SWITZERLAND

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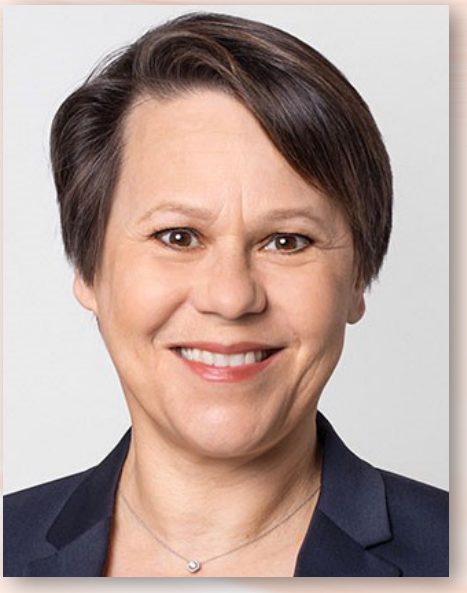
Lorenza Ferrari Hofer is a Partner in Schellenberg Wittmer's Intellectual Property Group and co-heads the Life Sciences Group. She specialises in intellectual property, unfair competition, data law and contract law. She has profound knowledge of the development, manufacture, licensing, and distribution of technology products, including therapeutic, food, and automotive technologies. Her life sciences practice also includes legal and regulatory matters and product liability defence. Also, she has broad experience in media, advertising, marketing and sponsoring matters, particularly in the leisure and entertainment business. Lorenza Ferrari Hofer advises her clients on intellectual property related deals and transactions and represents them in legal proceedings in front of Swiss courts, arbitral tribunals and administrative authorities.

Lorenza has achieved remarkable recognition across various prestigious rankings, solidifying her position as an outstanding professional in the legal field. Chambers & Partners Europe lauded her in Intellectual Property (17 years ranked) and Life Sciences (8 years ranked). Legal 500 recognised her achievements in Intellectual Property, Data Privacy, Data Protection, and Life Sciences. Lorenza's proficiency extends to IAM Patent 1000, IP Stars, WIPR Leaders, World Trademark Review 1000, and Who's Who Legal, where she is esteemed as a Thought Leader in various categories, including Patents, Trademarks, Copyright, Data, Telecoms & Media, Product Liability Defence and Life Sciences. Notably, she was featured among the Top 250 Women in IP 2023, highlighting her leadership in the intellectual property landscape. These rankings collectively affirm Lorenza's unparalleled skills, knowledge, and impactful contributions to the legal and intellectual property sectors.

Lorenza has been playing a pivotal role in advising a leading car manufacturer in the launch and maintenance of e-cars in Switzerland. Simultaneously, she has represented a global pharmaceutical leader in several patent litigations (among others, SPC infringements) and assisted a leading medical device manufacturer in a decade-long and worldwide litigation on trade secrets and patents against one of its suppliers. She has also represented manufacturers of metal-on-metal hip prostheses in liability proceedings and co-represented Sosei in the acquisition of Idorsia's Asian business. She has assisted Kinarus in a reverse takeover of a listed company.

Schellenberg Wittmer's Intellectual Property Team has been recognised by the IAM 1000's Patent 2023, receiving high recommendations for litigation, prosecution, and transactions. Lorenza Ferrari stands out with individual rankings across various patent law areas. The firm has also been named "Switzerland Firm of the Year" at the LMG Life Sciences Awards EMEA 2023, celebrating excellence in the Life Sciences industry. Furthermore, Schellenberg Wittmer is acknowledged as "Switzerland Firm of the Year" at the Women in Business Law Awards 2023, highlighting its commitment to gender diversity and progressive policies. This achievement reflects the firm's core values and ongoing success in promoting diversity as an integral part of its strategy and vision.

Lorenza is a lecturer at SUPSI (Scuola Universitaria professionale della Svizzera Italiana, Lugano), specialising in intellectual property and contracted law. She concurrently serves as the first Vice-President of AIPPI International. She is an active member of the INTA Editing Committee, IBA Life Sciences Committee, and GRUR Ausschuss Recht der Daten.



