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Challenges and key aspects of life sciences M&A in Switzerland

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M&A in the life sciences sector remains not only stable but is also increasing. The growing appetite for M&A activity in the life sciences industry is of particular importance for the Swiss M&A market since many pharmaceutical and biotech enterprises, both large multinationals as well as small and medium sized enterprises, are located in Switzerland.

Life sciences M&A has several characteristics:

- The life sciences sector is highly regulated. The importance of compliance and the dependence on authorisations from regulatory authorities make a thorough due diligence indispensable.
- The most valuable assets in life sciences transactions are in general intellectual property rights (IPR). The assessment of their scope, ownership, validity and durability is much more demanding than with regard to tangible assets. Things get even more complicated if the product in question is still in the development stage.
- Business often very much depends on licence agreements. These have to be scrutinised with regard to several legal and commercial aspects.
- The life sciences sector is subject to specific litigation risks. On the one hand, the target's IPR may infringe third party rights, or it might be necessary to initiate proceedings to prevent third parties from circumventing the target's IPR. On the other hand, life sciences products are prone to product liability claims.
- Transactions often take place when the core product is still in the clinical trial phase. At this stage, there are question marks behind the marketability and profitability of a product.

Against this background, it is of utmost importance to carry out a careful and focused due diligence to assess the value and price of the purchase and to identify potential risks. In this context, it has to be considered that a buyer due diligence requires insight into very sensitive and confidential information about the target. Therefore, the seller should insist that strict confidentiality agreements are put in place before disclosing any information. Further, the specific risks of a life sciences transaction must be reflected in the transaction agreements.

This article illustrates the challenges for parties to life sciences transactions in Switzerland, and the key points which should be taken into account in view of the complex and evolving legal and regulatory environment. In particular, it examines:

- Due diligence in the life sciences sector.
- Structuring the deal and transaction agreements.

DUE DILIGENCE IN THE LIFE SCIENCES SECTOR

IPR, regulatory issues, product liability and merger control aspects are commonly of particular interest in life sciences M&A transactions. A solid understanding of these fields is a prerequisite to ask the right questions, and identify potential issues to be addressed in the transaction agreements or potential deal breakers.

Intellectual property rights (IPR)

General considerations. The focus and scope of an IPR due diligence depend on various factors:

- Firstly, a sound understanding of the business in question and the buyer's intentions are crucial to identify key IPR, licences and approvals. As regards the core product or technology, it is important to know whether it is a product that is already on the market or whether it is still being tested in clinical trials. Further, the involved countries are to be determined to assess the suitability of the IPR's geographical scope.
- Secondly, the target's size and structure and its relationship with affiliates and parent or sister companies, if any, have to be analysed with regard to the target's dependence on licences of such companies.
- Thirdly, the structure of the transaction (share deal, asset deal or alternative transaction forms) is of great importance for the analysis of the agreements between the target and third parties.

List of all relevant IPR and scope of IPR. All IPR of the target relevant to the buyer's purposes have to be identified. The term IPR is understood in a broad sense and covers:

- Patents.
- Patent applications.
- Supplementary protection certificates.
- Unregistered inventions.
- Trade marks.
- Domain names.
- Trade names.
- Copyrights.
- Trade secrets and know-how.

Regarding health IT and mobile medical applications, it should be noted that computer programs are in general protected by copyright law in Switzerland.

While establishing the list of all relevant IPR, the following should be taken into consideration:

- Is the IPR portfolio well managed?
- Are all important events regarding IPR, namely assignment, registration, payment of fees and granting/obtaining licences, adequately documented?
- Does the target have an IPR policy, and if yes, is this policy respected among staff?

Once all relevant IPR are identified, their material scope must be determined. This is particularly complex with regard to patents. The assessment of their scope of protection requires an analysis of the objective meaning of the patent claim(s). While examining

whether the intended use of the patent by the buyer is covered by its claims, it has to be taken into account that national substantive laws on patents may differ, that is, the type of protection may be different from one country to another.

Ownership: chain of title. The buyer should seek to verify that the target is effectively the owner of the IPR which it claims to possess.

In fact, the target's IPR list may not be accurate even though the target is not aware of any deficiency. For instance, the target may not be aware that IPR created on its behalf by third parties has not been assigned to the target, or that such IPR were assigned to and registered in the name of a parent company.

Under Swiss law, the right to the grant of a patent principally belongs to the inventor, and in case of several inventors as a joint right. Where these rights are jointly owned, each person can only exercise the rights with the consent of the other right holders, subject to the right of disposing of one's part and bringing an action for infringement of the patent.

