. It's effectively the same thing—it is a biosimilar. When seeking approval for a subsequent entry biologic or a biosimilar, rather than having to submit an extremely detailed NDS ,a new drug submission to health Canada, biosimilar manufacturer or SCB companies can file… it's called a New Drug Submission, but it's not quite as detailed as the original submission would've been.

HP: What is contributing to the popularity of biosimilars right now?

GM: In my view, one thing that is contributing to the rise in popularity of biosimilars is that a lot of the small molecule drugs that have been very popular, some would call them blockbuster drugs, like Lipitor might be a good example, are now off patent. Which means the key patent covering that molecule has expired and therefore generic drug manufacturers in Canada and abroad have been able to capitalize on that patent expiry and come up with generic versions of their own, which in turn, once those hit the market, have taken away market share from the brand companies. So those brand companies, many of them are looking for other drugs to pursue and biologics are out there, and SEBs (subsequent entry biologics) or biosimilars are an interesting area to focus on.

HP: And how does the cost compare between biologics and biosimilars?

GM: Well, typically a biosimilar is significantly less costly to the consumer than its biological comparator, so as an example, in Canada, one of the SCBs to be improved is Inflectra which was compared to Remicade, which is a Janssen product. In Canada, the biosimilar version was 34.2% less costly than the originator biologic product. That's a significant cost saving for the average consumer.

HP: What kind of afflictions are these drugs meant to treat?

GM: That particular drug is a monoclonal antibody used for rheumatoid arthritis, ankylosing spondylitis, and psoriasis and things of that nature. You see biosimilars useful for treating various kinds of indications, everything from Crohn's disease, to colorectal cancer, so there are a variety out there.

HP: I know one of the important distinguishing factors between biologics and biosimilars is the approval process. What are the difference sand why is this important?

GM: Right, so over the past 15, 20 years, the PMNOC regulations, which are the Patented Medicine Notice of Compliance Regulations have governed the approval process for small molecule drugs—you know, Lipitor is a good example, Nexium, things of that nature. Basically what happens in those cases is a brand or an originator files a new drug submission, an NDS, basically with a room full of boxes to support the safety and efficacy of that drug.

With a small molecule drug, a generic company can come along and file what's called an abbreviated new drug submission. An abbreviated drug submission is just that—it's as series of boxes much less substantive in size, but also in cost, whereby they just compare the bioequivalency, and they just have to establish that their product is bioequivalent to the brand's small molecule drug product. With biosimilars or SEBs, it's not nearly that simple because the SEB is not bioequivalent to the originator biologic, it's merely similar. That distinction lies in the complexity of the molecules because of the

size and the complexity trying to get one, arrive at a biosimilar product that's identical is very difficult, if not impossible.

HP: And so from an IP perspective, what is something that IP lawyers should be keeping in mind in light of this approval purpose. Are their IP considerations for the approval?

GM: When you're revising your clients, you're either as biosimilar sponsors or hoping to be biosimilar sponsors that they pay very close attention to what patents are listed on the patent register, as well as make sure they get their submission in a timely fashion if they anticipate there might be a pending patent application relating to the product of the innovator.

HP: How do you see this area of law shaping up the next few years?

GM: There has been a lot of discussion about that. Certainly when you look around the world and see all the both originator traditionally brand companies and the traditionally generic companies, they're all going after biosimilars. So you would expect the amount of litigation to grow, the amount of patent finals to continue to grow, so it's not developing quite as quickly as I think some may have suspected, but nonetheless, I think the patent impeachment action coming up, the PMNOC proceeding, I would expect to see more SCBs or biosimilars approved in Canada in the next few years, I would hope, and even more after that. It's an exciting time, it's a very interesting area, and for patent litigators, it's a lot of fun because it's complex. The issues are interesting and not clear cut by any means and you have to rely heavily on the expert evidence because the science at play is very complex and often new.

HP: And what are some other issues that IP lawyers should be aware of in light of this debate between biologics and biosimilars?

