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Key Territory-Split Licensing Lessons For Life Sciences Cos.

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Territory-split deals typically involve a licensor granting a licensee exclusive exploitation rights for a product or technology within a specific geographic region, while retaining the rights to the product or technology in other regions for itself or for other parties.

These deals can enable the licensor to maximize a product's potential across as wide a range of territories as possible. For example, licensors can obtain nondilutive funding through licensing-out product rights for noncore regions, or leverage the expertise or footprint of regional exploitation partners. However, they also present unique challenges and complexities — how these deals are structured can make or break the value of an asset.

Recently, there has been a rise in life sciences companies wishing to enter into territory-split license deals. Part of this is fueled by a significant increase in licensing deals for China-originated assets.

Over the past decade, China has developed considerable research and development capabilities, which enable the country to discover first-in-class and best-in-class pharmaceutical assets that are desirable to pharmaceutical licensees outside of China. These China-based licensors often wish to retain rights to exploit their product in their territory, leading to a split-territory licensing structure.

Territory-split deals are highly bespoke, and their structures can vary widely depending on factors such as the stage and type of the product, the territory split and the negotiation power of the parties.

As an illustration, these deals can range from structures that are akin to distribution arrangements for commercial-stage products, to deals that more closely resemble collaboration arrangements for development-stage products.

This article explains some of the key legal considerations when negotiating territory-split licensing deals in the life sciences industry, as well as potential practical solutions that can be included in the license agreement.

Scope of License Grants and Exclusivity

The parties may initially seek to divide up the licensing and exclusivity rights entirely between their respective territories. However, the lines between these territories are often somewhat blurred for certain exploitation activities.

For example, a party may have preexisting supply chains or ongoing clinical trials in the other party's territory, which can be difficult to transfer or wind down.

It may not be practicable to recruit patients solely in a party's territory for the program, or to identify cost-effective manufacturers solely in that territory that have the necessary expertise.

Operationally, a party may need to share or store data with other business functions or affiliates based outside that party's territory.

Given this, each party should consider what exploitation rights it should have in the other party's territory, whether by way of a nonexclusive or co-exclusive license, or carveouts and exceptions from the territorial restrictions that might be needed.

Territory-specific noncompetes, including each component of the definitions and activities covered by them, should be carefully considered, to ensure that a party is not inadvertently blocked from conducting activities that would involve work in other territories.

Arising Intellectual Property

One of the starting assumptions in relation to arising IP ownership is that ownership follows inventorship. A common justification is that the inventor has generated the relevant IP using its intellectual capability and, in many cases, its own financial resources.

However, in the case of territory-split licensing, complications arise from the fact that the licensee and licensor are exploiting the same technology. There is a greater potential that a party might generate intellectual property that would block the other party's exploitation of that technology.

This is an area of potential tension between the parties, as the licensor may seek to own improvements to its technology even if generated by the licensee, but the licensee would likely wish to own or control inventions it generates. Parties sometimes try to resolve this issue by granting each other freedom-to-operate licenses under certain improvements they make.

If the parties co-develop the product, the parties' respective financial contribution to those activities could also influence the allocation of arising IP ownership.

Patent Prosecution, Maintenance, Enforcement and Defense

It will typically be in both parties' interest to ensure that the patent strategy for the applicable product or technology is closely coordinated.

Although patent rights are specific to the jurisdictions in which they are filed and granted, patents covering the same technology but filed in different jurisdictions can be interdependent in certain respects.

A licensee in a territory-split deal will often file patent applications with overlapping subject matter and

claims, and assertions of priority. Such overlap means that the grounds for any adverse rulings, inconsistent claims or limitations on a licensee's patent may also have a negative impact on the licensor's patent.

As such, in split territory deals, the licensor may seek to retain control over the prosecution, maintenance, enforcement and defense of the licensed patents and applications to ensure global consistency.

However, the licensee may expect to control these activities for at least the patents and applications in its territory, and also expect the control of patent enforcement in its territory as a core right of being an exclusive licensee.

A way to bridge these differing expectations is to build in notice, discussion and consultation obligations that apply to the parties; however, which party has ultimate decision-making authority will be an area of significant negotiation.

For licensees in a territory-split deal, it is crucial to consider the scope of disclosure in the licensor's priority patent applications. Claims in future patent applications in the licensee's territory that claim the benefit of the filing dates of the priority patent applications will be limited by this disclosure, particularly under the strict added-matter rules that apply at the European Patent Organization and EU member states.

For example, if a priority application discloses two separate active ingredients but not their combined use, this could prevent the licensee from successfully claiming the use of the combination of the two active ingredients in its European patent applications that claim the benefit of the filing date of the priority application.

Development Activities

For development-stage products, a territory-split licensing deal will often necessitate a significant degree of cooperation between the licensee and licensor to avoid a party undermining the other party's development activities, and to seek to ensure a cohesive strategy to present to regulatory authorities.

The licensor, or the main exploiting party, will often want to retain primary control over the global development strategy for the licensed technology.

