Medical device litigation trends in Canada and the U.S.

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At BLG's annual medical device webinar on Nov. 28, 2022, BLG product litigators Keegan Boyd, Josiane Brault, Beverley Moore, Edona Vila, and Glenn Zakaib were joined by Lana Varney from King & Spalding LLP to discuss the current state of medical device litigation, considerations for handling medical device claims in Canada and the U.S., and predictions for future trends.

The current state of medical device litigation in Canada and the U.S.

In the common law jurisdictions, we continue to see lawsuits being filed against medical device manufacturers and distributors across the country as both class actions and individual claims.

Ontario has historically been one of the main jurisdictions where class actions are commenced. Given recent changes to class proceedings legislation, including in Ontario, we are seeing class actions move towards provinces with more favourable class actions legislation, such as B.C. and Québec.

Québec is a leading market for life science and biotech companies in Canada, which may be a reason for the ongoing life science litigation in the province.

In the U.S., medical device liability litigation is in a slightly different state. For the most part, claimants do not seek class actions for medical device personal injury claims in the U.S. thanks to successful arguments by the defence that there is no common injury, given the diverse medical histories of claimants.

U.S. medical device claims are often advanced under what this known as the **multi-district litigation model** (MDL model). This means hundreds or thousands of cases will commence in multiple jurisdictions before being consolidated in a single jurisdiction for pre-trial procedures, such as discovery or preliminary motions. The numbers of individual claims in the U.S. significantly exceeds what we have seen in Canada. For instance, one recent MDL involving medical device manufacturers grew to about 150,000 claims.

The term ‘mass tort’ refers to lawsuits that effectively pool together a group of plaintiffs, by combining the cases of many different claimants who are advancing claims against the same defendants. While mass tort litigation is a relatively new phenomenon in Canada, it has grown exponentially in the U.S. One notable factor leading to mass torts in the U.S. is the non-stop advertising, especially on social media, that enable potential claimants to sign up with a simple click of a button.

The U.S. is also seeing an increase in the number of mass tort claims funded by venture capitalists and other litigation funders. These litigation funders are becoming extremely sophisticated at spreading litigation around the world, typically starting in the U.S. and moving to Canada and other jurisdictions, such Australia, South Africa and the U.K., where the evolving legal systems are now more favourable to advancing these types of claims.

Is there a shift from class action to mass torts in the context product liability claims involving devices in Canada? What does this mean for companies preparing for these kinds of claims?

In Canada, we are starting to see a trend towards a mass tort style of litigation, but we are still about 10 years behind the U.S. In the Canadian common law jurisdictions, we are seeing plaintiffs’ firms that would typically be commencing class actions, advancing a large number of individual actions in more of a mass tort approach.

We do not currently have MDL legislation in Canada, but we are seeing some cooperation between counsel in advancing mass torts for reasons of efficiency. Canadian firms often take the lead from counsel south of the border who are managing similar disputes so as to avoid duplicating efforts.

Prosecuting and litigating medical device patents

In Canada’s smaller market, it is rare for patents to be litigated here and not outside of the country. As a result, it is critical that strategy is consistent globally.

Canada’s discovery requirements are significantly smaller than the U.S., so, we can typically start with the U.S. discovery documents to reduce workload and give the other side only what’s relevant in the Canadian context. Patentees should waste no time in mapping out their litigation strategy with inventors and experts.

Québec perspective

Québec law favours consumers. This means manufacturers face an increased risk of litigation. Pharmaceutical and medical device manufacturers are subject to a rigorous contractual regime that applies to safety defects and guarantees of quality.

We always recommend **disclosing all material risks to consumers/patient** . Like other jurisdictions in Canada, it is up to the treating physicians to **obtain the patient ’s informed consent** after disclosing all inherent risks.

In litigation involving a manufacturing or safety defect in Québec, it is similarly important to **join forces** with other defendants in defending a plaintiff's case. The law is already on the plaintiff's side in Québec and you do not want to strengthen their case further. Joining forces also enables some efficiencies, such as sharing the cost of expert witnesses.

We also recommend coordinating the defence with those defending similar actions in other provinces and the U.S. and ensuring clients engage experienced counsel who are familiar with cross-border issues.

Tips for joint defence agreements

- **Finalize agreements early on** with the co-defendants or other parties that may be future defendants.
- **Make sure all defence counsel is hinged at the hip**, as plaintiff's counsel in the U.S. has learned how important it is to stay unified.
- **Start with the company's end goal**, then work backwards to map the strategy to get there. If your client is not the target, you may want to avoid agreements that would require significant time and expense.

Overall medical device litigation trends

Both the U.S. and Canada have unique issues that should be monitored to mitigate risk and achieve better outcomes in medical device litigation.

U.S. trends

- **Sophisticated litigation funders** are spreading potential risk across global jurisdictions, including Canada.
- **Claims are shifting from "failure to warn" to "design defect"** because of the cap on damage awards against doctors and the increase in doctors paying for their medical records.
- **More sophistication of the plaintiffs' bar**, including using the media to spread misinformation.
- **Regulatory agencies around the world may break from the FDA's approach,** and the plaintiffs' bar may exploit those differences in global litigation.

Canadian trends

- **Mass torts are becoming more common** and the added complexity of these proceeds will be top of mind for both counsel and clients defending these actions.
- Use of **social media advertising** will likely impact the medical device litigation landscape in Canada.
- **Increased reporting of medical device issues** by manufacturers and healthcare institutions could lead to more product advisories, product recalls and potential medical device litigation.
- **Potential harmonization of digital health regulation** with AI regulatory framework may well add an additional layer to emerging connected medical device litigation.

