



Assessing Litigation Risk

Whether you're faced with the prospect of litigation or performing due diligence on a partnership or acquisition, it is to your advantage to assess any potential litigation risk quickly and accurately. Watch the on-demand webcast with Omar Jabri, Assistant General Counsel, IP at Apotex Inc., and Neil Magenheim, Director of Client Relations at Lex Machina to see how with just a few clicks, you can gather critical insights about parties, counsel, judges, that will help you get a clearer picture of your litigation risk. Our speakers will cover questions such as:

- Is this plaintiff a credible threat?
- What litigation has this company been involved in previously?
- How likely is this plaintiff to settle?
- How long is this going to take?

Speakers:



Omar Jabri
Assistant General Counsel, IP
Apotex Inc.



Neil Magenheim
Director of Client Relations
Lex Machina

Neil Magenheim (00:00):

All right. Hello, everyone, and welcome to the Lex Machina Legal Analytics and Practice Series Webcast. Today, we'll be talking about how to use Lex Machina to make more informed, data-driven decisions regarding the assessment of litigation risk. Before we get started with the program, a couple of reminders. One, this is being recorded. And two, we will be having some time at the end of our session today to address any questions you might have. And you could ask your questions via the Q&A feature in the bottom of the Zoom link. My name is Neil Magenheim. I'll be your host of today's webcast. And I'm really excited to introduce our guest speaker, Omar Jabri. Omar is the Assistant General Counsel of IP at Apotex, which is Canada's largest generic pharmaceutical company. I've known Omar for many years, and we're really excited to have Omar join us today. Omar, maybe you could say hello, give a brief introduction of yourself, tell our audience a little bit about you.

Omar Jabri (01:02):

Good afternoon. Thank you, Neil. Good to be with you. Thank you for allowing me to participate in something I'm very interested about because using data and analytics to drive forward our decisions are a key component of what we do as in-house counsel. I've been in-house counsel at Apotex for approaching 10 years now. I have carriage of legal matters arising out of the Hatch-Waxman system in the United States and the PMNOC Regulations in Canada, as well as international patent disputes from time to time. So we have been utilizing Lex Machina for a number of years to assist us in digesting the huge volume of information that we have to deal with to make thoughtful, data-driven decisions with our legal strategies. So good to be with you. Thank you, Neil.

Neil Magenheim (01:48):

Thanks again, Omar, for that background, and, again, really excited to have you join us today. I thought it might be interesting tee up a quick conversation starter here. Maybe you could just share with the audience a little bit, how do you use Lex Machina specifically to make those more informed business decisions that you're talking about?

Omar Jabri (02:08):

So litigation for the introduction of generic products into the market is the backbone of the business model. So having a handle and getting arms around the complexity of the litigation and the factors and the costs and the intended legal budgets are part and parcel of what we do to ensure that we have the ability to introduce these affordable medicines for our customers and for the patients. So we routinely have to evaluate the IP risk and the ability for us to get to market minimizing the legal risk, minimizing the legal costs, and ensuring that we have the proper strategy to go into litigation and to utilize appropriate counsel to further those goals and ultimately to obtain the resolution that we feel is the most efficient.

Omar Jabri (03:04):

And so we constantly refer to the data from cases involving the branded companies, competitors that are in litigation, with other [inaudible 00:03:15] cases. Counsel selection, we look at their track record, their scorecard. When we get into a district court suit, we look at the data associated with the district court judge that is assigned to the matter, time to trial, looking at other historical activity associated with the patents are being enforced against Apotex in a given proceeding. So there's a large volume of

information that needs to be assessed and reassessed to ensure that we have right sized the legal strategy with the particular product opportunity.

Neil Magenheim ([03:50](#)):

Wow. So much to work off of there. That's absolutely amazing. I know you've been with Apotex now, Omar, for just about 10 years. You've been consuming Lex Machina there for quite some time. Maybe just to set the audience's expectations a little bit, how would you go about checking all those boxes that you just so eloquently laid out without a tool like Lex Machina at your disposal?

Omar Jabri ([04:15](#)):

Yeah, so that's a good question. Before I joined Apotex I was in private practice working on Hatch-Waxman cases out of the New York office of a major law firm, and it was very cumbersome and time-consuming to cross-reference all of the data, generating information from PACER and from other sources. And it took a lot of time and it was a very inefficient process. Now, with Lex Machina software, it's really available at your fingertips and it's all laid out in a very user-friendly format, and it really allows us to drive forward thought and consideration of some of the issues in a much more efficient manner. So I find it to be an invaluable service for us to ensure that we're not missing anything, because oftentimes, if you don't really dig in and you have the time to ensure that you've cross-reference all of the available information that you need, you might be overlooking a key fact or a key data point that is necessary to drive forward the decision.