In addition, while the licensee will usually seek to have control of their own development plan specific to their territory, the licensor may also wish to have a degree of oversight and decision-making authority over the licensee's development plan — in particular, for development decisions that could affect the development or the regulatory pathway for the product in the licensor's territory, such as decisions on patient dosing in clinical trials or development of new indications.

At times, this results in the parties agreeing to collaborate on certain global development activities. Detailed governance mechanisms are required to establish a clear framework for oversight and decision-making, and the parties should consider carefully what decisions fall within the governance framework and what decisions could be made solely by a party.

Sharing of Clinical Trial Data

Commercially, sharing of clinical trial data can be beneficial as it avoids duplication of efforts and can accelerate development timelines, and regulatory requirements might necessitate the sharing of certain clinical data, for example if it relates to product safety.

Any such sharing requires coordinated efforts between the parties, and clear provisions on each party's rights to use the other party's data, whether by a right of reference or a license, or transfer of data.

Clinical trial data is valuable and can be costly to generate. The party conducting the clinical trial may therefore require the other party to fund part of the trial if the other party uses the arising data for regulatory filings in its territory. This could be by way of cost-sharing for global trials in accordance with a budget, or requiring the other party to reimburse part of the trial costs if it uses the arising data for its own regulatory filings.

As data sharing may involve personal data and is often cross-border, parties should pay close attention to local privacy laws that inform the final data sharing framework. In early stage deals where personal data is not exchanged at the outset, it may be sufficient for the parties to agree to enter into a separate agreement governing sharing of personal data at a later date.

Pharmacovigilance

Many regulatory authorities expect licensors and licensees to have access to each other's safety data for the same active ingredient. Such safety data will need to be included in regulatory filings.

The holder of a regulatory approval in one jurisdiction will often need to submit to the authorities individual reports of relevant adverse events occurring anywhere in the world.

As such, pharmacovigilance coordination and the sharing of adverse event reports would need to be carefully considered in territory-split deals, particularly where a licensor has out-licensed to a number of parties in different territories. These considerations are typically dealt with in a separate pharmacovigilance agreement.

Manufacturing

The parties should establish who is permitted to manufacture and supply licensed products, and to what extent the manufacturing party owes clinical and commercial supply obligations to the other party.

If the licensee has the right to manufacture the products itself, it would want to receive a technology transfer from the licensor to enable the licensee to exercise these manufacturing rights.

For an early-stage deal, it may be appropriate to leave supply agreement discussions until a later stage, but this approach would need to be weighed against a party's desire to ensure certainty in supply.

Commercialization Strategy

A lack of alignment in commercialization strategies between regions could lead to inconsistent market penetration and reduced profitability. Accordingly, the parties may agree on a global commercialization plan to which they are required to adhere when making commercialization decisions in their respective territories.

In addition, the parties should discuss the extent to which a party will provide support or resources to assist the other party in its commercialization efforts in its territory, such as providing market research, product marketing materials, or medical affairs or technical expertise to help ensure a coordinated approach.

The parties should consider how marketing, branding and product positioning will be handled in each region. For example, the parties might consider the possibility of co-promoting and co-marketing the licensed product, and whether the product will be marketed under the same name and branding worldwide or whether local adaptations are necessary to meet regulatory or other regional requirements — and if so, who has ultimate decision-making authority.

Consideration will be needed on who controls any product trademarks and whether these should be coordinated globally, as events that damage a brand in a particular region could affect that brand elsewhere.

If the licensor permits the licensee to develop a separate brand for the product in its territory, the licensor will likely seek commenting rights or even a veto authority over the brand's creation and implementation. The level of coordination could be limited by competition law restrictions which should be carefully considered in the design of this framework.

Pricing and Reimbursement

The parties to a territory-split licensing deal are often concerned about the loss of control over product pricing, as national pricing and reimbursement processes are increasingly interconnected from country to country.

Many countries — particularly in Europe — operate international reference pricing systems, under which price negotiations with payors in a particular market are influenced by the price of the drug in one or more comparable countries. This creates a risk that, if a party agrees to a lower price for the licensed product in its territory, the price in other comparable jurisdictions is influenced downward.

There is a growing trend of countries coming together to carry out joint health technology assessments and engaging in joint drug procurement — the Beneluxa Initiative being one example. Such initiatives can lead to practical challenges for the parties of territory-split deals.

The trend looks to continue into the future, with the U.S. Inflation Reduction Act introducing a requirement for manufacturers of certain drugs to submit a data package including global and U.S. revenue data as part of Medicare price negotiations.

The price negotiations could be used to implement a most-favored-nations requirement in the U.S. based on international reference pricing, as Donald Trump pursued when he was president.

Competition law rules generally prohibit a party from controlling — or, in certain jurisdictions, influencing — another party's pricing decisions in the licensee's jurisdiction. The parties could potentially follow a high-level global pricing strategy, as well as other limited information sharing, but this sensitive issue requires careful compliance with relevant competition laws.

Conclusion

This article only touches on some of the key issues of territory-split licensing, and parties must consider a range of other issues that this deal structure presents, such as parallel import considerations and provisions on governance and termination rights and consequences.

Despite the challenges we have discussed, in our experience they may be overcome with careful planning and drafting, and can result in a successful partnership that is beneficial to both parties.

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