

Addressing the Changing Landscape in Healthcare

Securing Healthcare Innovations through Intellectual Property Protection

Nicole Francis:

Welcome. We are so glad you are here. Thank you for joining us today. And where we are talking about securing healthcare innovation through the use of intellectual property and securing insurance coverage options for intellectual property. As the healthcare technology landscape continues to evolve at a very rapid pace, it brings with it a host of new opportunities, but there are some significant risks. Before we get into our agenda today, I wanted to take a minute to introduce our panelists. I will start with myself. My name is Nicole Francis. I am a member of the financial lines practice here at Marsh, and I help lead the financial product discussions and solutions for our healthcare clients. Paul, I will turn it over to you now.

Paul Murray:

Thank you. It's good to be here. I am Paul Murray. I work within FINPRO and I'm the leader of intellectual property. I work in New York office. Looking forward to a good discussion today. Thanks.

Geoff Pope:

Thanks Paul. And thanks Nicole. My name is Geoff Pope. I'm a managing director here at Marsh. I lead growth for our IP [intellectual property] group, focusing

on IP risk transfer, monetization strategies, and IP debt. So, looking forward to this discussion as well. Thanks.

Nicole Francis:

So, to start our discussion today, we wanted to just map out our agenda where we're going to go today. So first we wanted to frame the intellectual property landscape and the market conditions within the insurance risk transfer space. A lot is going on. We thought it would be a good idea to kind of frame the state of the market first. Next, we'll talk about the types of intellectual property and healthcare that we see. Anything from patent infringement to copyright and trademark secrets. These are hallmark issues for all other industries that touch IP, but risks as we know are starting to bleed into healthcare and not just from a biotech and life sciences side. We want to explore more of this today and its relation to healthcare. We also wanted to talk about the emerging risks within healthcare and identify the key risks associated with intellectual property infringement and how that impacts our healthcare providers specifically.

As we all know, generative artificial intelligence or AI as we like to refer to it, is here to stay and so are some potential landmines. We want to discuss from a healthcare lens and analyze key real-world examples of intellectual property disputes in the healthcare sector specifically. We also wanted to take that and frame real life case studies in the applications for IP within healthcare, we'll discuss strategies to mitigate those risks and protect intellectual property effectively. We'll take a look at these cases, apply lessons learned within those case studies to help safeguard against future risks when delivering and creating new solutions for patient care delivery. And finally, and most importantly, we want to talk about risk mitigation strategies and how to apply these to your specific risk profile within the healthcare space. Safeguarding your strategic investments within the healthcare sector are key to ensure future success in delivering affordable care to patients. With that, I will kick it off to talk about the state of the market.

Geoff Pope:

Thank you, Nicole. So, from a high level, as Nicole laid out the framework, the landscape is dramatically changing specifically in the healthcare space. Intangible

assets, which includes intellectual property, drives market value. We know that. Roughly 90% of the value in the S&P 500 is considered intangible assets. There's a direct correlation across all industries and sectors including the healthcare space. Innovations specifically in the healthcare space are dramatically transforming the industry. When we talk about AI specifically in healthcare, it's currently a \$27 billion market and analysts projected to be a 300 and nearly 50 billion market by 2032. And so, as we talk about the adoption of AI, I think it's important to note that so does risk. Risk is heightened by the adoption of AI. We talk about IP litigation. It has dramatically increased over the last five to 10 years. Any folks who practice law or are used to dealing with these type of claims or losses know that IP litigation can be extremely costly in a very time-consuming process.

AI patents have exceeded, excuse me, global AI patent litigation has exceeded \$10 billion in costs. And over the past three years, that has been nearly \$2 billion has been paid out in development. We expect those numbers to continue to increase. So as a result, IP strategies, compliance and best practices have been slow to evolve. We believe that's where we come in in helping our clients address these issues. Regulation continues to remain fragmented as well. And last but not least, there is a need for a proactive approach to not only protect organization's financial position, but to protect their competitive position.

So intellectual property, IP in the healthcare space. From a high level. Patents, documented proprietary processes from organizations, innovations in areas such as medical devices, pharmaceuticals, biotechnology. We continue to see a rise in patent filings. Trademarks, the branding of healthcare services and other products all across the healthcare sector. Copyrights the protections of medical literature, proprietary processes, and other educational materials that are released by healthcare systems, hospital networks, and other healthcare organizations. And last but not least, trade secrets. Undocumented proprietary processes that are extremely confidential information often falling in the area of research and development from a high level.