Get in touch

Medical device litigation changes are happening quickly on both sides of the border. Although Canada is still behind the U.S. in some respects, we can use trends in the U.S. to predict developments in the legal landscape in Canada.

If you are developing a product, looking for a disputes or risk management strategy, or interested in chatting about any of the topics covered by our panel, please reach out to any of the key contacts listed below.

**This webinar recording and transcript are available in English only.*

Read the full transcript here

Glenn Zakaib

Welcome and thank you for joining us at BLG's annual medical device webinar, which is a forum for our lawyers and clients to discuss medical device law and related trends. At BLG, we combine our long-standing tradition of healthcare and life sciences expertise with our product liability bench strength to represent national and multi-national device manufacturers, suppliers and healthcare organizations in regulatory and litigation matters. At this year's webinar, my colleagues from Toronto, Ottawa and Montréal, and our guest from Texas will zero in on practical perspectives on the state of the law and recent trends in respect of medical device litigation. So let me introduce you to today's panel, the speakers we have for today.

Edona Vila is a partner in the Toronto office of BLG. Edona's practice is focused on both regulatory and disputes matters involving product liability in relation to healthcare and life sciences products, including medical devices. Edona is going to be your moderator for today's panel.

Our guest from Texas is Lana Varney. She's a partner at the firm of King and Spalding in Texas. Lana is a renowned trial and global disputes lawyer with a specialization in drug and medical device product litigation. Lana currently serves as national counsel for several international companies defending drug and medical device litigation, and we're very fortunate to have Lana here today with us.

Josiane Brault is a partner in our Montréal office at BLG. Her practice is focused on litigating healthcare and produce liability disputes including in respect of defensive claims involving alleged medical device defects.

Keegan Boyd is a partner in the Toronto office of BLG. Keegan's practice is focused in healthcare and life sciences regulatory litigation matters, including medical device pre-litigation and litigation matters.

Last but not least is Bev Moore. She is a partner in our Ottawa office at BLG and national leader of our IP litigation. Bev is an IP trial lawyer with a focus on patent

infringement cases. And with that let me turn it over to Edona Vila to lead us through the panel discussion for today's session. Thank you.

Edona Vila

Thank you Glenn and thank you everyone for joining us today for this discussion on medical device litigation and will cover both product liability and also IP issues specifically, because we've got one of our IP litigators in the panel here. As part of our panel discussion today, we'll explore three main themes; the current state of medical device litigation, litigation strategies and tactical considerations in handling medical device claims. And third, we'll get into some horizon scanning that perhaps some of you may actually find of interest to more of a trends discussion. So, without further ado, let's tackle the first bucket with our panel. I'll turn to two of our panelists, Keegan and Josiane. Keegan to cover the common law perhaps aspects of this and Josiane to cover the civil litigation piece, the Québec piece. Always troublesome for a common law lawyer to even refer to la belle province. So there we go. What are some new case developments nationally, Josiane and Keegan that are instructive on the management of device litigation in Canada?

Keegan Boyd

Thank you Edona and Glenn for your opening remarks. I'll start by providing an overview of some of the common law case developments. So, as many people on the call will know, Canada has a thriving medical devices sector. Our market is valued somewhere in the realm of $8 billion dollars U.S. And more than a third of Canada's medical devices are supplied by the U.S. so I am also very grateful that Lana Varney is here today to share her views on managing medical device disputes in the U.S. and globally because it does impact a lot of what we do in Canada. In Canada, in the common law jurisdictions, we continue to see lawsuits being filed against medical device manufacturers and distributors across the country both by way of class action and individual claims. A few notable examples: there was a class action commenced in B.C. against the manufacturers of surgical staplers alleging both product defects and failure to warn of increased risks of complications. We saw in recent years a national class action commenced in St. John's, Newfoundland on behalf of patients alleging harm as a result of toxic foam in CPAP and BIPAP machines following recalls of those devices. We also saw a related proceeding commenced in the federal court in Ontario on behalf of consumers alleging that the manufacturer of those machines knew or ought to have known of the alleged defects prior to selling them to consumers. Given recent changes to class proceedings legislation, including in Ontario, how we are starting to observe a trend of class actions moving away from Ontario, which has historically been one of the main jurisdictions in which these are commenced. Class counsel are tending to prefer provinces with more favourable class actions legislation such as B.C. and Québec. Despite the judicial slowdown throughout the pandemic, we have continued to see some class action against medical device manufacturers being certified. So one case in particular I'll highlight was certified in May 2021 in relation to a medical device used during open chest surgery at a number of hospitals and health institutions across Canada. The common issues in that case included whether certain bacteria was present at the manufacturing and testing facilities. Whether the defendants were negligent in the design, manufacture, testing or distribution of the device. Whether the defendants had a duty to warn. And also whether the defendants ought to have recalled those devices that were contaminated or potentially contaminated. We also saw the divisional court in