Neil Magenheim ([05:13](#)):

That's so great. So tell us a little bit maybe about how you and your team use Lex Machina, how widely deployed it is and the different types of efficiencies and productivity that you're able to gain from one set of data that's easily able to share it and export the data, et cetera.

Omar Jabri ([05:34](#)):

So a lot of times when we introduce a product into the pipeline for our internal development with the goal of submitting an application to the FDA or to Health Canada, we definitely want to look at historical data associated with the branded company, because, obviously, the name of the game is the patent protection and their exclusivity and our ability to break their exclusivity and to get to market through litigation, which is the primary way you get to market on these valuable products, and or a resolution. But the backbone of the business model is smart litigation strategies designed to overcome the patent blockade. So what we do is that we'll look at things holistically, we'll look to see if there's any historical information associated with the patents covering a particular Orange Book product, and we'll see if it's been enforced and the resolutions thereof, if there is prior case activity, prior PTAB activity.

Omar Jabri ([06:37](#)):

We'll look at claim construction. That's important when it comes to understanding if the Apotex product that's being developed may be outside or inside the scope of certain patent claims based on the definitions that the courts have entered into in the past with respect to claim construction. So you have to look at things very holistically because the business needs to understand, and it wants predictability. It wants to understand, what's the time to market? What's the likelihood of success? What's our ability to navigate the number of patents that might be enforceable against us? What have other competitors done? What's their end game? So just to understand, the business wants to understand, if I want to

bring this product to the market, what does that mean as a business? What does that mean when it comes to litigation spend, when it comes to the time it will take to resolve the patent case?

Omar Jabri ([07:25](#)):

Ultimately, it's front of mind for management to understand, because a lot of the products that are very valuable are, of course, protected by ample patents, and getting around patents or being able to have a thoughtful legal strategy is the backbone behind our ability to bring these products to market in an expeditious manner.

Neil Magenheim ([07:46](#)):

That's great. One last question for you. Then we'll start looking at some of this data. 10 years of experience at Apotex. Are you getting more and more pressure from your organization to run your specific group like its own individual business? Are you being asked to do more with less? Any sort of pressures or different types of business methodologies that you've seen over the last 10 years that makes you want to work a little differently, more effectively, et cetera?

Omar Jabri ([08:16](#)):

Yeah, that's a good question. I think ultimately given that we're a mature organization in our legal group, I'm probably the most junior member of the legal group handling IP matters and I've been there for almost 10 years, to give you an example of like how much seniority we have on our legal team. But I think we're being constantly asked to do more with less. And oftentimes it's proving to be we're a victim of our own success because we have done I think a good job historically with driving forward good legal solutions to allow our products to get to market with good product opportunities. So I think there's a constant ask by management to try to do more with less, stress your legal dollars as much as possible, drive forward creative outcomes.

Omar Jabri ([09:00](#)):

Actually, one of the underappreciated facets of what the legal group does at Apotex is not just to manage the legal function and legal services, but to also think opportunistically, where can we find something that is maybe overlooked or under appreciated to drive forward a legal strategy that may have been overlooked by our competitors? So I think the group has evolved to be less a manager of legal services and legal spend and to be more working hand in glove with the business to ensure that we can drive forward business opportunities to generate a lot of value for the organization.

Neil Magenheim ([09:36](#)):

It's so amazing. I can go on and on, so many questions, so much curiosity here. You guys are really you're saying all the right things, doing all the right things, and it shows in the product that your organization and your group in particular puts out. So let's take a quick look at this transition here into Lex Machina. I thought it was interesting, as we were preparing for our time together, we talked a little bit about, when you're thinking about assessing risk, one of the first key metrics there or components is, our opposing party, what type of threat or risk is posed by this particular matter? So Takeda recently served Apotex, you can see here, in June for a potential patent infringement case. So maybe you could tell us a little bit about this case in particular, but also how you use data to assess the threat or risk posed by the brand in this case.

Omar Jabri ([10:35](#)):

Yeah. So this is a good illustration of what we can use the data and analytics for at an early part of the case. So we were served with a complaint for patent infringement in respect of our ANDA submission for a cancer drug in this case. And one of the early decisions that you have to make, and it's a very important decision is, do you want to challenge venue? Because you do have the opportunity before filing your answer to challenge the venue that the plaintiff in this case Takeda has selected to sue Apotex. So what we can do here is we can decide to move to change venue or transfer venue. But you have to do that early on in the case, and if you pass on the decision, then you're locked into that district court and that judge for the duration of the case. There's a very important front-loaded decision that you need to make and we absolutely use the data and analytics to drive forward that decision.