GM: One thing that came out of the Abbve v. Janssen was the injunction that was ultimately granted. The court seemed open to a more customized injunction that took into consideration the patients who ultimately used the medicinal ingredient or biologics in question. What you find with biologics is that which is again somewhat different from small molecule drugs, one person might react to a biologic different than they might react to a biosimilar. If a person is already using a biologic product, it might not be in their best interest to switch to a biosimilar product, or even between biosimilars and so, if a person has already started using, well in the case of Stelara for example, the Advi v. Janssen case, certain patients were already using Stelera as a product. It may have been contrary to their health to take them off that product or they might have suffered adverse reactions if they went back to one of the other products that were already on the market for the same indication.

The court seems to be those types of issues—or aware of those types of issues and open to creative injunctions, and they seem to be willing to grant them.

HP: Given the complexity of this subject matter, what is something that IP lawyers should be mindful of if they are involved in a litigation matter of this sort.

GM: One interesting thing we saw in the Abbvie v Janssen case and actually has also been proposed in these PMNOC cases we've seen related to biosimilars is a technical primer. When you're preparing your case for a hearing, preparing a technical primer that can be submitted in advance to the hearing itself to get the judge hearing the case well up to speed on the science of it all because these are extremely complex technical issues you don't want to have to waste valuable hearing days trying to educate the judge on.

HP: Okay. Geoff, thanks so much for your time on this.

GM: My pleasure.

HP: The final issue for today will be the doctrine of the promise of the patent. This is an issue which affects inventors who promise results when they apply for a patent, and there's been a new direction on the case for the past couple years, which will have locations on determining the liability of indicators who produce a variety of products. So, Geoff, what is the promise of the patent?

GM: So section two of Patent Act states that you must have a new and useful invention to obtain a patent, and so useful—the utility threshold has often been held to be quite low. Basically, as long as you demonstrated some utility by the Canadian filing date, then your patent will meet that threshold, and the demonstrator utility didn't even need to be in the patent itself

The caveat that actually goes back for a number of years is that while you don't have to make any promises of utility in your patent, if you do make promises you're going to be held to those promises. If you have a patent application, you don't have to actually state what the utility is as long as you had demonstrated the utility. But if you went as far to make a promise of an elevated utility, for example, in the case of a small molecule drug, if you have promised it would work for a certain indication but it turns out that you either hadn't demonstrated it would work for that indication by the Canadian filing date, or there was no sound basis for prediction of utility in that way, then your patent could fail on that basis.

HP: So this whole issue of the promise of the patent—in what context would this become a contentious issue?

GM: This becomes issue when, say you have a party, the patentee decides to sue somebody else for patent infringement as an example. The defendant, the party alleged to infringe, as a counterclaim or as a defense they say the patent is invalid. You can attack the validity of the patent on various grounds, one of which is utility or lack of sound prediction. So what you would say as the defendant is you'd read through the specification of the patent, the description, you'd look for anything that would seem to be a promise of utility.

If there is a promise of untidily, you would allege that the promise has not been met. Maybe through the discovery process or through some other means, you've determined that the product, as of the Canadian filing date, the patentee did not actually know the product would work for a certain indication. So you'd say as of the Canadian filing date, that promise in the patent was not met.

HP: When you're applying for this patent, I guess there's a patent office when you submit your application. Is that the context we're talking about, when we're making promises in that application?

GM: Yes, exactly. You prepare and final the patent application with the Canadian patent office. There's a bit of back and forth with the patent office, they tell you to amend the language a bit. The patent office may challenge you on the wording or the scope of your patent claims.

Once you're ultimately granted a patent, then there's a grant date and it's enforced from 20 years from the filing date and you can enforce it. But if you then try to enforce it and the validity is challenged, the court looks at the description of the patent and if in that description, so what was originally filed, if there's words or phrases in there that suggest that the inventor or the patentee is promising that it works for certain things, that's the promise you're going to be held to.

HP: How has the Plavix case changed this?