However, the Federal Code of Obligations (CO) provides for a different regime for employee inventions. Under Article 332:

- The inventions produced by the employee in the course of his work for the employer and in performance of his contractual obligations belong to the employer (so-called direct job-related invention).
- Further, the employer can additionally reserve the right to acquire inventions produced by the employee in the course of his work for the employer but not in performance of his contractual obligations (so-called indirect job-related invention) against fair remuneration.

Inventions with no relation to the job whatsoever belong to the employee. Despite this legal provision, the parties can contractually agree that any invention made by the employee in the course of his work for the employer will be assigned to the employer against fair remuneration.

Consequently, the review of the employment contracts should establish:

- Whether the target reserved the right to claim indirect job-related inventions (and if so, acquired any such invention in a timely way).
- Whether any employees involved in the development of IPR have otherwise assigned their rights in the IPR to the target.

Article 332 of the CO does not apply to agents and directors. Therefore, any inventions created by such persons have to be transferred to the company.

As regards inventions made in the context of clinical trials, due to the concept of joint rights under Swiss patent law (*see above*), and the fact that clinical trial agreements often provide for joint ownership of any inventions or other IPR created in their scope of application, it is essential to check whether the target has the right to independently use the inventions made under the respective clinical trial agreement, and to request a corresponding closing condition if this is not the case.

Specific attention has to be paid to the ownership of copyrights, as under Swiss copyright law such rights arise automatically with the creator. Therefore, employees are the owners of their copyright, unless a contractual clause in their employment contract states that any copyright created during the work will automatically be assigned to the employer, or unless such copyrights have been assigned to the employer by explicit agreement. However, the Federal Act on Copyright and Related Rights (CopA) provides for an exception relating to computer programs. Where a computer program has been created under an employment contract, the employer is exclusively entitled to exercise the rights of use. However, this exception applies only in case of an employment relationship and not to a freelancer or agent.

As regards the review of contractual clauses providing for the assignment of IPR to the target, it has to be assessed whether such clauses effectively trigger the assignment of the IPR in question, or whether it only provides for an obligation of the third party to do so.

To avoid a third party inventor or author trying to obtain additional remuneration for its invention or copyright, the buyer should insist on representations and warranties from the seller that any person (including employees) performing inventive or creative activities on behalf of the target was fully compensated.

It should also be examined whether the relevant IPR are pledged or if any other encumbrances exist.

Registration and other protective measures. The buyer should check whether all relevant patents, trade marks, designs and domain names have been duly registered in the name of the target and that the applicable fees have been paid, bearing in mind that publicly available sources are not always entirely reliable and up to date. Copyrights are not subject to any registration in Switzerland.

It may be that the target is not the registered owner of the patent or trade mark in question, if the assignment of the IPR has not yet been registered or, in a group of companies, the IPR has been wrongly registered in the name of another affiliated company.

Even if registration of the assignment of a trade mark or patent is not constitutive for the transfer of ownership in Switzerland, protection of good faith is derived from it. Further, it may be more difficult to enforce unregistered IPR against infringers. Therefore, wrong or missing registrations should be rectified.

Regarding domain names, it should be established that the domain names that the buyer wishes to acquire are effectively registered in the name of the target, and not in the name of a group affiliate or even an employee or manager.

If IPR and/or domain names have yet to be assigned to and registered in the name of the target or the buyer, it has to be assessed how likely it is that the actual owners will consent to such assignments and what costs will be incurred. In particular, changes of registrations in foreign jurisdictions may be quite expensive, as the services of foreign legal counsel and translation offices are required. These costs will also occur in an asset deal, as all registrations will have to be changed to the name of the buyer.

In addition to the registration of patents, the target may have obtained grants of data exclusivity. In Switzerland:

- Data exclusivity is granted to the holders of marketing authorisations for pharmaceutical products for a period of ten years.
- Holders of marketing authorisations for new indications, new modes of administration, new preparation of forms or new dosages benefit from another period of three to five years.

The buyer should enquire if the target has put in place other protective measures such as policies regarding know-how and confidential business information, limited access to such information and confidentiality agreements.

Validity. As to the validity of IPR, the buyer should first seek to verify if there are any pending or threatened IPR infringement suits or invalidity proceedings (for example, opposition and cancellation proceedings) against the target. In particular, it must be examined whether patents held by the target are actually challenged or likely to be challenged by third parties.

Secondly, it has to be assessed if any of the target's IPR have been violated by third parties and, if not, which risks exist that third parties might successfully circumvent the target's patents in future.