Omar Jabri ([11:31](#)):

So what we did in this instance is that we looked at the district court, in this case, District of New Jersey, we looked at the particular judge assigned to the matter, and then we also looked to compare it against, well, let's say we were trying to move to transfer the case out of Jersey into another case like, let's say, a high volume patent case venue like the District of Delaware, what does that look like in terms of our ability to get to trial earlier and then with a scorecard when it comes to some of the outcomes in patent disputes and ANDA disputes? So I think doing a comparison between a District of New Jersey and a District of Delaware will definitely inform our willingness to potentially spend money, and [inaudible 00:12:11] practice to transfer venue out of a given district court.

Neil Magenheim ([12:17](#)):

Yeah. So much to work off of there, Omar. Thanks again for breaking that all down. What's really interesting is, do you take into consideration where the opposing party spends most of their time in similar cases as part of that analysis? So, for example, we're looking at some of Takeda's patent cases here, ANDA cases, and you can see that 61% of their cases are in Delaware. Only 23 are in New Jersey. Does that have any bearing on your decision-making process?

Omar Jabri ([12:48](#)):

I can't say that the data is too surprising. The majority of the cases are going to be brought in New Jersey and Delaware, especially for these Hatch-Waxman ANDA cases. It is interesting that they made a choice because they ultimately can make a choice to bring suit against Apotex in either Delaware or New Jersey. So for them to work against their trend lines and select Jersey I think would be interesting, and you can probe a bit more about that as to the reasons why. And so maybe the more you dig into the data the more insights you can generate in terms of the decision-making process from their standpoint. But it's definitely useful to understand that their predisposition is to bring a suit in Delaware, but here they zigged a bit instead of zagged and they selected their secondary choice of venue.

Neil Magenheim ([13:31](#)):

Got it. Super helpful. So you can see here comparing and contrasting in the small screen here, we're looking at the District of Delaware. And then, on the bigger graphic here, we're looking at the District of New Jersey and we're looking at both districts and venues in ANDA cases. So you can see some really interesting information like the median time determination in Delaware is 223 days slower than New Jersey times to trial, et cetera. As we were talking and we've talked over all the years, the timing analytics is a really critical component of your decision-making process. I know it checks a couple of

different boxes, but maybe you could talk about how you approach timing in general and just compare and contrast Delaware and New Jersey here for purposes of just wrapping up this Takeda scenario.

Omar Jabri ([14:26](#)):

Yeah. So I think here, it informs a decision because the longer it takes to a particular resolution, particularly time to trial, the more budget, legal budget, you may have to accord that case because there is just maybe a slower schedule. So my understanding in general is that in DNJ it tends to be a bit slower to get to trial because the district court judge is less likely to give you a comprehensive case schedule at the beginning of the case. It's more done as they'll give you intermediate milestones like conclusion of fact discovery, conclusion of expert discovery, before now setting a new milestone, including the trial schedule. Whereas in Delaware, you're given a comprehensive case schedule upfront and then the parties can seek to vary that schedule if issues come up. So if we look at the data here, and maybe you can expand your screen, Neil, just to get a better look. So, in Delaware, the time to trial on average is what?

Neil Magenheim ([15:25](#)):

732 days.

Omar Jabri ([15:26](#)):

Okay. And then we'll contrast that with the time in New Jersey.

Neil Magenheim ([15:30](#)):

910 days.

Omar Jabri ([15:31](#)):

Okay. So that actually aligns well with my instinct, is that the cases are taking longer to get to resolution and trial in New Jersey rather than Delaware, which is going to be a factor when it comes to making sense of, how long is it going to take us to get to trial, when we can see a trial decision, what impact, if any, does that have on the legal budget? So I think, again, it level sets your expectations going in so if management asks you, "Well, when are we thinking we're going to see the trial hit the books?" Just a budgetary question. [inaudible 00:16:07] because you can chug along at a certain clip during the case schedule, but then there's going to be a ramp up of spend when you get to trial. A basic question from finance and from the business is, "When am I going to now accrue that cost, that ramp up cost?" And then this data will give you a sense of when that's going to hit the books and when they should figure out how to smooth out the budget. So, it's very valuable information.