Ontario reverse a lower court decision that had denied certification outright in relation to a proposed class action relating to medical filters designed to prevent blood clots from reaching the heart and lungs. And what was interesting about that case was the divisional court agreed with the lower court's decision not to certify the design defect claims. But the divisional court reversed the lower court's decision and certified the failure to warn claims. And in that case, they noted that there were product advisories that had been released after the relevant instructions for use and those advisories in and of themselves provided some basis in fact but the earlier warning in the instructions for use or IFU's were deficient. In that case the divisional court expressly noted the low bar that exists for finding that the duty to warn is a common issue. Well, some proceedings, like the ones I'd mentioned had been certified, we've also seen some cases go the other direction. I'll highlight one in Saskatchewan, a late November 2020 decision, the Queen's Bench for Saskatchewan declined to certify a proposed class proceeding involving allegations that a contraceptive device was associated with bleeding, bloating and other side effects. The lawsuit in that case alleged that there was a danger posed to women, either due to a faulty design or a failure to train physicians who were inserting those devices. In that case, the court implemented the test from the Supreme Court of Canada in the process and Microsoft case regarding evidence. And in order to be certified, the evidence must offer a realistic prospect of establishing loss on a class wide basis. It cannot be totally theoretical or hypothetical but must be grounded in the facts of the particular case in question. And what was interesting in that case was the Plaintiff's expert relied solely on a review of scientific literature whereas the defendant's expert had extensive experience using the actual device in that case. And so the Queen's Bench found common issues did not predominate over individual issues and a class action would not be the preferable procedure. We've seen a number of settlements. I won't give a big review but lots of medical devices and hip implants, transvaginal mesh, storage tanks used to store frozen embryos and while there are fewer reported decisions in Canada over the last few years, likely the result of the pandemic, we can tell from what has been filed and what has been decided, that medical device litigation is alive and well in the common law jurisdictions. And with that I will pass it over to Josiane to share her perspectives on the civil law in Québec. Thank you.

Josiane Brault

Thank you, Keegan. I am pleased to provide the Québec perspective. As many of our clients in attendance know, Québec is a leading market for live science and biotech companies in Canada. This may well be a reason why we continue to see ongoing life science litigation in Québec. There are some interesting statistics to review. While the number of new applications for authorization to institute class actions dropped in Québec in 2021, there is plenty of activity before the courts. Just last year more than 200 authorized class actions were active before the Superior Court of Québec. The highest number ever which is a sharp increase over the several years. Unfortunately, while I don't have a specific statistic on the proportion of such case involving medical device, class actions continue to be an area of liability risk for medical device stakeholders. In Québec, in terms of recent instructive case law in the management of medical device litigation matters, we have to look a little into the recent past. Like Keegan said, recently we had a lot of settlements out of court and very few decision on the merits. But as of 2 years ago in Québec, we were not completely sure of the reliance one could make on the learned intermediary doctrine. However, it was confirmed in 2019 by the court of appeal, in the context of a pharmaceutical case, that the doctrine is

alive and well in the province of Québec. This is a welcome decision for the medical device sector as it is a helpful defence to assert in attempting to disclaim liability. Also, I would like to briefly mention that we continue to see individual actions commenced by Plaintiffs who allege harm in relation to the use of medical devices. The victims often institute legal action against hospitals, doctors and manufacturers directly. We will talk about it later but this is the reason why it is important to work with the co-defence and make sure we are strategists towards the Plaintiff.

Edona Vila

Thanks Josiane. That's very helpful. Now I wonder, I wonder perhaps we can switch gears here because we're lucky to have Lana with us. From your experience as a trial and global disputes lawyer, Lana, litigating and managing litigation across different jurisdictions, what is the state of medical device liability litigation in the U.S. that perhaps is helpful in terms of what the developing here in Canada?

Lana Varney

Thank you Edona, thank you Glen for those nice words. It's a pleasure to be with you guys. Welcome or greetings from Austin, Texas. I'll just rub it in, it's a beautiful 75 degrees Fahrenheit today. The state of medical device litigation in the U.S., its fun listening to Keegan and Josiane about the status of class actions in Canada. We here in the U.S. continue to think that our class action practice has evolved maybe 5-10 years from where it is in Canada. That is to say, for the most part, claimants do not seek class actions for medical device personal injury claims. The defence has been quite successful in being able to argue that there is no commonality amongst the injuries, amongst the claimants because of the diverse medical history that they each will have. Additionally, the learned intermediary defence makes a very strong argument that doctors perceive and receive information from many sources. In the United States, of course, our law says the duty for medical device companies only flows to the prescribing physician, not to the end user. And so, if we can get the doctors to say that they received that information and learned it from other places, like medical school, scientific journals, then that defeats the class. We do see class being used for settlement purposes. Mainly for the ease of processing that type of class. But we're certainly seeing an increase in the number of claims and its generally in the form of a mass tort, as we refer to them. I call them now massive torts with the infusion of venture capital or litigation funders putting money into the hands of what I refer to as aggregators. These are the lawyers who can't fund litigation on their own and so they do rely upon the VC or the litigation funders. I've heard them often say that they can, with one phone call, get $100 million dollars from one of these venture capitalists. Again, the non-stop advertising, people will respond. They do no screening of the respondents, they just sign them all up, file them, because it's a numbers game, where they try to increase the number of cases so that they can put maximum leverage on the companies to try and settle before litigation is pursued. So we are continuing to see the infusion of this great amount of cash by these litigation funders because they continue to believe it's where they'll get their highest ROI. It's not going to be in real estate. It's not going to be in the stock market. It's going to be in U.S. litigation. And then they're getting extremely sophisticated about trying to spread the litigation around the world. As I like to call it, its viral litigation. So it typically starts in the U.S., spreads north to Canada and then lately now to Australia, South Africa and the U.K. a little bit as those systems continue to

evolve and allow for these personal injury type claims. Does that provides some information….

Edona Vila

Wow! I know, its astounding the dollar amount that you cited. Thank you for that, Lana. We'll move to Bev now from products to product litigation in relation to device claims to IP claims. Is the landscape different at this stage in respect of IP litigation Bev, involving medical devices? Not sure if you can offer any comments there in terms of where we stand now.

