How new technologies are reshaping IP and deal terms in life sciences transactions

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Complex IP licensing and collaboration agreements underpin the transactions that are crucial to pharmaceutical innovation. To ensure the long-term success of these strategic alliances, IP licensing lawyers must look into their crystal balls to identify key opportunities and risks, and seek to draft a framework that precisely allocates the IP rights but also embeds sufficient flexibility.

Moreover, different technologies present specific IP and legal considerations. Collaboration agreements must evolve with the science that they serve to represent, and IP licensing professionals should strive to understand the new technologies that are driving deal-making.

To help them do this, here is a deep dive into some of the key technologies currently driving life sciences deal-making – and how those technologies are reshaping deal terms.

Antibody-drug conjugates

There were more than 70 antibody-drug conjugate (ADC) -related deals close in 2023 alone, including a number of very high-value acquisitions and collaborations in this space.

Enthusiasm for ADC-related transactions has continued into 2024. In particular, we have seen an increasing number of deals involving companies in Japan and China, where there are a number of innovative ADC developers.

Part of this deal activity is driven by the increased confidence in the science behind ADCs, including the antibody linker technology that underpins how ADCs work safely and effectively to selectively kill cancers.

ADCs are a cancer treatment modality that enables the selective delivery of highly cytotoxic (ie, cell-killing) payloads to tumours. ADCs are made of building blocks – an antibody that is connected with a cytotoxic "payload", via a linker. The antibody acts as a "homing device" that is directed to certain markers on cancer cells, and thus delivering the payload that is intended to kill cancer cells selectively, with the goal of not destroying healthy cells.

This technology generates specific considerations when structuring licensing and collaboration transactions.

The fact that ADCs are comprised of different component parts triggers a question about how we see "combination products" in the context of ADCs – in a traditional sense, a combination product would be a product comprised of two or more active ingredients that are co-formulated or co-packaged. However, in the case of an ADC where it potentially involves

a combination of proprietary elements (whether it is the antibody, the linker or the payload), agreements may need to consider such "combinations" differently, to ensure the licensee has the desired flexibility to modify any such ADCs, and also that that royalties and milestones are appropriately paid on the value attributable to the licensed component.

In cancer treatments, ADCs could be administered sequentially or together with other types of treatments. Licensing and collaboration agreements should take this into account and provide the framework and flexibility for any such future combination studies.

Radioligand Therapies

Another type of technology for cancer treatment that is currently driving recent deal activity is radioligand therapy, which uses radioisotopes as a way to selectively kill cancer cells.

In some respects, radioligand therapy technology is similar to ADCs, in that it is a technology made up of different building blocks: the radioisotope, which kills the cancerous cells, the peptide or ligand, which effectively acts as a homing device to direct the radioisotope to the cancer cell and, often a linker to connect the radioisotope with the ligand.

There has been a renaissance in radioligand therapy technologies and an uptick in licensing and collaboration deal activity in the radioligand therapy space as pharmaceutical companies look to invest in their pipelines in novel opportunities in this space. This is partly being driven by the opportunity the technology presents as a seemingly effective targeted approach to difficult-to-treat cancers.

There are similar points to consider in licensing and collaboration deals for radioligand therapies as for ADCs.

In addition, the fact that the "payload" of radioligand therapies comprises a radioisotope with a defined shelf-life adds complexities with respect to the supply chain. The radioisotope is often difficult to source and it can be difficult to find suitable second source supply. Coupled with this, the short half-life of the radioisotope means that there is short timeline from manufacturing to delivery to patients before the radioisotope decays and is ineffective.

Treatment providers will need robust supply chains to meet patient demand. This is another aspect of this technology that needs to be carefully considered when negotiating deals in this space, including in the context of supply chain diligence and crafting obligations to take into account supply chain issues.

Gene therapy

In recent years there has been a well-publicised surge in gene therapy licensing and collaboration deals.

Gene therapy seeks to cure and treat diseases by modifying or introducing genetic material in patients. It is considered a potential next generation therapeutic modality, backed by strong clinical data in a number of products and the promise to be a one-shot curative treatment for conditions ranging from hard-to-treat cancers to blindness.

Gene therapy licensing and collaboration deals are often complex IP platform deals. Take the vector-based gene therapy technology as an example: typically a virus (such as adenovirus or lentivirus) would contain a "cassette" that carries the genetic material for delivery into the patient. This could involve a number of potential platform technologies, including the viral vector, the regulatory elements in the cassette or the method of delivery. The gene therapy would also likely require complementary technologies, such as companion diagnostics or conditioning therapy.

The platform licensor typically sees its platform technology as its crown jewel that is central to the value of its business model. This generates a tension and an area of significant negotiation, as the licensee seeks to gain ownership and control over the intellectual property related to the gene therapy product and the licensor seeks to do the same over intellectual property related to its platform, but there is often no bright line between these two types of intellectual property.

Further, the licensee may consider that it should have a stake in the platform improvements generated using its funding or intellectual capability, as well as access to next generation platform technologies created by the licensor – however, the licensor may consider that such technologies and improvements are within its control and domain.

Another example is the autologous chimeric antigen receptors (CAR-T) cell and gene therapy.

This type of therapy is complex and labour intensive, as the patients are first enrolled at the medical centres, where their blood is extracted. The blood samples are sent to contract manufacturing organisations, where the relevant immune cells are separated out and then genetically modified to express a chimeric antigen receptor. These "supercharged" immune cells would then be infused back to the same patient at the medical centres, which would target and kill the patient's tumour.

The therapeutic effect of the product is derived from how it is made – meaning such technologies blur the traditional boundaries between what constitutes the product and what constitutes the manufacturing process, and what is typically considered as development and what is typically considered as manufacturing. These concepts have ripple effects throughout the transaction documentation both in terms of intellectual property ownership and licensing as well as development and technology transfer obligations.

AI in drug discovery

Last, but not least, AI in drug discovery is a rising star in the licensing and collaboration deal landscape. This was one of the top focuses at the 2024 J.P. Morgan Healthcare Conference, and promises to reshape drug discovery processes.

Part of this is by automation, as AI technology can test and analyse a far larger number of drugs within a set timeframe when compared with traditional R&D processes – in a manner that is potentially more focused and more intelligent. This is an area where we would see increasing collaborations between pharma companies and technology companies, and it would be interesting to see how these industries with distinct cultures will work together. One of the key concerns of pharma companies when seeking to access AI platforms for drug discovery, is that the inner workings of the platform is often a "black box".

As such, for AI drug discovery platform deals, there is often much negotiation around the control of the AI platform and improvements to the platform, in particular to mitigate against the risk that the pharma-funded insights could enable its competitors, who may use the same AI platform for their own drug discovery processes for similar targets or indications.

This is yet another illustration that the technologies driving life sciences IP deal-making have their own challenges and risks which shape how deals are negotiated and structured, meaning that there is no one-size fits all approach to the documentation of such deals and that successful collaborations require bespoke terms to deal with the complexities that deals in this space present.

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