My colleague, Paul, will talk about what exactly IP infringement is in healthcare space. We'll talk about common forms of infringement in healthcare such as patent infringement and counterfeiting. We'll explicitly define intellectual property and significance in the

healthcare space. And last but not least, we talked about the adoption of AI. We will define AI in this application in healthcare, which can take on many forms, but such as diagnostics, drug discovery, the curation of data and treatment planning. With that being said, I'll hand this to my colleague, Paul.

Paul Murray:

Excellent, thanks Geoff. Yeah. So in this context, in healthcare, we're really kind of paring this down to the types of IP that are most relevant to what we're talking about here, the confluence of IP and artificial intelligence. So, looking at the more common forms of IP infringement within healthcare, we're concentrating on patent infringement, trade secret misappropriation, infringement of copyrights, and something called inducement. And just hitting some high notes, patent infringement, just what you would think of. The use of patented drug device method without permission. But it's important here to remember that patents can be protected methods, not just inventions and products. And that's, as we can imagine, increasingly important within the medical field.

Trade secrets -- keep in mind that you need to keep an eye on the flow of employees. Do you have nondisclosure agreements? Do you have confidentiality agreements so that when employees leave your company or vice versa, or when students and researchers leave different universities, some of that information doesn't follow them because that can be a little bit of a pitfall. Inducement -- probably something that we don't talk about every day, but the higher tech nature and the more that AI gets involved in these products and these methods, the more it's the case that, look, you bring something out to the space. And any kind of drift in the use of that AI or that technology or that IP, any kind of use that drifts beyond the intended use, can bring about infringing situations. And that's known as inducement. It's not like you're out there looking to rip somebody off. It's just that the implementation of this, you started using it for a slightly different purpose than it was intended. So, these are the things that we kind of try to watch out for in this space.

So, AI, as we know it refers to software systems. They simulate human intelligence increasingly, impressively. And what that really means in our context is that for lack of a better term, AI is really becoming like a new doctor. And so along with that, we have the aforementioned

risks that kind of start popping up within this context. So, diagnostics, treatment planning, drug discovery, synthetic data, use of synthetic data. These bring up all kinds of issues. Can you patent software that mimics a doctor's reasoning? AI, how do you deal with the fact that the AI is starting to blur the line between the tool and the inventor. Because only humans can be inventors. But what about the question of patenting something where the AIs played a huge part in making the key discovery? This is where we start to see those gray areas where the risk can really deserve a second or third look.

Geoff Pope:

So, I think when we broadly talk about the types of IP that is relevant to AI healthcare, and one, we have to talk about the current trends, not exactly the state of the market, but what do we see? What we tend to see for not only clients, but what else is going on in the market when we talk to some of our partners. Of course, patents, copyrights, trade secrets. And last but not least, the financial, excuse me, implications for opting said AI and what that means contractually for organizations that have various vendor relationships who are using this technology. So, when we talk about the current trends in AI, right? The automation of some of these administrative services that are driving efficiency such as clinical documentation time, reducing that time period. Image analysis and other diagnostics. These are all tools that are currently being used and are trending extremely fast across the healthcare sector.

So not only administrative services and driving efficiencies, but driving operational efficiencies as well, such as scheduling, emergency workflows. These are all things that we're seeing in the healthcare space. And again, for larger organizations that are partnering with vendors to render these services contractually, are there protections there? And are there insurance solutions that exist that can help them transfer this risk or address this risk if or when a claim arises? I think it's important. I won't spend time on all of these, but another major issue happens to deal with patents. Some of these AI algorithms, in some cases, novel diagnostic methods. We're starting to see a lot of those, particularly in the telemedicine space. My colleague Nicole and Paul will touch on a pretty relevant case study later in our discussion regarding telemedicine and how folks are adopting this technology. But also, diagnostics in other analytics and trademarks are pretty simple, but depending on the services that are being

rendered or who you are partnering with to render these services, there are implementations, implications there as well.