Beverley Moore

Sure. Practically speaking, historically we haven't seen a whole lot of IP litigation involving medical devices in Canada. But recently this seems to be changing. In the last 3 to 4 years, we've seen a case involving auto injectors like those for epinephrine where the patent was found invalid and that was upheld on appeal. We've seen a case involving those rollators, the wheeled walker type devices where again, the patent was found non infringed on appeal. And then in a third case, it involved an osmometer where the federal court held the patent to be obvious and then this was also upheld on appeal. I think part of that, one of the most recent decisions might have been in 2008 relating to a stent. I don't think it's a reflection so much on the Canadian courts that all of these cases were unsuccessful for the patentee. The courts do tend to be quite fair when it comes to infringements and validity issues, in all areas frankly. I do think that some of the sift in terms of increasing the amount of litigation might have come from changing trends in the federal court. It used to be that cases would take upwards of 10 years to get to trial and this was just exorbitantly expensive for anybody involved. Like nobody has the time or the patience, except for perhaps pharma companies, to deal with you know 10 or 12 year timelines to trial. And now the courts indicated that it will set a trial date within 2 years if you ask for it. And you will, like even if you don't push for a 2 year trial date, most get a trial date within 3 years. So it's a great reduction in the length of time to trial. We've also seen some real changes that allow for increased use of summary trials, which are sort of a version of summary judgment motions where the expert gets to be cross-examined live in front of the trial judge. The trial judge likes that opportunity to ask the expert questions and get things for themselves. So that's really where we are in the IP landscape I think.

Edona Vila

Thanks Bev. Now's actually a really good time to switch gears to practical litigation strategies and perhaps on the technicalities of defending some of these claims. We'll turn to my partners Keegan and Josiane again. Picking up a little bit from the discussion that we had with Lana in our first segment; Lana, I'm going to borrow this as in use this term from now on, the massive torts. Mass torts kind of move that we wanted to hear from Keegan and Josiane more in terms of whether that's sort of the trend that we're seeing here in Canada a little bit. Perhaps as a result of these viral litigation as you call it. Keegan, Josiane, leave it to your discretion, whoever wants to respond first from a common law and then civil law perspective. But have you noticed a shift from class action to mass torts in the context product liability claims involving devices? And if so,

what's contributing to this trend and what should companies do to better prepare for the management of these kinds of claims?

Josiane Brault

I can answer first because my comments will be brief. So the exception, Edona, to this trend, is probably Québec. Because as of today, we have not seen this phenomenon. We don't know what will happen in the future but I doubt that this trend will be followed in Québec. Why? Because Québec is generally regarded as a more friendly jurisdiction for the certification of class action than the common law provinces. And also in Québec we have this first to file rule that avoids class action carriage fights among Plaintiffs firm then provides greater certainty to the first firm to seek authorization as to which action will move forward. So maybe Keegan you have more details to provide us regarding this trend.

Keegan Boyd

Sure. I like Lana's analogy that we're sort of 10 years behind on the class actions front. And I feel like we're probably 10 years behind in the mass tort front as well. But I would say that we are starting to see a trend towards more of a mass tort style of litigation. By way of background for people who aren't familiar with the U.S. model, in the U.S. medical device claims are often advanced under what this known as a multi-district litigation model or the MDL model. So thousands or often tens of thousands of cases will be commenced in multiple jurisdictions in the U.S. They'll then get consolidated in a single jurisdiction for pretrial procedures such as discovery or preliminary motions. There is legislation to facilitate that process and often it leads to bell weather trials or test cases that then help to determine the fate of all the cases to follow. If those other cases don't get settled or dismissed, then they would get referred back to their originating jurisdiction for trial. I may be oversimplifying things so Lana, by all means sort of clarify the process if and when that makes sense. In Canada… Sorry, did you want to say something now Lana?

Lana Varney

No. I said you got it right, for the most part. Yep.

Keegan Boyd

Perfect. So in Canada we are seeing efforts by the Plaintiff's bar, and I guess I'll have to say in the common law jurisdictions, since this phenomenon doesn't seem to be taking place in Québec. But we are seeing Plaintiff's firms that would typically be commencing class actions, commence a large number of individual actions. And we suspect the reason for that is in part because the class certification test is becoming more difficult in certain provinces. And likely also, Plaintiff's counsel here are realizing some of the same challenges that their contemporaries south of the border faced a decade ago. While its still early days for the mass tort approach here, it does seem that, as I was saying, Plaintiff's counsel are commencing lots of actions, sometimes in multiple jurisdictions and we haven't yet seen how those cases are going to work their way through the Canadian courts. We don't have this MDL legislation that they have in the states and so, you know, we're sort of left, as counsel, to craft the process a little bit. We see Plaintiff's

counsel looking to choose cases to advance more expeditiously as test cases. In some cases we see Plaintiff's counsel requesting case management of a group of cases and often times, we're seeing defence counsel agreeing in some respects because the cost and inconvenience of trying to defend tens, hundreds, in some cases thousands of cases, is a burden in and of itself. And so I think that what we're going to see, absent some legislation introduced in Canada, is sort of more co-operation between counsel in figuring out how to advance claims in this mass tort framework that seems to be coming up more and more in Canada. I think you know I can talk a little bit more about the pros and cons of that but I think it would be interesting Edona, to hear from Lana on some of the strategies that exist. Because one of the things that we often do in Canada is look to counsel south of the border managing similar disputes and take our lead from them so that we're not duplicating efforts. It's more economical for her clients. And so really Lana, I'd welcome your views on sort of this trend in Canada and sort of what you see in terms of you know, co-operation north and south of the border.