These two analyses should also include a calculation of the potential costs of litigation.

Thirdly, Swiss law imposes certain obligations of use and of placing on the market. These relate to trade marks and authorisations for medicinal products:

- If a trade mark is not used for a period of more than five years in relation to the goods and services entered in the register, it may be deemed to have become invalid.
- The Swiss legislator introduced the Sunset Clause in 2010. According to this clause, the authorisation for a medicinal product is revoked if it is not actually placed on the market within three years from the granting of the authorisation, or if it is no longer on the market during a period of three successive years after it has been placed on the market (*Article 16a, Federal Act on Medicinal Products and Medical Devices*).

Finally, the Federal Act on the Protection of Trade Marks and Indications of Source has recently been revised, introducing in particular new provisions regarding the use of Swiss indications of source (so-called "Swissness legislation"). These provisions entered into force on 1 January 2017. The buyer should carefully examine if indications of source or other designations used by the target are in compliance with these new rules.

Duration. Patents expire after 20 years. In the context of a due diligence, the buyer should analyse the target's strategies to optimise the patent life cycle, in particular the measures taken to prolong patent protection, such as:

- Supplementary protection certificates (or patent term extension in the US).
- Grants of data exclusivity.
- Orphan drug and paediatric protection.
- Second-generation drugs. It should be careful examined if, in the case under review, compliance with anti-trust laws is ensured with regard to the so-called "product hopping".
- Contractual agreements with generic producers (for example, early entry agreements or pay for delay settlements). Compliance of these with anti-trust laws requires careful examination, as pay for delay agreements raise competition law concerns.

Trade marks are valid for a period of ten years (beginning at the date of registration) with the possibility of renewal for further ten-year periods. Renewal must be requested before the expiration date or, at the latest, six months after that date. Compliance with these deadlines should be confirmed.

Licence and other agreements. With regard to IPR, the following agreements are typically relevant:

- Licence agreements.
- Manufacturing, supply and distribution agreements, or other collaboration agreements.
- Research and development agreements and clinical trial agreements.
- Co-existence and delimitation agreements for trade marks.

Assessment of the following points of such agreements between the target and third parties is crucial:

- Duration and possibility of termination.
- Does the transaction trigger a change of control clause?
- Enforceability of the IPR licensed by the target.
- What representations, guarantees and warranties have been given by the target as licensor? In this context, it is important to ensure that the target is the actual owner of the licensed product (for example, open source products).
- Are there any exclusivity rights granted by the target as licensor to third parties?
- Does the target have any exclusive purchase obligations regarding key active ingredients or other product components?
- Are there any anti-trust issues? Particular attention should be paid to exclusivity clauses in distribution agreements.
- Are all contracts in compliance with the prohibition on granting material benefits to and accepting such benefits by persons who prescribe or dispense medicinal products or the organisations employing them?
- What commercial and financial obligations does the target have? Are there any service level commitments or milestones obligations?
- Do the agreements include any non-competition clauses? For instance, the buyer's existing products could be affected by them.
- Are the agreements compliant with data protection laws and regulations?
- Does the target have the necessary insurance policies? This is particularly important if the target is involved in clinical trials.
- Regarding IT licensed by the target as licensee (for example, IT structure, software programs, and so on), it has to be determined whether the buyer intends to take on these licences or not. If the buyer plans to continue the respective licence agreement, questions regarding maintenance, data protection, risks of interruption, source code, and so on arise.
- It has to be determined if the buyer will need additional licences, for example the target may depend on various licences from a parent company in case of a carve-out. Further, software licence agreements may be based on a group licence.

Freedom to operate. The buyer has to assess whether the target's key commercial products, processes or technologies as well as trade marks can effectively be used, developed, manufactured and commercialised by it, and whether it will be in a position to further develop the respective products or technologies. Potential risks of third party rights infringements and the resulting costs have also to be considered.

Regulatory issues

Authorisations. Due diligence should verify whether all necessary authorisations have been granted and are still in full force and effect. Subject to certain exceptions, medicinal products can only be placed on the market if authorised by the Swiss Agency for Therapeutic Products (Swissmedic). Any person applying for a marketing authorisation for a medicinal product must have a registered address, registered office or a branch office in Switzerland. Swissmedic can attach conditions and requirements to the marketing authorisation, such as the obligation to deliver further clinical-experimental data or other post-marketing obligations, the existence of which should be verified by due diligence.

