



Trade secrets protection in the life sciences sector

[00:00:00] Gaia Gasparini: Hello everyone, welcome to today's podcast on trade secret protection in the life sciences field. My name is Gaia Gasparini, and I'll be mediating the discussion between Roberto Valenti, Partner at DLA Piper Italy, based in the Milan office. And Ray Miller, Partner at DLA Piper USA, based in the Philadelphia office.

[00:00:19] Before we get started, I would just like to say that both Roberto and Ray are top players in the intellectual property life sciences field, and their knowledge and experience can definitely teach us more on this topic today. So without further ado, I would dive into this discussion by first asking you what are the main issues when it comes to trade secrets and why is their protection so relevant both to clients in the US and Europe?

[00:00:44] I think we can start off with you, Ray. You can break the ice.

[00:00:47] Ray Miller: Sure. Be happy to. So first I'm very happy to be here, appreciate the opportunity to talk about trade secrets and its role in life science companies in the United States.

[00:01:13] So from my perspective, trade secrets in the United States are relevant to life science companies because they add another asset that can be valued by third parties. I've spent my career trying to create assets and provide exclusivities and using trade secrets as a balancing between patent rights and regulatory exclusivity really avail life science companies of an opportunity to create assets and protect things that are not easily deconstructed by third parties. So, from my client's perspective, what I am focused on is identifying those trade secrets that are important to their operations, and then balancing whether we want to risk disclosing those trade secrets in a patent application because of the requirements to do so in order to get patent rights.

[00:02:04] So it's all a balancing act and it's another prong in asset creation for clients in the United States that are focused on the life science space.

[00:02:14] Gaia Gasparini: Roberto, I think that's your cue.

[00:02:17] Roberto Valenti: Yes. Hello everyone, Roberto Valenti from the Milan office of DLA Piper. Well, I can echo what Ray just said about the increasing importance of trade secrets not only in the life science sector, but in every sector.

[00:02:36] In Europe, we do have a uniform protection for trade secrets since 2016. And this has created a trend towards trade secret protection in many companies. As Ray was saying, many companies find the trade secret protection more appealing than patent protection in some cases, because trade secrets protection is potentially perpetual. And also with trade secret protection, you can protect not only technical innovations, and whenever we think of trade secret, we think of the Coca-Cola formula. But actually the scope of application of trade secrets is much wider. , There is an increasing importance of trade secrets, thanks to aggregated data, and artificial intelligence.

[00:03:33] So our experience with clients operating in the sector, and also with client operating in other sectors is that they understand trade secrets are very important. They understand they want protection and need guidance on how to manage their trade secrets because still even in - let's say - sophisticated companies the protection of trade secrets is often not correctly managed. So, there is an increasing importance of trade secrets as an alternative or a complement to the patent protection in the life science sector and in other sectors.

[00:04:27] Gaia Gasparini: Yeah, exactly. And when it comes to clients specifically in the life sciences, what is it that they don't know about trade secrets, and what should they seek for their business?

[00:04:40] Ray Miller: Yeah, so I'll go first. This is Ray Miller. So, I want to echo a little bit of what Roberto talked about, and that is that there has been a shift in the law, and it's interesting to me effectively, at the same time, Congress in the United States in 2016 passed the Defend Trade Secrets Act and really what that was the first time where there was a federal cause of action for theft of trade secret. And it was an attempt to put teeth into an earlier economic espionage act, recognizing the importance that trade secrets were playing. And at that same time, around 2016, is where you start to see less reliance on patents in the United States. And when Roberto talks about the fact that trade secrets are often thought as the coke formula and as technical innovation, we should expand the concept to trade secret to be operations of our business, who our key clients are, what our partnership arrangements are.

[00:05:49] Anything that has value to us and is not known to other people and cannot be easily deconstructed, should be considered to be managed as a trade secret. Now getting to the question of why the protection of trade secrets is particularly relevant to life science companies is because of the emergence of more technically important and

convoluted resolutions and solutions to problems in the life sciences. And what I mean by that is if you take a small molecule and all you're trying to do is replicate that small molecule like generics do, it's a fairly easy deconstruction most of the time. But if you take a look at a biologic product or an algorithm used in digital solutions, those things are very difficult to deconstruct.

[00:06:41] And so I think using the trade secrets as a balance to the heavy importance that has traditionally been placed on patents in the life sciences sector is why it has become particularly relevant in the life sciences. The other aspect of it being important in the life sciences is outside of that Hatch Waxman litigation, where you're entitled to an injunction for a period of time, it is increasingly difficult in the United States to get an injunction based on a patent in the life sciences sector. The law shifted in the early portion of this decade, around 2012 or 2014, the law shifted where you were no longer entitled to an automatic injunction when you asserted your patent in the United States.

[00:07:39] And as a result, if you look at the prongs, that would result in injunctive relief when you are trying to enforce a patent against someone who has a solution to a healthcare problem. The public policy consideration is going to far outweigh the need to be able to enforce your patent in most cases. But that's not the case in a trade secret issue. So a trade secret issue, if you are out, and you are prepared, as Roberto mentioned, making sure that you have your trade secrets managed appropriately. You're going to be able to go out and seek an injunction because the only way you're going to be able to resolve the issue of irreparable harm is through injunctive relief. So I think it's a balancing act again, and I think it's important for companies in the life sciences sector to consider the trade secret aspect as an important approach.

[00:08:36] Gaia Gasparini: Very interesting. Roberto, do you have something to add on that?