Lana Varney

Well your description of the appeal process is spot on, Keegan, and I am hopeful that it will stop at the border and not spread north. However, we have seen it get abused, in my defence counsel opinion. Because lets take for example the mass litigation, that litigation was put into MDL. Each manufacturer had its own separate MDL and it grew to 150,000 claims in the United States. One of the Plaintiff's lawyers stood up and told the MDL judge that in his estimation, 80% of those claims were not of merit, which is just astounding when you think about it. Again, the non-stop advertising while I do fear that it is going to ooze on into our northern border is because the place where they like to advertise the most is social media. I've been told it's 500 a click to sign up a potential lead that is supposedly vetted by the websites that are posting these things. That is definitely leading to massive tort. We saw it in the 3M earplug litigation similarly. There the MDL judge started a shadow docket. So in the MDL process, Plaintiffs don't have to file a filing fee which does explain it down too much anyway it's about $400 here in the U.S. But we've seen many of the MDL judges begin a process of setting up a shadow docket so it's for those claims that have not yet been vetted but they'll be part and then in case there is some reason to activate them, they'll be moved over into the active MDL. This has led to great abuse, as you might imagine, and thus there's great scrutiny in our MDL process to explore ways to try and address some of the abuses. What we do see is these MDL lawyers definitely reaching out to counsel in other countries and in particular Canada for support because what they're looking is inconsistencies in companies in terms of how they market their device, how the device was brought to the market, inconsistencies in the IFUs that accompany the devices, and those are the places where the Plaintiff's bar likes to try and exploit those differences. Well if you felt that the Canadians warranted a warning on such and such, why wouldn't you feel like Americans get the same warning. But interestingly enough, and I was going to go back to this, Keegan, what we are seeing and I think we've seen it now in several of our MDLs, is the shift away from a failure to warn claim to a design defect claim. When I was a baby lawyer, the number one cause of action was the failure to warn cause it's so easy to just through a whole bunch of mud on the wall, try and drive up the sympathy for the injured Plaintiff and then juries would respond to that sympathy. In the most recent MDLs, within the last 5 years, we have seen it switch from a failure to warn to a design defect claim and the Plaintiffs are now focusing on the type of materials used for the medical device, are they biomaterials that are compatible, also they look is there a safer alternative design. They'll find anything to say a safer alternative design including they'll

use it. So it's interesting and they've been ringing the bell with these design defect claims as apposed to the failure to warn claims. Last but not least I would say in terms of how to try and address it, number one is alignment across all fronts. I continue to see how critical that is. You need to have a strategy that crosses all borders and coordination with all counsel who are representing the company in every country and of course laws are different, the various IFUs may well be different for different reasons but getting that alignment up front is just critical in terms of not creating more discrepancies that the Plaintiffs can take advantage of.

Edona Vila

Very helpful, Lana. Thanks so much for those comments and underscoring the importance of alignment across jurisdictions as we see time and time again that it's really important in ensuring that certain jurisdictions don't take an inconsistent position that hurts the company elsewhere around the globe which is really helpful in our case, in our jurisdiction, cause we're often directed by US counsel like you who are really the lead when it comes to the global litigation strategy. So we'll switch gears in terms of perhaps on some winning strategies when it comes to prosecuting and litigating medical device patents. Bev we'll turn to you for some comments there.

Beverley Moore

Sure thanks. I think I have to echo what Lana said about alignment across all jurisdictions, it's where in Canada we recognize by the smaller market so it's rare that patents are litigated here and not elsewhere so I think it's critical to make sure that we've got that strategy that is being maintained across the world. We also typically rely on a smaller subset of the U.S. discovery documents. Our discovery requirements are much well significantly smaller in the Canada than they are in the U.S. so we can typically start with a set of discovery documents in the U.S. and use that as our starting point to shrink it down and give the other side only what's relevant. In terms of other strategies for IP cases, as the patentee I think it's important that you sit down early with your inventors and your experts in order to map out that strategy. The Canadian judges really like to hear an invention story when it comes to the development of the thing that you got the patent on so they like to hear from the inventors as to that whole story behind the invention. So you want to make sure that what the inventors say aligns with the expert opinion that you end up having to defend the validity of the patent because again the other side will look at all the discrepancies between those two parts and then compare to what goings on in the U.S. and in other jurisdictions. It's also pretty common for the experts to be the same across all jurisdictions. The Canadian courts don't show a preference for a Canadian expert as long as the expert has the right expertise they'll be fine coming in. On the medical device side, it's not always as clear cut who is the innovator and who is the, you know, generic the way it is in pharma right so you end up with device companies on both sides of the litigation. So if you're the alleged infringer, you wanna be also spending time with your experts early to map out that invalidity allegation so that the appropriate document requests can be made. You wanna make sure that you're getting everything that you need in order to make your allegations. And then you know other than that, the typical regular litigation strategies apply right like don't get bogged down on the leaves, on the trees, make sure you're advancing the strongest arguments. Make only the procedural challenges that are necessary. You don't want to waste time with the unnecessary ones and personally, I find it's always better if you can maintain a cordial relationship with opposing counsel. So you fight

about the case as opposed to fighting about the little things that don't really matter at the end of the day.

Edona Vila

Good well picking up on these nuggets of advice I'll turn to Keegan, Josiane and perhaps Lana too. Often times in medical device litigation claims especially the massive claims where you have Co-Defendants involved and you're sometimes tied to the hip where it makes sense to actually put together joint defence, formal joint defence agreement and work then very much in close collaboration to advance the Defence position. In the cases you've handled, perhaps maybe you can help me and then the audience here on sort of some of the key takeaways how to best advance the Defence's position in working jointly with friendly or apparently friendly Co-Defendants in such arrangements in terms of class actions or even in massive torts.