And then last but not least, financially, because the AI is being adopted so fast, as I talked about in the state of the market, there really has been a lag in the evolution of compliance and regulatory frameworks. And so strategically, what are organizations doing to protect themselves in the event of a claim as they adopt some of these innovations? And one of our goals here at Marsh is to protect our client's financial balance sheet, but to also protect the patients and customers that they serve. So again, we talk about the changing landscape, the convergence of AI and IP in the healthcare space. These are some of the relevant topics that come to mind and some of the topics that we're talking to our clients about.

And so, trust me, this could have been much bigger, but we tried our best to narrow this down to two, three topics, emerging IP risks due to AI, data privacy and security concerns. And the last but not least, liability issues. And so emerging risks, we talk about the innovations that are being driven by patents, other trade secrets such as AI algorithms, medical device companies and software. What does that look like now that we're bringing a lot of people to the party, so to speak, to render these services, I think that's important. One of the things we're doing here at Marsh is strategically having IP strategy sessions with our clients to whiteboard some of these issues and talk about some of the solutions that exist, but also bring their legal folks to the fold to talk about how some of these risks can be transferred extremely important.

And then trade secrets. The undocumented proprietary processes that many organizations hold dear to their heart and for a lot of reasons have chosen not to patent. How do we protect those trade secrets? Data privacy and security concerns. We talk about the implications of a cyber threat and what does that look like when there is IP infringement that occurs via a breach. How does your insurance program respond? Do you have the best practices in place internally to minimize that risk? Extremely important. We talk about the curation of healthcare data and what does that look like and the risk that AI brings to fold all relevant topics and conversations that we're having with our clients. And obviously data in the healthcare space is HIPAA related, so there's heightened risk around HIPAA data. Again, very, very important to discuss. And last but not

least, the liability issues. We've talked about them contractually; can you transfer this risk? What are your options to review existing contracts? And as you continue to go down this road, how can you amend or put forth new language that offers protection in the event of a claim in your ability to transfer that risk? Infringement risk -- not only for the IP holders, but the folks who are licensing and using that IP on a regular basis.

Paul Murray:

There is a lot of change in the legal framework that governs IP healthcare and this first sort of area, an overview of the laws and regulations there is, United States codes are Title 35. Let's not get into the minutia, but it is important to understand that these little sections each have and represent potential pitfalls in IP for healthcare. So just to give you an example, number 1 0 1 says, is it even patentable So you can't patent nature genes body function, things that you can't patent how you use it. A method, 1 0 2 says, is this thing truly new, never been done before? So, think therapy and diagnostics. 112 is interesting because is this invention well explained? And what we mean there is in the healthcare context, could a doctor understand this and replicate it? So, these are the hurdles that are represented by this US code, and they do have direct applicability to the healthcare field. Beyond that, Geoff mentioned HIPAA, some of these things that in the healthcare field, you guys will be familiar with the difference between FDA as patent trademark office.

So I really wanted to kind of center on those hurdles in the front end that represent what can and can't be patented.

Nicole Francis:

Well quickly though, Paul, I just think it's important to kind of stay on the topic of HIPAA because I think that's really important because HIPAA is, while largely is a significant cyber event exposure, the breach of HIPAA related to personal health information is definitely going to be front of mind for any one of the healthcare ecosystem as to comply with all of the appropriate regs for safeguarding that patient information. We've seen actually a potential rise in new exposure around personal health information that is accessed through certain artificial intelligence applications such as chatbot. So, I don't know if you've logged into your provider's website lately, or there are new MyChart functions or different chart functions where there could

also be sometimes a chatbot that you can utilize. I think that could be an emerging area of risk if there is personal health information that is embedded within or providing personal health information to that chatbot.

So it's really important that we manage that personal health information specifically should be managed to prevent unauthorized access and data breaches. These chatbots can potentially expose sensitive information if it's not appropriately secured. I think all of us can agree that as all of these artificial use cases start to emerge and develop, our healthcare leaders will need to stay up to date as much as we humanly possibly as much as it is possible. It feels like the goalpost is always moving just so that we can comply with the quickly changing regulatory environments. And just to note on that Q3 of 2025, it sounds like there will be a Utilization Review Accreditation Commission that will start to review artificial intelligence. This is a, or shorten for URAC, is an independent not-for-profit accreditation entity. So, what they'll do is they'll develop standards through collaboration with industry experts within artificial intelligence, but also healthcare, to release a new healthcare AI accreditation.

