

The complexities of territorial licensing

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Companies in the biotech and pharmaceutical industry are well known for developing and implementing innovative deal structures in order to realise the maximum value from their assets and get products to market. One of those innovative deal structures is geographical licensing. Whilst apparently simple on the face of it, the devil is in the detail.

Geographical licensing is the practice where the owner of the rights to a product grants to a licensee the exclusive right to develop and/or commercialise the product in a specific country or territory only. The licensor may grant a separate licence to several different licensees, each in a distinct country or territory. The licensor may, or may not, reserve for itself the right to develop and commercialise the product in a particular country or territory.

The complexities of this deal structure arise from the fact that there needs to be a degree of either centralised control or decentralised coordination in relation to a number of matters - particularly regulatory compliance and intellectual property management. Such centralised control or decentralised coordination needs to be acceptable to all parties involved, not all of whom may be known or identified at the time of entering into the first licence. Clearly, the complexities increase as the number of licensees increases. The deal may be further complicated if, prior to commercialisation, the licensor works with one or more of the licensees to undertake development work to get the product to market.

Set out below are some of the issues to be considered when engaging in geographical licensing:

Product Development

Where multiple parties are conducting activities, each in their own territory, to develop a product, there needs to be a high level of coordination between those activities to ensure that the activities of one do not damage the value of the product for all. It is likely that the results of the development activities will need to be shared between the parties to avoid duplication of work and ensure compliance with regulatory obligations. However, development results are costly to produce and parties may not be willing to freely disclose this information without being compensated in some way. This is particularly the case where the licensor wishes to disclose to subsequent licensees the development results produced by a first licensee. The development work may also give rise to intellectual property rights, and the licensor may need to consider the degree of access it will need to those intellectual property rights. Ideally the licensor would retain the right to grant exclusive rights to such improvements to other licensees.

Regulatory Compliance

Each of the parties involved in commercialising the product is going to have reporting obligations to the regulatory authorities in their own territory. Satisfying these reporting obligations is likely to require

that the parties share information held by them relating to safety and regulatory matters. Where there is more than one licensee, the licensor will need to consider whether all regulatory information should flow through the licensor, or whether it should flow directly between the licensees. The "standard" confidentiality obligations in the contract will also need to reflect this exchange and onward disclosure of, what would otherwise generally be considered, confidential information.

Regulatory Authorisation

Where the product requires some development by a licensee or in any other case where the licensees are interacting with regulatory authorities, there will need to be a degree of coordination of the submissions made to regulatory authorities. All parties will wish to avoid inconsistent statements being made, and to protect against one "rogue" licensee making statements that may be unintentionally damaging to the product worldwide. Once again, this could be centralised by the licensor or could be organised directly between the licensees. Conflict may arise if the licensees are unable to work cooperatively. Such conflict is more likely to arise where the licensees have not had a right to elect or veto the other licensees and are therefore required to work with parties they may not have chosen to work with. Conversely, the licensor is unlikely to be willing to give the first licensee a veto right over the identity of subsequent licensees.

Manufacturing

Depending on the nature of the product and its maturity, the licensor may need to consider whether to maintain control over manufacture of the product and supply it to the various licensees, or whether to give one or all licensees a licence to manufacture the product themselves. Where licensees are given the right to manufacture the product, there may need to be a degree of coordination and cooperation, and potentially sharing of manufacturing process data to ensure consistency of manufacture and compliance with regulatory obligations. Once again, where information is intended to be shared, the "standard" confidentiality obligations in the contract will need to reflect this. Where the licensor wishes to maintain central control over manufacture of the product and supply it to licensees, the licensor will need to consider the potential liability it is taking on as "middle man", and whether it can ensure that it is able to meet its supply obligations to the licensees, whether by manufacturing and supplying itself or engaging contract manufacturers.

Intellectual Property Management

Licensees who are taking an exclusive licence under certain intellectual property in a territory are likely to want control over the prosecution, maintenance, enforcement and potentially the defence of that intellectual property in their territory. Licensors may be happy with this arrangement as it releases the licensor from the cost of maintaining the intellectual property. However, the prosecution of patent applications must be coordinated worldwide to ensure that statements and amendments made by a party prosecuting in one territory are not inconsistent with or damaging to the prosecution of a corresponding patent application in another territory. The same considerations apply where individual licensees are entitled to defend patents in their own territory. Statements made or amendments submitted in the course of defending a patent may have an impact on the strength of a corresponding patent in another territory.

In addition, where the licensor licenses rights in a centralised trade mark to various licensees, care needs to be taken to ensure licensees are properly restricted in their use of the mark and that the licensees act in a way that avoids damaging the value of the trade mark.

Centralised Control - Advantages and Disadvantages

A theme coming through most of the points raised above is that a decision needs to be taken as to whether the relevant matters should be controlled centrally or coordinated in a decentralised manner. If a licensor wishes to maintain central control, it will need to consider whether it has the time and resources required to maintain such control. In addition, the licensor will be liable to its licensees for any failure to comply with its management obligations, which increases the potential liability of the licensor overall. Conversely, central control may enable the licensor to increase the value of the product, the brand, and the intellectual property portfolio and thus achieve higher returns. If a licensor opts to avoid centralised control it may face greater demands from licensees who wish to have input into the identity of the other licensees.

The Way Forward

The most efficient way to navigate these and other issues when engaging in geographical licensing is for the licensor to thoroughly consider the intended commercialisation strategy and structure of the relevant licences upfront. A well-thought-out term sheet at the beginning of negotiations should help to ensure that all relevant issues are raised and discussed as part of an overall package and no key issue is subsequently raised, or required to be compromised on, in isolation.

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