Keegan Boyd

Sure I can start off on that one and I know that Lana will have some great points to add since I think this was her topic at a recent seminar I attended in the U.S. so I won't steal your thunder. But from the Canadian perspective, just a couple of comments. So first of all, I think in Canadian cases often times we're not seeing all of the relevant parties named for whatever reason and so I think one thing that counsel should do when they are engaged in a new case is really turn your mind to "are there any other parties that should be involved" and identifying them early on whether it's other distributors in the supply chain, you want to understand how it is that the device that that issue came to be sold, where it was used and used where it was used. We have seen and again in Ontario but some recent Court of Appeal case law dealing with what are called "litigation agreements" and there's developing case law I would say where parties to litigation need to immediately disclose agreements between parties to a lawsuit that have the effect of changing the adversarial position of the parties as set out in their pleadings to a cooperative one. The cases that are being reported tend to be when you have a Co-Defendant who changes side, so to speak. They used to be adverse to the Plaintiff but they've reached an agreement behind the scenes, now they are helping the Plaintiff and those have been certain the subject of these recent cases but the language that the Courts are using is very broad and could easily taken to apply to Co-Defendants as well. So, I think the key takeaway from that developing jurisprudence in Canada is, think about it early on and if there's an advantage to entering into a joint defence agreement with the Co-Defendants or other parties that are not currently Defendants but may be later, think about that early on and maybe finalize those agreements early on and decide "are we advancing cross-claims against one another or are we gonna keep that all off the table and deal with it sort of behind the scenes". What I worry about is that there's gonna be significant agreements finalized after pleadings that are then going to be subject to production by virtue of this developing line of cases in Canada.

Edona Vila

That law by committee is always interesting from my experience in joint defence groups but Lana I'll pass it on to you for any comments. You had a great presentation on this at the DRI (Drug and Medical Device Litigation Seminar) early on.

Lana Varney

Yeah thank you. I wrote a paper with one of my brilliant associates – be glad to share with anybody who might want to see it because the law in the U.S. is very unsettled in this area. You know I start with the premise that it's always best to stay hinged at the hip amongst all defence counsel. Plaintiff's counsel is very keen in trying to divide and conquer so if they can wedge something in between the Defendants and get one to turn on the other, that's their payday. So very important to try and stay aligned at the hip or hinged at the hip. However, it's often challenging particularly if the devices are still on the market in your active competitors. So those relationships need to be managed carefully. But in general, all defence counsel do recognize there are certainly some common ground that we can all present as a unified front in to try and keep our distinctions where we need to for later on in the process. The MDL process in the U.S. has certainly allowed the Plaintiff's counsel to learn how to stay unified. Part of that process as Keegan was explaining allows them to form committees and combine resources to pursue a Defendant so that means in terms of discovery, in depositions, all of those things. They've learned very well how to play well together in the sandbox and even marginally better how to reach out to other counsel in other countries to see if they can export some of the discovery that they do acquire in the U.S. to pursue claims just like you're talking about like the IP claims or government investigations or any type of kerfuffle that they can stir up in any other part of the world to try and put maximum pressure on the companies to try and settle litigation as opposed to fight its merits. So there is joint defence agreements or fraught with peril, I typically like to keep them oral because of it but there's certainly great law in the U.S. which encourages you to think about putting them into writing but like I say they have long tails that can come back and bite you where you least expect it so. Staying coordinated is essential. You know often one of the other major goals that we start with is what is the company's end goal and then work backwards to map out the strategy to figure out how you can achieve that end goal. In terms of global litigation or viral litigation, it may well be that you want to contain it early on and so strategic settlements in the right venues may be strategically advantageous play to try and stop the further spread across the borders. But once those Plaintiffs get our discovery, I mean we've seen it particularly discovery against J&J in the Mesh litigation took it over to the UK, got a special hearing in front of parliament where they could display some of the internal memos and documents that they had obtained in the discovery in the U.S. to stir up government investigations and regulatory evaluations of Mesh in the UK. Just one example of how the coordination amongst the Plaintiff's bar is very well coordinated, I think they're quite ahead of us in terms of the Defence bar recognizing the value of staying coordinated.

Edona Vila

Very helpful comments. Josiane, I'm not sure if perhaps your experience in Québec in jointly defending different cases, if you have any comments on that before we move on the last segment.

Josiane Brault

Yeah well I would like to talk a little bit about our specific regime in Québec because, as you probably all know, the laws are especially favourable to consumers in Québec meaning that manufacturers face an increased risk in litigation and also pharmaceutical and medical device are subject to an extra contractual regime specifically applicable to

safety defect and contractual regime such as a general regime relating to contractual undertakings and a specific regime relating to the guaranty of quality. So, Plaintiff often benefits from what is known as the presumption of liability in Québec. Therefore available defences in such circumstances when the burden shifts to the Defendant include that for example the Plaintiff knew or should have known of the defect or could foresee the injury. This is why it's always suggested to disclose all the risks and in the case of specific surgery involving the use of a medical device, it is up to the treating physician to obtain the patient's consent by making sure to disclose all inherent risk. Other defences available include the contributory negligence, for example, the Plaintiff may fail to use a medical device in accordance with the manufacturer's instructions and the recommendation of treating physician. The manufacturer could prove that the industry knowledge at the time could not have detected the defect but the Defence is subject to the duty to inform clients upon becoming aware of the defect and also the injury results from superior force. But in litigation involving a manufacturing or safety defect in Québec, it is important to join forces also to defend a case if you have the opportunity to do so as not to add to the Plaintiff's case which is already in a strong position because of the law in their favour here in Québec. So what we often do in defending theses actions is that we share, for example, our expert reports between the Defendants before providing a copy to the Plaintiff. If the expert reports are not necessarily favourable to the Defence, we will use them to have discussion between us, between the Defendants in the determination for example of the potential share of liability between the Defendants but we will make sure not to share our expert report with the Plaintiff. In addition, when possible for example, when it comes to the determination of the value of the damages, it will be also useful to join forces and share the cost of defending experts in this field. And, even if we have a different system of laws in Québec, we have to coordinate with the other provinces and also with the U.S., it is really important. So, I know Lana that you're dealing with some cases in Québec, so do you have anything that comes to your mind when you think about handling those medical cases in Québec?