The accreditation will aim to provide healthcare organizations with guidance on the safe and ethical implementation of artificial intelligence within healthcare while supporting patient safety. So definitely this will involve elements of the safeguarding of that HIPAA that Paul just mentioned as it relates to the ever-changing uses of artificial intelligence within the healthcare setting. This not-for-profit is not a regulatory body, but it will be an independent not-for-profit accreditation entity. So just wanted to note that is a very important delineation between personal health information within HIPAA and very interesting that there is now going to be a not-for-profit accreditation entity that will be monitoring ways to safeguard artificial intelligence as it relates to PHI in the very, very near future.

Paul Murray:

Yeah, that's a good point Nicole. And I would note too, those two are not mutually exclusive HIPAA and copyright information. You can actually be sued for both one's federal and one's civil, so definitely something to keep an eye on for sure.

Nicole Francis:

Yeah, thanks.

Paul Murray:

So, we want to talk about a few relevant case studies. In other words, just trying to tease out some of these issues with different cases. The first one has to deal with PTAB, the patent trial appeal award where in May, 2025, there was a patent that was challenged at the patent trial of review board (20:46), and the issue was not so much that the patent owner, the assertor was a infringing on the underlying method and the underlying patented material, but the fact that he just used the AI to generate something off the top of that. And the lesson here kind of is, look, if you just slap AI onto something, and I'm leaving out a lot of detail, but if you just put AI onto something, it doesn't really mean that it's going to be patentable no matter how complex or groundbreaking the underlying basis of that is. The second one is a complaint where this is a lot more traditional. Traditional patent infringement suit. So Guardant [Health] sued Tempus [AI] for a number of patents. I think there were nine patents.

Tempus claimed that their platform was built on their own AI models and not on Guardant's patented workflow. In the same way as our PTAB example, this failed in that it was ruled that, okay, you may have created your own AI and you may have created your own AI application, but still that is not enough to get you over the hurdle. And they lost that case, and to Geoff's earlier point that's pretty expensive to get to that part. We're talking about a lot of defense costs, talking about a lot of legal fees. The third one here in Teladoc is really about telemedicine. And this is the case that I think is becoming much more frequent and something to look out for, and that is anytime you have a traditional industry combined with or colliding with high tech, there's going to be some issues. Telehealth. So Teladoc had these sort of carts that were video carts that had capabilities on them to perform medical diagnostics. The thing is, telemedicine used to be the province of rural doctors where there was no access to traditional healthcare. That's not the case anymore. These are force multipliers. These are very main street now. And so, it's something where we need to take a look at and we need to be very cognizant of how much we're incorporating high tech into just regular practice of medicine.

Paul Murray:

Sorry, Nicole, you were going to say?

Nicole Francis:

Oh, no, I was just going to say exactly to your point, Paul, is that I think the remote access delivery of medical services will continue to be an issue as we see critical access hospitals close within the healthcare setting or the healthcare space, unfortunately. There is going to be such more of a need of telemedicine as a way to deliver care to populations that are in rural communities. But you're right, it's not going away. Telemedicine's not going away. And we have COVID to thank for this new emerging technology, but I think that it's really important to understand that using artificial intelligence and creating platforms that utilize artificial intelligence, you unknowingly could reach intellectual property belonging to someone else if you create your own methodology or if you create your new way of delivering medical services, there can be an unintentional use of intellectual property that belongs to others. And so, I think that just to manage through those processes, bringing in the appropriate legal team to evaluate the LLMs that you're using and any third party vendors that you're also utilizing to provide the provision of care in a telehealth environment is really, really important.

Yeah, absolutely.

