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Mitigating counterparty bankruptcy risk in partnering transactions

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In 2023, the number of bankruptcies in the pharmaceutical and biotechnology space doubled from the year before to reach a 10-year high. A number of factors have contributed to this trend, such as increased debt levels, rising development costs and challenging market conditions.

In light of this, it has never been more important to address counterparty bankruptcy risk when engaging in a partnering transaction with a pharmaceutical or biotechnology company. If the transaction structure does not properly address this risk, a partner's rights to mission critical intellectual property (IP) needed to develop and commercialise therapeutic or diagnostic products may be frustrated without adequate recourse.

Focusing on the bankruptcy vulnerabilities that are inherent to certain types of partnering arrangements, we address how parties can seek to structure these transactions in a manner that mitigates the adverse consequences of a counterparty bankruptcy.

Partnering transactions involve collaboration between pharmaceutical and biotechnology companies, often to develop and commercialise therapeutic or diagnostic products. These transactions are highly bespoke and heavily negotiated so they can involve a variety of structures, but often include an IP licensing component. Commercial contracts are frequently negotiated as part of these arrangements, where one or both parties perform services in support of the collaboration, such as manufacturing and supply or regulatory related services.

In certain jurisdictions, these arrangements are vulnerable if a counterparty to the contract enters bankruptcy. For example, in the US, a debtor may elect to 'reject' certain contracts, known as executory contracts, where material ongoing performance is required by both parties. This mechanism under the US Bankruptcy Code allows a debtor to eliminate ongoing contractual obligations that may be burdensome or undermine the debtor's ability to restructure and emerge from bankruptcy.

Importantly, many partnering arrangements adopt structures that would

qualify as executory contracts and thus are vulnerable to rejection by a debtor. The US Bankruptcy Code provides certain protections for non-debtor counterparties with respect to certain types of contracts, especially IP licensing agreements, but not others.

In particular, section 365(n) of the US Bankruptcy Code generally serves to mitigate an IP licensee's exposure to the risk of the licensor's bankruptcy by allowing the licensee to treat the licence as terminated or elect to retain certain of its rights under the licence. If the licensee accepts termination of the licence, the licensee can file a claim in the bankruptcy proceedings, which would typically be treated as a pre-petition general unsecured claim.

If the licensee makes an election under section 365(n) to retain its rights, as long as it satisfies certain conditions, the licensor must comply with, among other things, the confidentiality and exclusivity provisions of the licence agreement and continue to provide access to the licensed IP as it existed immediately before the bankruptcy filing. However, the licensor is not required to comply with ancillary obligations, such as providing the licensee with services or access to improvements, or prosecuting, maintaining, enforcing or defending the licensed IP.

Section 365(n) applies to most forms of IP licences, but not trademark licences. However, in 2019, in *Mission Products Holdings v. Tempnology, LLC*, a case that involved the rejection of a trademark licence by a bankrupt licensor, the US Supreme Court held that rejection of an IP licence in a bankruptcy does not operate as a rescission of such agreement, but rather as a breach.

This is a groundbreaking decision as it allows a licensee to retain its licence to use the licensed IP following rejection of the licence agreement by the debtor-licensor. The licensee may also pursue a claim for damages for the breach, which like a claim for rejection under section 365(n), would typically be treated as a pre-petition general unsecured claim.

Although section 365(n) and the *Mission Products Holdings* decision permit an IP licensee to continue to use the licensed IP following a rejection by a licensor, additional risks may arise in connection with the bankruptcy of a licensor under a partnering arrangement. Moreover, the bankruptcy laws of many jurisdictions outside of the US do not contain similar protections for licensees.

Therefore, seeking additional protections when negotiating partnering arrangements may be warranted in a variety of contexts, such as when the licensor is not a US company or important aspects of the partnering arrangement are not protected by section 365(n) or the *Mission Products Holdings* decision.

For example, following rejection, under section 365(n), the licensee would not be entitled to improvements to the licensed IP that the licensor may develop and the licensor would no longer be required to prosecute, maintain, enforce or defend the licensed IP. In addition, if the licensor is responsible for providing services to the licensee, such as manufacturing and supply services, it may no longer be required to provide those services following rejection.

A licensee may mitigate these risks by seeking to gain access to all tangible embodiments of the licensed IP as early as possible in the arrangement by obtaining a technology transfer. If ongoing development will be conducted by the licensor, the licensee should evaluate the licensor's ability to complete that work in the timetables contemplated, how such work will be funded, and how frequently the output of the development work can be transferred to the licensee.

With respect to manufacturing and supply services, the licensee should consider whether those services can be transferred to it or its contract manufacturer early in the arrangement to remove the dependency on the licensor. If manufacturing and supply responsibility must remain with the licensor for commercial reasons, the licensee should consider whether it can nevertheless establish a second source of supply, either itself or through its contract manufacturer.

Moreover, the licensee should consider obtaining an exclusive manufacturing licence for the licensed products but that permits the licensor to perform its services to the licensee. This approach would ensure that the licensee has the requisite rights to assume manufacturing of the licensed products and, given the exclusive nature of the licence, would incentivise the licensor to cooperate with enabling the licensee to take on such manufacturing should the licensor no longer be able to do so.

Similarly, a licensee concerned about licensor bankruptcy risk should ideally seek to obtain control over the prosecution, maintenance, enforcement and defence of the licensed IP from the outset of the collaboration. However, there may be commercial reasons that would prevent this result. In such cases, the licensee should have robust step-in rights to assume these responsibilities if the licensor fails to perform them and obtain the licensor's consent upfront to ensure the licensee will have the necessary authorisation to do so.

In addition to these approaches, to the extent it is commercially practicable, the licensee should seek to defer as much consideration as possible for the licence and services under a partnering arrangement. Doing so may incentivise a licensor in bankruptcy to not reject its agreements with the licensee given that preserving them would entitle the licensor to a much needed source of ongoing payments.

A licensee could also consider whether it could acquire title to the IP or technology of interest, which would be the only way to completely protect the licensee's interest in the IP and technology. However, that may not be commercially available, particularly with respect to partnering transactions where IP and technology is typically only available for license.

Another option may be to take a security interest in the IP and underlying technology that would be licensed under the licence agreement. In that regard, if the licensor sought to reject or breach its agreement with the licensee, the licensee would either be able to foreclose on the IP and technology or have a secured claim for such breach. This approach is not always available, however, as the licensor may have already pledged its IP and technology to other lenders as collateral or may desire doing so in the future.

Parties may also seek to require that any critical IP and technology be held by a

special purpose bankruptcy remote vehicle. However, this is often not a commercially available option in the context of partnering transactions given that it may create an administrative burden to implement and a variety of other tax and legal considerations must be taken into account. At the same time, it may also provide a licensor with the ability to engage in some tax planning and allow it to create an optimal structure for the transaction that mitigates the tax burden on the company.

Ultimately, the choice of which protections to seek in a partnering transaction will differ based on the unique dynamics and terms of each arrangement. As parties enter partnering transactions with the goal of achieving a successful outcome, addressing bankruptcy protections is often not a topic of focus.

However, given the increasing number of bankruptcies in the pharmaceutical and biotechnology space in recent years, protecting against this risk upfront in a planned way, when one still has the leverage, may prove to be essential. ■

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