Lana Varney

Yes, call you. I really am very serious actually. It was fabulous working you Josiane.

Josiane Brault

Thank you Lana.

Lana Varney

Absolutely, that's one of the first things I would absolute recommend to a client is the attention of experienced counsel who are familiar with the cross border issues and getting that network of lawyers who are familiar with it, how the Plaintiffs bar coordinate, is very very helpful in terms of coordinating. I enjoyed hearing you talk about how you shared defence in Courts, we sort of do it the other way around in the U.S. We'll share information about the Plaintiff's experts and share their expert reports. Typically in these massive torts, Plaintiff's part "will use the same experts", I'm definitely putting air quotes around those words. We always start in our MDL process with the science day where we try and challenge the alleged expertise of the Plaintiff's experts and to be successful in bringing dab or challenges as we call them or whatever applicable law there might be

on a state level is sharing information about what they said in the past at prior depositions or prior expert reports and then coordinate amongst the defence bar to figure out ways to tear them up.

Josiane Brault

Very important.

Edona Vila

Always fun though, always fun. We'll move on to, to perhaps, I'm looking at time. We'll move on to the last segment of our discussion today and to the extent I'll issue a reminder for those in the audience there is a Q&A tab, so if you have any questions, feel free to add your question in and to the extent we don't get to the question if we finish close to time then we'll be sure to be in touch with a response. But on the last piece, we wanted to do a little bit of a sort of a trend discussion, a bit of a horizon scanning if you will. I'll pass it on to, we'll start with Bev this time, on the IP side and then we'll move to the product liability litigation piece and perhaps product litigation. But Bev, what hot buttons sort of issues have you seen or are you sort of monitoring or should be monitored to assist companies with risk mitigation and better outcomes in litigation when it comes to the medical device industry?

Beverley Moore

Sure, thanks Edona. I think because we've had this rule change that's allowed for more summary trial motions, this is something that counsel should seriously consider early on and it's a change in practice because if there is an opportunity that summary trial on an isolated matter it could get rid of things or streamline things moving forward to trial in a very easy way. We also have the opportunity in Canada to advocate the images from liability issues in continent country cases so that can be helpful just to again it streamlines discovery people aren't worried so much about money and they are focusing on the liability first and then often you can settle the liability issues, sorry the damages issues once, once liability has happened. We just also recently had a Supreme Court decision on accounting of profits which it's still all very new but it sort of narrowed what could be used as a non-infringing option considered by the Courts when determining whether like how to make that accounting a profit so we have an account as an alternative to damages as one of our statutory remedies for patent infringement. And then I guess finally there are some copyright amendments right now that are before parliament that they have to do with the right of repair and there is a potential for that to affect both patent infringement, copyright infringement litigation as well as on the product side so.

Edona Vila

Helpful, well thank so much Bev. We'll switch gears perhaps we'll go back to Lana on the U.S. and then we ground back for the Canadian trend piece with Josiane and Keegan. Lana, any sort of comments on sort of these the latest and the greatest what should folks sort of pay close attention to.

Lana Varney

I think I'll focus on three things and sound a bit like a broken record. Number one is the litigation funders. I think we're going to see them get more sophisticated. I'm working on a litigation right now where I've had the unfortunate pleasure of learning more and more about their business model, these funders will take a pool of money, do the advertising, collect the cases and then farm them out to generally somewhere between 10 and 15 different law firms. I think they're getting more sophisticated to recognize that if they can give some to firms in Canada and other venues besides the U.S., they can spread the potential risk even greater than what they're doing currently. So I think we're going to continue to see litigation funders get more sophisticated in the global market. There's two states in the United States that have just changed laws that allow non-lawyers to participate in law firms, this is the back door that the litigation funders are coming in to start to drive the decisions of law firms and I think we'll start to see that occur more and more. I think we're going to continue to see better coordination amongst the Plaintiff's bar and I say that, a couple of years ago there was an international consortium of journalists who took the task on of showing the world how bad medical device companies are. It led to a mockumentary, as I like to call it, on Netflix. Don't watch it, we don't want it to rise in any level of yeah, with the more viewings, but it was called "The Bleeding Edge". It tried to focus on birth control devices, Mesh and hip implants around the world trying to allege the manufacturers were just evil and they're going to continue to do these evil things if they remain unregulated. I think we're going to see more sophistication of the Plaintiff's bar using the media to try and spread this misinformation. And then the third thing might be regulatory actions. I fear, just from the U.S., that the FDA has recently taken a couple of black eyes and perhaps it has reasoning it's stature in the world as being the gold standard and we might start to see other regulatory agencies break from the FDA gold standard that thinks differently and that is the place where the Plaintiffs bar will exploit and try again focus on those differences around the world.

Edona Vila

Yeah that would be a make for an interesting assessment of standard of care if that's no longer the case. We'll switch perhaps Josiane maybe you can offer some comments from the Québec perspective and then we'll close of with Keegan from a common law perspective.

Josiane Brault

I think we will go the way around if Keegan will start.

Edona Vila

Yes ok sorry.