Omar Jabri ([16:33](#)):

Now, look, that also weaves into the decision to potentially challenge venue, because if you're in a big hurry to get to a trial based on your legal strategy, then you may want to force the issue and move out of New Jersey and move into Delaware. Now, in this particular case, we were blocked by a patent we were not contesting so it made less sense for us to move to change the venue because we were not in as much of a hurry. It's not like we had a race to get to market as of the trial decision. We were still going to be blocked by an intervening patent that was going to expire. So for us, it was a less relevant factor. But in some instances, if you're really in a race, in a foot race to the market, this data would make an important decision because you might be spending almost a year delayed in New Jersey relative to the Delaware faster schedule.

Neil Magenheim ([17:26](#)):

That makes so much sense. I mean, you're painting such a vividly clear picture of how to use the data and the real life use cases and how you can really get to these answers quickly, effectively, accurately. I can only imagine the pressure you get from your management, "Omar, how long has this case going to take? How much is this case going to cost? When are we going to start writing checks, et cetera? How can we most effectively leverage our outside counsel spend? Are we going to win this case?" It seems like those are the key questions that you're using Lex Machina to help your answer, which is fantastic.

Neil Magenheim ([18:01](#)):

Let's pivot quickly here. I readjusted my screen. We're looking at ANDA cases in New Jersey. Another interesting case that we talked about as we were preparing for our time together was a recent Celgene case where Celgene came after Apotex for potential patent infringement. There's nine patents in that portfolio, et cetera. And [Judge Wiggington 00:18:22] was assigned to that case. So my question to you is, how important is it and how do you use judge data when you're assessing litigation risk and informing your strategy, Omar?

Omar Jabri ([18:39](#)):

Yeah. So this I think ties into your query about the chances of success, which is paramount when it comes to... Because we have finite legal dollars. You have to bet on the products that you think has the best chance of getting to market. Not all cases are created equally. Not all cases are worthy of top tier counsel, top tier legal spend. So we have to place our bets prudently. So here, the data on the judges is going to be important because when a case is assigned to the judge, you actually need to look at the predisposition and the track record of the judge to find out generally the lean and the likelihood that she's going to entertain the type of defenses that you have. So here is a nice snapshot that is very user-friendly when it comes to the presentation to management if you wanted to use this just to find out, what cases actually go to trial?

Omar Jabri ([19:30](#)):

It seems like the vast majority of these cases before Judge Wiggington settle. So consent judgements typically indicate a settlement where there's a consent judgment agreed to by both parties. So you see that. You see settlement on the right hand side also being a large numbers. So that's 40% there, 20% on the consent judgment. Those are both, adding together, 60% of the cases will settle. Very few go by the way of summary judgment. So it suggests that probably an uphill battle if you were trying to win an early dispositive summary judgment before this particular judge. It might be challenging. Maybe you want to dig into the data more to find out why. When are you going to likely want to spend the money on a summary judgment versus maybe standing down and waiting for the trial, for instance. And then an actual snapshot of the wins and losses.

Omar Jabri ([20:23](#)):

Actually, it doesn't seem like there's any trial decisions. It seems like the majority of the cases are resolved before trial. So that's interesting because it'd be interesting to see how many patent disputes the particular judge actually handled at a trial. And that might be a conversation you would have with your local New Jersey counsel to find why it is that most of these cases seem to disappear before a trial.

Neil Magenheim ([20:54](#)):

Yep. That makes a ton of sense. Just very quickly, I'll scroll down here because just to magnify one of the points you said, I think you mentioned something like, what are the merits of those cases? What arguments were effective or not? As you know, being a user of Lex Machina, we build out these analytics, these amazing, insightful, actionable charts and graphs at the case level and in turn the document, doc, and entry level. So you can see, if I scroll down here, here are all 87 ANDA cases for Judge Wiggington. How important is it for you to have at the click of a button all those underlying cases so you can see the merits of those cases, how those arguments were framed, et cetera?

Omar Jabri ([21:37](#)):

Yeah, it's very helpful. But again, in the absence of this information, it would be a lot more work to get your arms around in all of the matters that relate to a particular product. If you go down, if we just select the Apotex case here, the Celgene versus Apotex matter, then we can drill down. What's nice, if you scroll down here, you'll see the snapshot of other patent enforcement activity, either in a district court or PTAB. And I find that to be very useful because you'll notice that here not all the patterns are being enforced equally across district court proceedings or in PTAB. So, again, it's probably beyond the scope of this webinar, but it's very informative to drill down as to why? Why is it that a subset of patents are being enforced against some of the generics and not others?