[00:08:41] Roberto Valenti: Yes. Life science is a sector where there is a lot of effort for innovation, not only in the pharmaceutical part of the sector, but also medical devices are based on innovation. And we have said that trade secrets do not cover only technical innovation, but still the most important part of trade secrets is the part that cover technical innovation. And there is a lot of data in the trade secrets in the life science sector. So a lot of data that potentially can be protected as trade secrets from the very early stage. I mean, to come to a patent it takes several years and then you have to obtain the marketing authorization.

[00:09:47] Having part of the information, (for example the process of manufacturing), protected as a trade secret, is extremely relevant for a pharmaceutical company, but again, also for medical device producers to complement their patent protection.

Pharma companies and medical device companies are among the most important applicants for patents worldwide.

[00:10:23] But also, the same effort should be put in the correct management of their trade secrets, and again, there are at least two aspects that need to be taken into consideration. The first is that companies need to share confidential data internally and sometimes externally. Having the correct management in place, with regard to sharing of data is extremely important for the protection of trade secrets. And the other point that I would like to point out is the importance of managing employment agreements. One of the most common ways for disclosure of trade secrets and for the loss of competitive advantage on the trade secrets, is through employees at the different stage and the different level of the organization. This is why, again, having in place the correct provisions in the employment agreement and having in place the correct policies to react to a trade secrets misappropriation is crucial for companies of the sector.

[00:11:58] Gaia Gasparini: Yes, exactly. So you've mentioned these problems regarding management and implementation of policies regarding trade secret protection. So what are some pragmatic suggestions that you would give to your clients?

[00:12:13] Ray Miller: Sure, I'll go first again. Roberto mentioned a couple words that I want to sort of make sure that I highlight from a trade secret perspective, and that was employees, because employees are typically, one of the key places that you'll see trade secret misappropriation occur. That's either when an employee joins your organization or when an employee leaves your organization you have to be aware that there are going to be the potential for trade secret issues. The second thing that Roberto said was react, and understanding that when trade secret misappropriation happens, you're not in a position where you are able to then recreate all of the things that had went on in the past because you have to act very fast because the key to trade secret protection is to keep that trade secret a secret.

[00:13:10] The longer the time passes that it takes for you to build your case, the less likely the remedy is going to be to keep it as a secret. So from my perspective, it's very pragmatic that when a client has an employee join the company, that they do an interview that includes identifications of issues that they should be worried about from their prior employment because most of our clients, all of our clients, want to avoid the situation where they're faced with being contaminated with trade secrets from a previous employer. So from an entrance interview perspective, and similarly on an exit interview, that you want to make sure that you identify the things that your employee has been exposed to and those things that they should be aware in the exit interview are important to your operation. And almost as a warning, as they approach the next employment, not to use those trade secrets. But more practically, I think it is managing

trade secrets as an asset. So, you know, too often when we go to clients and we talk to them about trade secrets, of course they know that they have trade secrets, but they don't have them discretely identified.

[00:14:32] They haven't educated their employees on the importance of trade secrets. They haven't assigned priorities and they're treating the trade secret that is, where are the bathroom keys, as the same as the trade secret, where is the Coca-Cola formula? And those two things just don't need to be treated the same way, and if you do and you go to a judge and you try to explain why it's important that, you get the relief that you're seeking and you're not able to tell that judge how you've protected the trade secret and discreetly what is the trade secret that you're worried about, cases in the United States have shown over and over again that's going to be unlikely that you get your relief.

[00:15:17] So from my perspective, I think it starts when the client has the employee join, they start educating the client on the importance of trade secrets. That's an important aspect when they join, they then repeatedly expose the employee to the fact that trade secrets are important to our organization. We want you to not only get into a system where you're disclosing them to us, we're going to manage those, we're going to audit those, and we're going to make sure that trade secrets are treated accordingly. And if we decide to allow a trade secret to become part of a patent application, then we're not going to treat that as a trade secret any longer.

[00:16:03] So it's all about education, management, auditing and making sure that your employees understand that you respect the intellectual property of third parties, and they need to make sure that they respect your intellectual property.

[00:16:18] Gaia Gasparini: Yes, I completely agree, and Roberto, have you been working on some solution for your clients or in general, what are your thoughts on this?

[00:16:28] Roberto Valenti: Well again, I'm going to echo what Ray said and, to my understanding, the situation is very similar in the US and in Europe. I will say that the magical word is governance. And so, the appointment of a trade secrets manager, the draft of trade secrets policies, and the draft of a misappropriation response plan are the basics for trade secrets protection that any life science client should have. Ray already mentioned, so I'm not going to repeat, the importance of the employment agreements, both inbound and outbound. Ray also mentioned the criteria for identification, classification, and recording of the trade secrets. And the importance of the awareness and education policies, so that the employees at different levels shall be trained on the kind of information that they manage and the importance that the information can have for the company and that, sometimes, confidential information

shall be shared with third parties, and in this case, having confidentiality agreements in place, which can be enforced after all, is important.

[00:18:06] As said still, even in a sector which is very mature in terms of trade secret protection, like the life sciences one, we have seen that some clients do not have all these things properly managed. And in this regard, we have created a legal tech tool called Trade Secrets Score Box. This will be launched very soon. Basically, it is a way to understand the level of maturity of the management of trade secrets within organizations. And it should raise the attention of the companies on the importance of trade secrets and on the importance of the correct management of trade secrets. And this is a truly international issue because, in many cases, pharma companies and medical device producers are multinational. So you have to put in place an organization and rules that allow you, as Ray was saying, to enforce your rights in the case misappropriation takes place.

[00:19:29] Gaia Gasparini: That was very well said. I think we can end on that. Thank you both for participating in this podcast and thank you all for listening.

[00:19:38] Ray Miller: Our pleasure.

[00:19:39] Roberto Valenti: Thank you.

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