Paul Murray:

Excellent point. And you really kind of framed it very well, and it's when you have the collision or the integration of these, the high tech into this industry, think of a Venn diagram. All of these patents, there's many patents involved and a lot of them overlap. And so, this overlap can lead to situations where that's the infringement is, and that's where the deals are made. And if those are completely different companies and completely different industries, yeah, exactly. As you said, it's hard to keep track of that and there can be a lot of pitfalls. So very good point. Well put. I think just revisiting our PTAB example. It's not a lawsuit; it's a challenge of the validity of a patent in front of the patent trial appeal board. Essentially the patent trial appeal board said, look, just because an idea is augmented by AI doesn't mean that it's safe from third party challenges. Third party challenges here meaning there was another company that came to the patent trial review board and said, Hey, we don't think that should be patented. It's probably a competitor, but the point being you can't just overlay AI over traditional medicine or traditional practices and then say, aha, I've really got something here that's patentable and it's really going to

survive challenge. By the way, back to the point of legal fees, having PTAB issues and going through that process, again, extremely expensive in terms of defense costs, just legal fees, expert testimony, that sort of thing. And then look back to our Gaurdant Health and Tempus a lot similar to sort of the PTAB case, but this is an actual lawsuit. So, they enhanced what was a patentable method, no question about it. The underlying method was patentable, not a problem. Traditional patent enforcement ruled the day where they said, okay, you haven't done something new here, new enough. And so, Tempus loses this one, and it was expensive, not disclosed how much, but it just highlights the fact that I guess AI is not a panacea, but at the same time it is forming a crucial path forward in this industry. So, there's a lot of potholes, there's a lot of very complex sort of issues that we really need to work through.

Geoff Pope:

Paul, again, we talk about this change in landscape. How can we address some of these risks, I think is extremely important and kind of where we're at in this discussion with a lot of our clients. So best practices, it's something that we've mentioned but best practices, what does that look like? I would argue that organizations, whether they are directly filing patents and launching their own IP or adopting others' IP, often that convergence with AI should have an IP strategy. They should actually have an IP strategy. Public record allows you to look up an organization or a vendor's most cited patents, their most litigated patents. Has there been previous litigation? What happened with that litigation? Was it a settlement? IP trends of your competitors I think is all very important information that organizations need to dedicate time and resources to. Thorough patent researches, trademark registration and so forth, all extremely important.

Next, the importance of employee training specifically as it relates to IP, again, the IP strategy, whether you're launching the IP or you're adapting and contracting out the use of other IP that's often converging with AI. It's extremely important. I would say this is very similar to making sure key employees are trained on how to handle a breach, a cyber breach. When you get a suspicious email or a phone call or a system is shut down, that normally isn't shut down, how do you respond to that? Specifically, Nicole and Paul talked about the curation of data, specifically HIPAA data, making sure employees that handle that data are

trained as it relates to that IP strategy is extremely important. And then last but not least, probably the most important is the collaboration with your legal team, both internally and externally as it relates to not only the IP strategy, but what are you doing contractually to transfer that risk.

I think it's extremely important. Contractually, but also the insurance solutions that exist, the insurance markets continue to evolve. We have a proprietary policy that we think offers the broadest IP defense coverage in the market, and it also offers coverage for third party contracts where there might be a potential infringement of IP. Also, extremely important. A lot of folks talk about NPE, not practicing entities or also known as patent trolls. They are having success with settlements and in district courts as it relates to IP litigation specifically in the healthcare space. I think that's important. And then of course, your competitors, who would suggest that you're infringing upon their IP. And what does it boil down to organization's ability and our ability to not only help our clients remain proactive but help them protect their financial position and their balance sheet. So again, those are some of the strategies and discussions we're having with clients that help them mitigate their IP risk.

Nicole Francis:

Those are all great points, Jeff and Paul. I think as you can see, Marsh feels as though the intellectual property space for healthcare while novel, it is vast, and we feel as though there are many opportunities for us to work with our clients to enrich your risk, risk management strategies so that you can provide ultimately a more successful care deliverable to your patients. There is remarkable transformation in healthcare delivery driven by all the technological advancements that we talked about today, and we do believe that intellectual property is the backbone of innovation, especially within healthcare. So intellectual property, just as a reminder, protects the unique ideas, innovations, and processes that really drive these advancements in patient care. And we think that competition will continue to intensify within the healthcare and technology space, and they've never been more interconnected that the costly legal battles, reputational risks and loss of competitive advantage are all just to name a few risks that are on the line.

Healthcare and technology, as I said, has never been more connected before, but we think that together we

can help our clients explore new ways to navigate these emerging risks and ensure that you protect your innovation and that your healthcare deliverable continues to thrive with appropriate risk management techniques. We really appreciate you being here today and appreciate your time. Hopefully this was really enjoyable and useful for you. So, we really appreciate your time, and we look to talk to you really soon.

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