Omar Jabri ([22:25](#)):

It may be obviously driven by the legal strategy. It may be driven by the patents of the subject of the P4 certification. And then the PTAB activity I think is also very valuable because then you'll see at your fingertips, you can appreciate what's happening with PTAB activity. Somebody's taken a run at a challenge in the patent office. So I think that's where the data is also informative to understand the legal strategy and the likelihood of success. You'll see here that this particular PTAB proceeding, this IPR, resulted in a denied institution. So you can pull that information. You can evaluate to see if you want to change course. It's information that we use constantly to assess risk in a sense of legal strategy and we use it with outside counsel to ensure that we have all the information that we need to make a thoughtful decision.

Omar Jabri ([23:11](#)):

So this particular IPR was filed by Apotex. It led to denied institution. It wasn't successful. So, ultimately, it's all part of what we look at and evaluate carefully. And then I know you have an Orange Book tab, and I think it's also useful to see when and if patents in one particular set of patent cases on a particular reference product are enforced in a different set of cases for a companion drug. So you'll see here there's overlap. So if you're looking at the patent strategy, you would not just look solely at patents on the Orange Book connection with Revlimid. You would be able to identify that perhaps there's other patent cases on other active molecules that are held by that same brand that pertain to those patents to ensure that you have all that information available to your decision as well.

Neil Magenheim ([24:04](#)):

This is so great. We could spend hours on this, Omar. I love the way you frame it and position it. Thank you again for all those insights. One piece I wanted to share with the audience is, how do you go about using data to most effectively assess risk through the lens of who you're hiring from an outside counsel perspective? Let me just frame what we're looking at real quickly, then I'll let you speak to that. So one of the firms that Apotex commonly works with is Katten Muchin here, and you can see their data. And

we can see here there are 125 ANDA cases in which they represented the defendant. So I'll just tee it up for you here, and then, what are your thoughts on all the different outcome analytics that we could provide based on your outside counsel?

Omar Jabri ([24:56](#)):

Yeah. So this is useful because, again, not all cases are created equally and the choice of counsel bears into your legal strategy. Now, in some instances, a majority of these cases are such that there's a joint defense group amongst a number of generic defendants that are being sued at the same time, so they share resources and they're not running a case all the way to trial on their own. In other instances, you have a first to file opportunity and you're in the pole position when it comes to pushing the envelope on a legal dispute, and you may need to affirm that you believe it will take you all the way to trial. So what you would want to look for is, if you have a given case, and let's say it is a case where you have a novel strategy where you're not going to be part of a pack, but you're going to be a solo litigant, and you're likely to now need to go to trial, what's the confidence level of a law firm to actually handle a trial on their own against, unquestionably, a very strong plaintiff's law firm?

Omar Jabri ([25:53](#)):

So that's where I think [inaudible 00:25:54] come to fact, because, if most of their case is settled before trial, you may have maybe second thoughts or concerns about their ability to run the patent trial. But if they handle a lot of cases going to trial, you may have more confidence on the other hand. So to map out that decision-making I think is part of your assignment selection.

Neil Magenheim ([26:13](#)):

Yep. And you can see here, for example with Katten, of the 125 patent cases that we're looking at right now, 22 of them reach trial. So that's a check box for you?

Omar Jabri ([26:22](#)):

Yeah. You have more confidence that you're not going to be green or feeling that they're going to be outclassed by the brand's outside law firm at trial. There's a higher confidence level with that.

Neil Magenheim ([26:38](#)):

Got it. I hate to say this, Omar, but we're just about at our time. We could have spent a lot longer together on this really insightful, impactful discussion. And I can't thank you enough. We did have one question come in, and then I'll see if anything else comes in as I'm asking this question. How do you use data when collaborating with your outside counsel?

Omar Jabri ([27:05](#)):

I think, again, it depends on the legalization. Oftentimes, you have to make a call. Let's say, we want to bring a motion. Let's say we would bring a motion for summary judgment or motion to transfer venue or we want to do something with claim instruction, you want to understand, what's the track record for success in those contexts? So I think a lot of times what we do is we look at the data with a particular judge in a particular district court to understand in some instances, district courts or judges don't like summary judgment. So that'll be born out by the data. Or they don't like hearing certain types of motions or the track record is not very strong. So we'll look at that. I think we just need to understand, before you make a legal decision that incurs spend, understand the options, the pros and cons thereof,

so it's really, data-driven, it's not just gut feel. Now, gut feel is important, but sometimes gut feel is also driven by the data as well.

Neil Magenheim ([27:58](#)):

Wow. Thank you, Omar, for that. And thanks again for your time, support, your preparation, and participation, Omar. It really means a lot to us and our audience. With that, I say thank you to the audience. And this does conclude our webcast for today. Thank you.