GM: Right, so we were seeing this promise of the patent doctrine rise and rise in prominence in Canadian patent decisions over the past number of years. In recent years specifically in the pharmaceutical area, you saw it rise in prominence. And so, there were a lot of concerns that this promise of the patent was somehow creating some sort of different threshold that patentees, especially those that file in Europe or file in U.S, don't see in those jurisdictions, some elevated threshold for utility that was invalidating Canadian patents and those patents were being upheld in other jurisdictions.

So in 2013, in the case or the Federal Court of Appeal on the drug Plavix or Clopidogrel, the Court of Appeal pulled the reins back a bit and advocated for a bit more restrained approach to the restrained approach of the idea of the process of the patent. In that case, the court basically said you needed an express promise, not just a statement of an advantage or something like that. You have to look more closely at what was actually said, there has to be an express promise.

HP: What does an express promise look like?

GM: It will be a case by case basis. Obviously if the inventor uses the words I promise, it will work for that, but I don't know if it needs to be that explicit. A mere statement of advantage or hopes that it will work for something are not going to be held to be a promise that will invalidate a patent. The court will really look at expressed promises that are then unfulfilled and look at those as self inflicted wounds. But the court should also not be looking to invalidate a patent for an otherwise useful invention.

HP: Can you give an example of when inventors have been held to their promises?

GM: I can think of at least two cases, and those as an example are, there are two Eli Lilly decisions, one on the drug Zyprexa. Tthe patent was, the claims were directed to use of Olanzapine for schizophrenia and then it was found that there was insufficient data to support that use of the drug for that indication. In a Strattera decision, which is another Eli Lilly decision on the drug atomoxetine, the court construed there were certain promises for use of ADHD of that drug, and looked at the studies that were actually done, and found the studies to be actually flawed, therefore they did not support a sound prediction of utility as of the Canadian filing date.

HP: What is the judiciary's rationale for holding inventors to their promises?

GM: If you look to the quid pro quo of the whole patent regime, the whole idea is that the patentee gives full disclosure of their invention. In exchange for that disclosure, they get their 20-year statutory monopoly. Where the patentee puts in their specification that the product will, they promise it will work for this or that, and that promise as it turns out was actually not a sound basis for obtaining their patent, they haven't fulfilled their end of the bargain.

HP: And so what are some takeaways lawyers should consider, if you're an IP lawyer and you're advising a client and their patent application process. What is something lawyers should tell them?

GM: So if you're advising your client with respect to preparing and filing the application, in particular if it's a client that's filed in other countries as well, you should make sure the client is aware of the way that Canada approaches promises and the specification.

Make sure that you would typically want to avoid promises; you can state advantages, you can state things you would hope it would result in, but you would typically want to avoid promises unless those promises are substantiated as of the Canadian filing date.

HP: Are there any advantages for promising anything in the patent application?

GM: The only time you would want to promise something in a patent, I think, is if it were a selection patent. A selection patent is basically where you were seeking protection for a sub, a certain drug, for example, that was part of a previously disclosed genus of drugs. If you could establish that the later compound that you're seeking protection for has unexpected results, to substantiate or to sustain that selection patent, you're going to need to expressly state what those surprising or unexpected results are.

HP: And given the restraint approach by a judge in this area, is this a positive change in the area?

GM: I think it is. We want predictability, and so this gives a bit more predictability. The brand companies, certainly, are probably relieved somewhat that the courts are being prudent in the way they apply this promise doctrine, if you can call it that. Others, like generics, they want their predictability and to be properly advised by their counsel, so I think it is any time you get court decisions that more clearly delineate what is and what is not a promise, it's a good thing in my view.

I guess the only other issue which kind of shows how significant this issue has become for some parties is the NAFTA challenge by Eli Lilly. Eli Lilly as a result of—likely linked to having lost a couple of key patents in Canada related to this so called promise doctrine, they brought a NAFTA challenge to challenge this approach by the courts, as different from what you would see from the international state. And then contrary to international treaty. So it will be interesting to see how that plays out.

HP: It's been a really interesting conversation learning about these current and upcoming issues. Geoff, thanks so much for your time, and thanks for joining me on the season finale.

GM: Thank you, it's been a pleasure.