Josiane Brault

There's not really a Québec perspective on that aspect, Edona, it's more like, Keegan will provide the Canada perspective and that will clear it…

Edona Vila

Clear it up, sounds good.

Keegan Boyd

Sounds good. But I will start with one that is I guess unique to the common law jurisdictions which is I think the mass toward litigation trend is something that is going to be very big in Canada in the coming years and sort of really learning from that trend, seeing how much Plaintiffs really are moving away from the class action model more to the mass toward approach and seeing procedurally how these cases are going to work there way through. I think we've been lucky in Canada you know Lana talks about you know thousands of cases and tens of thousands of cases. We're still talking about tens of cases and hundreds of cases in Canada but I do worry when I hear you talk about the advertising and some of those trends that you are seeing in the U.S. how that will impact things in Canada but because it's still early days here, I think tackling the increased complexity of the mass tort approach will be sort of top of mind for many counsel who are defending these cases and clients who are sort of the subject of these actions so we're not used to dealing with multiple Plaintiffs' lawyers in relation to the same issue, it's so much been a class actions focused practice or individual claims but now if you've got Plaintiffs' lawyers in different provinces across the country all cooperating in this mass tort approach, that I think is going to be something to watch for sure. And the other trend that I wanted to mention, as many people on the call will be familiar with, there were regulatory amendments made December of 2019 which we really geared at increasing the reporting of medical device issues in Canada so historically, it was just manufacturers and distributors that had that obligation, that's now been extended to hospitals and in some cases healthcare institutions and, what we're seeing, although Covid I think slowed things down, there was some forgiving of the strict reporting requirements but what we're seeing generally speaking is a trend towards increased reporting of issues not just from hospitals to Health Canada but also back to manufacturers and I think what we're gonna see if more in the way of product advisories, more in the way of product recalls and ultimately more in the way of product litigation including medical device litigation. I don't think I have anything else on the trends but I'm gonna just say, if you really want to predict things, look 10 years ago where the States were, add a year or two, and we're probably sort of right at that juncture in our evolution in Canada.

Edona Vila

Great, great crystal balling there. Josiane, any other comments before we close off on the third segment.

Josiane Brault

No, just I think it's really important for the medical device companies to make sure that they disclose all of the information and especially with the knowledge we have now today, it's important, it's also helpful with the arguments we bring in defence so.

Edona Vila

Yeah, accurate, accurate information certainly passed down from the manufacturer and distributor down to the supply chain and ultimately to the physician who's recommending

that device certainly important helpful to know that the learned intermediary rule is, or doctrine is alive and well in Québec as well so you can assert as a defence cause I know from a common law perspective it's always helpful to at least have a helpful defence as a full defence for the action often times with helpful evidence. I did want to add a few more, one more at least bucket to sort of the trends piece as we see a move toward certain digitalization and digital health generally that I think where so still Canada does lag behind other jurisdictions but certainly I think we may be able to see a little bit more direction when it comes to connected medical devices and so the enablement of those devices with various features including sort of the AI features to it, many of us when we deal with ongoing retainers right now with companies who are trying to break into the Canadian market, there's always this sort of great analysis that we tend to do about you know "is this a consumer product or is a medical device" cause it gets you into trouble when you to try that product into Canada but I think in Canada with the AI proposed legislation that's sort of making it's way in our parliament, I think we will probably see sort of a little bit of a shift, a framework there from a regulatory perspective and once that occurs, which is expected to occur probably in the new year, maybe not early in the new year, I'm hoping that that will sort of pass through from sort of the privacy world and our privacy commissioner to the Health Canada world to hopefully have more harmonization of what the regulatory view is on AI in Canada and maybe that might go through to Health Canada in helping the sector a little more and provide better guidance in that space so I think that certainly is something to watch for and also see how that may develop in future claims when it comes to connected medical device litigation which I'm gonna just hazard a guess that may well overlap in the realm of privacy and data security too but that will remain for us to see how that litigation may sort of develop. I think we're about 3 minutes to ending our program. If, I know Keegan you had one last question perhaps for Lana but I don't see any questions from our audience here.

Keegan Boyd

So one of the things I was noting in sort of taking look at the Canadian litigation is that it seems that the failure warn claims in Canada are becoming sort of more, I don't want to say more common, but more of the focus and I think you know it sort of echoes Josiane's comments that for our you know client's side parties on the call today, the importance of sharing product issues and timely communication and consistent communication is very important but I was sort of struck by one of your comments Lana about how you're seeing a move in the States away from failure to warn cases more towards design defect cases and thought that might be a good thing for you to elaborate on while we are fortunate enough to have you with us.

Lana Varney

Well I think it's been driven by two things; number 1, the laws in most of the States put caps on the potential damages that can be awarded against the doctor and so the Plaintiff's counsel don't see a business case of the chasing after a doctor. And then number 2, we've gotten much better and more aggressive at education doctors on how to pay for their medical records and I've participated in some of these meetings on behalf of my clients where we'll have small dinners and we will show them the impact of not putting, how well they consent their patients in their medical records and instruct them on how better to document the consent they are informing their clients and so we

really are seeing much more of a rest documenting in the medical records of the risks that were described.

Keegan Boyd

Interesting. Yeah, we might see the latter in Canada, I haven't heard any rumblings of the former and I think, I'm sure our medical community would love to see such legislation that limited the value of claims, but that may well be sort of the big difference between the trends we're seeing in Canada and the U.S. Thank you.

Edona Vila

Thanks, everybody. We're right on time, thank you to our panelists. A special thanks to Lana for joining us and thank you to all for joining us this afternoon. Feel free to reach out to any of us if you have any questions in follow-up. Have a great afternoon, everybody.

By

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