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INTELLECTUAL PROPERTY & Life Sciences

Dividing the Intellectual Property Pie in the Life Sciences Industry

Issues to consider prior to granting licenses to various collaboration partners

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Pharmaceutical and biotechnology companies go to great lengths and expend significant resources to create, develop and protect their intellectual property with the ultimate goal of commercializing pharmaceutical products incorporating its intellectual property throughout the world and for use in various fields. Often, especially in the case of biotechnology companies, a company may license its intellectual property to third-party collaboration partners in an effort to maximize the commercial potential of the intellectual property it has created. Many times, however, the licensor company does not adequately consider the issues which may arise when out-licensing the same intellectual property to multiple parties, either for different territories, indications or product formulations. This article sets forth certain matters that should be considered when a company decides to divide the rights to its intellectual property among

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multiple parties.

In order to maximize the global reach of a pharmaceutical product, a company may desire to license the same intellectual property to multiple third parties, each of whom has resources and experience in distinct portions of the world. For example, a biotechnology company may collaborate with one partner who can lead the development and commercialization of the product in the European Union, while at the same time collaborating with a different partner in North America.

One consideration when grant-ing licenses to the same intellectual property to different collaboration partners for use in different parts of the world is the scope of the rights granted to each partner to conduct development activities with respect to the pharmaceutical product. For example, a collaboration partner in one territory may want a general license grant to use the intellectual property to conduct development activities anywhere in the world even though it may only have the right to commercialize the product in a certain territory. However, a broad license granting development rights to multiple parties may lead to conflicting clinical trials being conducted in the same territory and also may lead to competition for

patient enrollment. As a result, it is important to carefully craft the license grants in order to delineate where each licensee's development activities can be conducted.

Even if the license grant is carefully constructed to contain a territorial restriction on where development activities may be conducted, issues arise when multiple parties are utilizing the same intellectual property to develop the same products in distinct territories. When intellectual property rights are bifurcated, the parties should consider coordinating global development in order to avoid duplicating efforts and to maximize resources. Typically the data generated by one licensee for a particular territory will be useful to another licensee in another territory, including use in regulatory filings.

As a result, the licensor company should consider requiring its various licensees to coordinate development on a global basis. The licensees also will also need to agree on cost sharing, division of activities, and decision making authority in connection with such global development. To the extent such global development is impractical, the licensor company should require, at a minimum, a grant-back license with respect to any data generated by an individual collaboration partner so that such data can be used by all collaboration partners throughout the world.

Another consideration when dividing the rights among collaboration partners in multiple territories relates to manufacturing the product, and in particular, who will control the intellectual property necessary to manufacture the product and where will

the manufacturing be conducted. For example, will each licensee be granted a right under the intellectual property to conduct its own manufacturing or will a single entity be granted the exclusive license to manufacture products for all territories?

While each collaboration partner may desire to obtain the intellectual property rights to manufacture product, utilization of a single manufacturing source may create economies of scale and global efficiencies. However, additional issues need to be considered if one collaboration partner is granted the exclusive right to utilize the intellectual property for global manufacturing, such as allocation of product supply in the event of shortages, coordination of forecasting and ordering, and changes/differences in product specifications that may be necessary for a particular territory. As a result, careful consideration should be given to manufacturing and supply issues when dividing intellectual property rights among different territories.

Trademarks are an item of intellectual property that should also be considered when dividing the world into multiple territories among different collaboration partners. Will each collaboration partner be able to choose its own trademark to commercialize the product in its particular territory or will the licensor require that a single trademark be used for all territories in an effort to create a global brand for the product? If a single trademark is chosen, which entity will own the trademark and who will be responsible for enforcing the trademark against infringers?

Another way to maximize the commercial potential of intellectual property is to utilize the same intellectual property to develop the same pharmaceutical product, but for multiple fields of use or formulations. For example, a biotechnology company will often license its intellectual property to different partners who each have expertise in a specific field of use (e.g., oncology, hypertension, etc.). Alternatively, a biotechnology company may bifurcate its intellectual property in order to develop the same product in multiple formulations (e.g., oral, topical, injectable, etc.). As with dividing the intel-

lectual property rights between various territories, several items should be considered and documented when granting licenses under the same intellectual property for different fields of use or different formulations.

First, when two or more licensees have been granted rights to utilize the same intellectual property for products with the same active ingredient but for different indications, if the end products are not distinguishable, it may be difficult for the various parties to track demand for their individual products given the potential for off-label use of such products. In order to alleviate these concerns, to the extent practicable, a licensor should require its various partners to differentiate their products, either through different product formulations, dosage strengths or other means. Alternatively, the licensor could consider requiring its collaboration partners to use different trademarks and packaging to distinguish between the various fields of use, although this would not necessarily prevent off-label use of products containing the same active ingredients.

Patent prosecution and maintenance is another issue that should be addressed if multiple licensees will be granted the rights to use the same intellectual property for different indications or formulations, especially when the same patents cover more than one indication or formulation. Often, while one licensee partner may question the benefit derived from developing a strong patent position for a particular indication or formulation, another collaboration partner may see that there is some benefit to maximizing the patent protection, particularly if the cost is being spread among all licensees.

Generally, the various license agreements should first clearly delineate which party owns the patent and controls the prosecution and maintenance. Then, if another licensee has a legitimate interest in such patents, it may have the right to do everything from reviewing the patent applications to providing substantive comments that must be considered by the prosecuting party, and may even have step-in rights to assume the control of the prose-

cution and maintenance of the patent itself. As a result, it is important for the licensor to consider the needs of all possible collaboration partners prior to relinquishing control of the prosecution and maintenance of its patents. Similar issues also arise with respect to controlling actions for infringement of such patents by third parties.

Treatment of improvements may also be a critical issue for multiple licensees of the same intellectual property. If, for example, one collaboration partner that has been granted a license to develop a particular indication for a given pharmaceutical product improves such intellectual property, what rights would the other licensees have to utilize such improvements for their indications? In order to maximize the commercial potential of the product as a whole, it would be most beneficial for each collaboration partner to have the right to use improvements made by any other collaboration partner, although the party that created such improvement may want financial remuneration. Again, these issues should be considered by a licensor prior to granting licenses to its various collaboration partners.

An owner of intellectual property will often grant licenses to the same intellectual property to multiple parties in order to maximize the commercial potential of such intellectual property, but in doing so, certain challenges may arise. However, if a licensor reviews and addresses the items set forth above prior to bifurcating its intellectual property rights, the licensor can begin to minimize the risk of finding itself in an awkward situation with respect to its various collaboration partners. Although there are a number of common provisions to address these concerns, the exact terms of any licensing arrangement are extremely variable. It is critical that the parties consult with their attorneys, accountants and financial advisors to carefully tailor the licenses in order to ensure that each party is able to protect itself and its interests while at the same time maximizing the commercial potential of the intellectual property. ■