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CONTRACT QUARRELS IN THE MEDTECH WORLD are disruptive and costly. They arise because the future is unpredictable. This article provides insights into the most common medtech disputes from the perspective of a lawyer who resolves them from both sides of the bench – as counsel representing companies, and as arbitrator deciding disputes.

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Medtech companies must protect their business deals against three common failures, especially in an international context where the partners may have different frames of reference and diverging understandings of a contract. The following tips serve to prevent disputes and avoid exposure.

Today's environment shapes contracts, tomorrow's environment shapes contract failures. The current business environment is reflected in common medtech contracts, many of which involve foreign partners. Collaboration agreements for R&D, production and marketing of a product (*e.g.*, joint development agreements, services agreements with contract research organizations, co-promotion agreements) decrease cost and risk in a changing and increasingly complex regulatory environment. Also licensing agreements and other contracts commercializing intellectual property (IP) are more and more important, as IP rights are a significant asset in innovation-driven industries. Finally, price pressure, production capacities and market demands around the globe lead companies to contract along a global supply and distribution chain. All of these contracts are typically long-term endeavors that must pass the test of time.

The most common contract failure is caused by the wind of change blowing through such contracts, making their performance more burdensome, uneconomic or unfeasible for one party. Such changes can come from different directions:

- Change in the commercial and regulatory environment. For example, rare earth metals become scarcer or subject to significantly higher import tariffs. If you buy components using rare earth metals, your supplier is likely looking for ways to increase even the fixed contract prices you benefit from to ease its financial burden.

- External business disruptions. One possibility, a supplier is hit by trade sanctions or extreme weather events, which disrupt or limit supplies to you that cannot easily be replaced. You need to decide which of your own customers you will supply with your reduced output, and which contracts you will not fulfill.

- Change in your business needs. Imagine you want to withdraw from a market where you sell through a distributor. Even with a yearly revolving contract term, your distributor is likely looking to prevent the termination or be paid significant damages.

The second most regularly occurring failure is caused by diverging understandings and expectations. Imagine you entered into a licensing or distribution agreement with a partner from a different jurisdiction, and you and your partner have very different views of what exactly is required to qualify as "*reasonable endeavors*" or "*commercially reasonable efforts*" to maximize sales or distribute a medical device. You can also run into this type of problem if the milestones or the split of responsibilities in an agreement with a contract research organization lack specificity.

The third common contract failure relates to unclear provisions regarding ownership, utilization and exploitation of IP that is subject to, or arises out of, R&D collaboration agreements. One scenario: you are party to an international co-development contract that entitles partners contributing to a joint invention to patent co-ownership, and you feel you have contributed to a US and European patent filed by a collaboration partner. You and your partner disagree on what quality of "contribution" entitles you to patent co-ownership under the contract, as different patent laws pose different requirements for such contribution.

How To Manage Risk From The Outset

The examples above are not imaginary, but have happened in the past, leading to costly and disruptive disputes. While no contract can be made 100% future proof, it is possible to protect your company and manage your risk from the outset through smart contract drafting and by putting in place an effective dispute resolution strategy.

To reduce risks related to the first common contract error outlined above, smart contract drafting can include clarifications about the consequences of changes in circumstances. For example, beyond a standard *Force Majeure* clause, the contract could make clear whether, and to what extent, economic hardship justifies non-performance, and define measurable thresholds (*e.g.* by giving examples). If hardship shall not justify non-performance, be clear about this risk allocation, in order to reduce the likelihood that your partner can invoke statutory grounds to adjust the contract based on changed circumstances.

Likewise, the consequences of any *Force Majeure* or hardship clause should be clarified. Does it only justify non-performance, or does it entitle a party to adjust or terminate the contract? In case of supply shortages, will you have the right to decide in your reasonable business judgment how to allocate decreased quantities to customers?

Finally, even if your distribution contract renews annually or includes termination clauses, be clear about your freedom to make business decisions – such as withdrawing from a market or restructuring your distribution network – according to your business needs. Agree on the consequences of any termination for inventories, pending or imminent orders, profits from consumables and maintenance, and other issues that are relevant for your business. You can be sure that these issues will be more difficult to negotiate in a business divorce, with greater risks for your company.

To reduce the risk of the second common contract failure, be clear in the contract about mutual expectations. Set out clear, measurable steps and/or key performance indicators, and use practically important examples to give shape to unspecific terms and obligations. Also keep in mind that terms such as "reasonable efforts" call for different levels of efforts in different countries. In addition, non-binding preambles ("whereas"-clauses) that set out the spirit of the deal in simple language can later help to interpret ambiguity in the body of the contract.

To escape the IP-related common contracting mistakesin R&D agreements, agree on contractual definitions of terms that may have different meanings in different patent and IP laws to ensure that you and your partner have the same understanding of them. Think about drawing up a list of background patents and other prior knowledge, and about covering improvements to background patents. You also may want to include appropriate language to ensure that your current and future affiliates enjoy access rights so as to avoid your current partner suing them one day for patent infringement.

Concise Language

When drafting contract clauses, like the ones addressed above, simple and concise language is recommended rather than long and overly complicated phrases that contain a lot of "legalese." With international contracts in particular, legal terms may have a different meaning depending on a country's contract culture. The clearer and more direct a contract, the more relevant examples used, the better the chances are that you and your contract partner will understand each other.

While none of the above tips and measures can guarantee that a partnership will be a success story, they increase the chances of limiting disputes. Thus, when moving forward with your business, think about whether you have:

- addressed the risk of changed economic circumstances affecting your contract;
- set out mutual expectations and measurable steps to give more shape to any "reasonable efforts" clause;

- and drafted robust IP clauses that do not assume the application of your own country's IP law.

Dispute Resolution

Finally, and most importantly, strong contracts should include an effective dispute resolution clause. The most fundamental mistake you can make is to let this clause escape your attention. Despite being short and typically hidden at the end of a contract, this clause is an important risk management tool and insurance for your business deal. All your carefully drafted clauses will not be worth much if you cannot effectively enforce them through a reliable dispute resolution mechanism if the need arises.

Given this importance, practical tips for drafting an effective dispute resolution clause that is aligned with your strategic goals will feature in an article next month.

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