Territorial Licensing in Collaboration Agreements

Life sciences companies often turn to geographical licensing to realise the maximum value from their assets, and to ensure their products reach markets worldwide, particularly where they do not have a global footprint.

In the context of a collaboration agreement, the owner of certain intellectual property rights may collaborate with a licensee to develop a product, and grant such licensee the exclusive right to further develop and commercialise the product, but only in a specific territory. The licensor may reserve for itself the right to develop and commercialise the product in another territory, usually where that licensor has a presence. In certain cases, usually after much of the development of the product has taken place, the licensor may also grant additional licences limited to *other* specific territories to third parties, further dividing up the territory it had reserved for itself in the initial collaboration agreement.

The above deal structures raise many complex issues of coordination between the parties. Some of these issues in relation to geographical licensing in the context of collaboration agreements are:

1. **Product development**: if multiple parties are conducting activities in their own territories to develop a single product, high levels of coordination between those activities are required. No party will want the activities of another party to damage the value of the product being developed. Sharing results of development activities between the parties could avoid duplication of work, and help to ensure compliance with regulatory obligations. However, development results are costly to produce, and some parties may not be willing to disclose this information freely. The development work may also give rise to intellectual property rights, and the licensor will need to consider the degree of access it will need to those intellectual property rights.

2. **Regulatory authorisation and compliance**:
    a. **Pre-approval submissions:** the collaborating parties will also need to coordinate their submissions to regulatory authorities in relation to the product being developed. Inconsistent statements between such submissions must be avoided in order to protect the value of the product worldwide and ensure timely regulatory approvals can be granted.
    b. **Post-approval submissions:** once the product is on the market, each of the parties involved in its commercialisation will have reporting obligations to the regulatory authorities in their own territory. The parties will likely need to share information relating to safety and regulatory matters. If any additional licensees have been brought into the mix, the licensor will also need to consider whether all regulatory information

should flow through the licensor, or whether it should flow directly between these licensees.

3. **Intellectual property management:**
    a. **Patents:** licensees who are taking an exclusive licence under certain intellectual property in a territory – particularly if they are developing improvements to such intellectual property under a collaboration agreement – are likely to want control over the prosecution, maintenance, enforcement and potentially the defence of such intellectual property in their territory. Although this may relieve the licensor of the cost of maintaining the intellectual property in such territory, prosecution of patent applications, and defence of patents, must be coordinated worldwide to avoid inconsistent statements or actions. Such inconsistencies could impede the prosecution of a corresponding patent application, or diminish the validity or enforceability of a granted patent, in another territory.
    b. **Trade marks**: if a licensor licenses rights in a centralised trade mark to various licensees, care also needs to be taken to ensure licensees are restricted in their use of the mark. Licensees should be prevented from acting in ways that could damage the value of such trade mark.

The above issues are tricky to navigate in a collaboration agreement, particularly where significant development of the product remains to be carried out, and the identity of any future additional licensees remains unknown.

A carefully considered term sheet at the beginning of negotiations can help to ensure that all relevant issues are raised and discussed as part of an overall package, as well as avoiding any key issue being missed which could potentially derail negotiations at a later stage.