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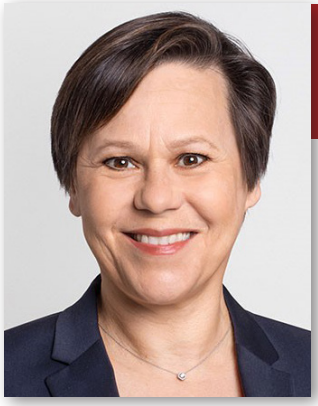
Licensing in Life Sciences: New Developments



Written by Dr Lorenza Ferrari Hofer, Partner at Schellenberg Wittmer SA, Switzerland - www.swlegal.com

In the context of life sciences, licensing has always played a major role. Companies rely on their own and third parties' know-how to achieve their business goals.

Pharma and medical device manufacturers license production techniques and supply facilities to more efficiently manufacture and increase the quality of the products they have developed. Other companies partner with selected research entities to improve the development process and speed up the long and uncertain regulatory assessment of their products.

Today, the importance of licensing intellectual property rights for the manufacture and development of pharmaceutical products and medical devices is recognised by most companies. Also, license agreements are among the most relevant assets of life sciences companies. The critical role of licensing for the life sciences business requires companies and their decision-makers to understand the basic legal rules of licensing so that licensing can be effectively used to implement strategic targets.

It is often forgotten that licensing can represent an exit alternative for start-up companies, particularly where intellectual property rights are the driver of the enterprise value, as this is the case for life sciences technologies.

As a matter of fact, licensing to strategic contractual partners

allows faster growth. It gives more revenue options during the period of consolidation of new companies, allowing acceleration and support of the product development processes. Once start-ups are no longer entirely dependent on venture or, more generally, third parties' capital, they have more flexibility to roll with business changes and unexpected events. Licensing specific technical know-how to bigger pharma or medical device manufacturers also signals potential investors the market value of start-up companies. This is particularly true when start-up companies early engage in discussions and licensing deals with strategic partners and established companies.

In the last couple of years, Europe and Switzerland have seen an increase in license out deals for product candidates in initial stage clinical trials and, more generally, technical data and know-how concluded between start-up companies on one side and big pharma and international healthcare companies on the other side. Often, the parties also agree on joint collaborations, in addition to license fees. Venture capital contributions are still relevant for start-ups, but they are no longer the only alternative for the successful development of new drugs, medical devices or diagnostics. Established healthcare and life sciences companies have become interested in licensing in entire product developments (based on patents), including clinical trials in areas of their strategic interest, manufacture and supply rights and also services, packaging and product release opportunities with the purpose of securing in advance exclusive distribution and promotion rights in selected countries.

Against this background, the structure of the license deals has changed, and the license agreements have become more complex. License fees for the use of intellectual property rights or technical know-how are no longer the only contribution; licensing agreements often provide for equity participation options and first negotiation rights under flexible engagement terms.

The subject matters of the license agreements also have evolved. Intellectual property rights, such as patents or copyrighted materials, and non-personal data related to clinical trials or contained in databases and often in digital format, are licensed. In most jurisdictions, no full-fledged ownership can be acquired in data, and exclusive rights of use can apply to non-personal data only if that may qualify for protection as an intellectual property right, particularly as a copyright-protected work. This may be the case for databases, digital works and software if they meet the specific requirements of copyright law. However, other non-personal data remain without exclusive protection. This is particularly controversial around data generated by artificial intelligence or mathematical methods, which both play an important role in the solution of technical problems in all fields of technology and which today are frequently excluded from patentability. Accordingly, appropriate contractual rules remain; for instance, it is essential to maintain the protection of non-personal technical data, thus also safeguarding the value of the respective data portfolio and the attractiveness of its holder as a transaction partner and licensor. Data collection and analysis through digital technologies become the basis of all future service offerings and business models. The establishment of data contracts between data suppliers, data receivers and data users should, therefore, be given specific attention, both with respect to the assignment of rights in data and the permitted rights of use to such data in the field of life sciences.

To sum up, licensing in life sciences has become more complex, and the drafting of licensing contracts is a challenging exercise. However, licensing has evolved into an essential and most efficient legal tool for the development and manufacture of healthcare therapies. Joint collaborations and cross-licenses between stakeholders of different sizes have proven to speed up research and development processes, also in the interest of public healthcare, as the development of the COVID-19 vaccines on mRNA technologies has shown.