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Trade Secret Licensing

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Trade Secrets in the Life Sciences Sector

The European Union (EU) trade secrets directive relates to the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use, and disclosure. The purpose of the directive is to provide effective and comparative legal means for protecting and defending trade secrets throughout the EU. The objectives are notably to encourage innovation-related cross-border activity within the EU and to protect the confidentiality of litigated trade secrets in the course of legal proceedings instituted for their defense.

Behind every patent there is a trade secret. This secrecy is interesting in a sector in which companies are among the most research-intensive companies in the world. Furthermore, part of the data resulting from research and development is not patentable or, in some cases, patents are difficult to file or to enforce. And, of course, patent protection is limited in time. Because of the significant time, energy, and funding expended in research and development, trade secrets should be part of a balanced intellectual property (IP) portfolio.

Examples of data that should be considered and protected as trade secrets include strategic business plans, data resulting from early-stage research, chemical formulae, clinical trial data (methods, results, etc.), bioprocesses to manufacture

biologic or biosimilar, analytical software, and proprietary biological databases.

Crucial Trade Secret Issues in the Life Sciences

Many pharmaceutical and biotechnology companies outsource some of their R&D and/or manufacturing, which requires the transfer of sensitive information which may qualify as trade secrets. Likewise, in the context of strategic deals (collaborations, joint ventures, licensing, and acquisitions), trade secrets may be shared during the diligence process or the implementation of the deal.

Therefore, it is crucial that the exchanges of such information are appropriately controlled, especially when the deal fails or when a collaboration lasts for years and is not successful.

What Is at Stake for the Life Sciences Sector?

First, the EU directive provides that alleged unauthorized disclosure of a trade secret shall be exempted from civil remedies (in other words, authorized), if the use or disclosure of the trade secret was carried out for exercising the right of freedom of expression and information or for revealing misconduct, wrongdoing, or illegal activity in the name of public interest. This exemption

is included within the French law proposal. One of the main issue here is to determine whether clinical trial data (especially negative data) would fall into that scope of exemption. One can also hope that the European Medicines Agency and national medicines agencies will take a safe course of action in their interpretation of what constitutes a commercially confidential information and become less inclined to disclose information—such as clinical trial data—that is in the public interest.

Second, within the context of collaboration between pharmaceutical or biotechnology companies and universities or research centers, and beyond the collaboration agreement entered into by the parties, the directive should ensure that a researcher cannot use or publish any information provided or generated by the company under the research collaboration. This greater protection should have a positive impact on research and innovation.

Conclusion and Recommendations

Internally, especially in case of high staff-turnover or partnership for research and/or production processes: be vigilant and proactive about maintaining secrecy of your trade secrets, strengthen the measures protecting all information considered as trade secrets in order to increase the chances to obtain the qualification of unlawful for acquisition, use, and disclosure of your trade secrets by employees or partners.

When negotiating collaboration agreements: precisely identify all parties' trade secrets and their authorized holders.

When performing collaboration agreements: be cautious

about overstepping the boundaries and making yourselves the targets of misappropriation accusations. Implementation of firewalls and/or clear rooms could help to ensure that those with knowledge of the partner's trade secrets are not tasked with developing substantially similar products.

Finally, even though the directive provides for legal means to protect trade secrets in the course

of legal proceedings, include an arbitration clause in your strategic deals and agreements.

Marie Fillon focuses her practice on IP law. She advises clients on IP agreements and IP-related issues in connection with mergers and acquisitions, private equity transactions, and licensing matters. Ms. Fillon has significant experience in patent, trademark

and copyright litigation, assisting clients in national, pan-European, and international large-scale disputes. Ms. Fillon also counsels clients in a variety of industries including life sciences. Marie Fillon is recognized as a leading lawyer by Chambers Europe 2018. According to Legal 500 EMEA 2018, 'she is extremely skilled and experienced enough to work fast under pressure'.

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