With some exceptions, the manufacture, commercial import and export, wholesale trade and dispensing of medicinal products also require an authorisation. As a general rule, these authorisations are issued by Swissmedic. However in certain cases, the Swiss Federal Office of Public Health (for example, regarding the use of certain narcotics as medicinal products) or the Cantons (for example, a licence for retail trade in a pharmacy, a drugstore or another retail trade establishment) are responsible for the grant of such authorisations.

With respect to products for which no marketing authorisation has been granted so far, it should be examined whether such authorisations are likely to be granted. The same applies to grants of data exclusivity.

Regarding medical devices, the buyer should seek to establish whether the target's product is certified, unless it is exempt from certification (for example, devices for clinical trials, cf. Article 8 (2) of the Ordinance on Medical Devices). Further, any person placing medical devices on the market must introduce and maintain a product-tracking system allowing the collection and analysis of experiences with the devices.

Clinical trials are in general subject to an authorisation by Swissmedic and the competent cantonal ethics committee.

Other regulatory compliance. As regards the assessment of the target's compliance with regulatory obligations, the following aspects should also be taken into consideration:

- Is the target compliant with good practices, such as good clinical practice (GCP), good manufacturing practice (GMP), good distribution practice (GDP) and good laboratory practice (GLP)?
- Does the target comply with pharmacovigilance?
- Are the promotional activities of the target in-line with the legal and regulatory requirements?
- Is there a code of self-conduct or an ethics code and if yes, are they respected by the target's staff?

If the target is not compliant with its regulatory obligations, this might result in the refusal of the grant of a permit or the withdrawal of an authorisation that has already been granted to the target.

Data protection. Buyers should assess whether the target is compliant with data protection laws and regulations. Under Swiss law, all information relating to an identified or identifiable person is considered personal data, irrespective of whether the data subject is a natural or a legal person. Information referring to sensitive aspects of the personality, namely data on health, is regarded as sensitive personal data. Sensitive personal data is subject to extended legal protection. Therefore, if the target processes any patient data, particular attention is required.

Under the Federal Act on Data Protection, personal data can only be processed for the purpose that is indicated at the time of collection, evident from the circumstances or provided for by law. Consequently, due diligence should seek to analyse whether personal data collected by the target can be used by the buyer for purposes other than the initial purposes for which they were collected by the target.

As regards the assessment of compliance with data protection law, under certain circumstances cantonal (and not the federal) data protection laws might apply, namely if a cantonal hospital is involved.

Pricing/reimbursement. If the core asset of the target is a medicinal product its value depends, among other things, on whether the product is reimbursable or not. In Switzerland, medicinal products are generally only reimbursed if they are listed by the Federal Office of Public Health (FOPH) on the so-called Specialty List. To be listed on this Specialty List, a medicinal product must be admitted by Swissmedic and must satisfy the criteria of effectiveness, functionality and economic efficiency. Based on these criteria, the FOPH determines the maximum price for the medicinal product in question. The medicinal products on the speciality list are re-examined every three years or upon patent expiry, or if the indications and limitations of the respective medicinal product are changed. On this re-examination, the FMOH can change the price for the medicinal product in question. An earlier revision of the legal provisions regarding the three-year review of medicinal products gave rise to several successful appeals to the Federal Administrative Court and ultimately the Federal Supreme Court. As a consequence, the respective ordinances have been revised, effective from 1 March 2017.

Product liability

The life sciences industry is particularly prone to product liability claims. Due diligence must include an assessment of any pending or threatened product liability claims. Further, the existence and extent of the target's insurance coverage for such claims needs to be examined.

Merger control

Due diligence should seek to determine whether the planned transaction is subject to merger control and triggers a duty of notification to the Swiss Competition Commission (ComCo).

Under Article 9 of the Federal Act on Cartels and other Restraints of Competition (CartA) planned concentrations of undertakings must be notified to the ComCo before their implementation, if both the following two conditions are cumulatively fulfilled in the financial year preceding the concentration:

- The involved undertakings reported together a worldwide turnover of at least CHF2 billion, or a total turnover in Switzerland of at least CHF500 million; and
- At least two of the involved undertakings reported a turnover in Switzerland of at least CHF100 million each.

Regardless of the above conditions, it is mandatory to notify a planned concentration to the ComCo, if both the following two cumulative conditions apply:

- One of the undertakings involved in the planned concentration has been held to be dominant in a market in Switzerland in a final and non-appealable decision under the CartA; and
- The concentration concerns either that market or an adjacent market, or a market upstream or downstream thereof.

The term concentration of undertakings is defined as either:

- The merger of two or more previously independent undertakings.
- Any transaction, in particular the acquisition of an equity interest or the conclusion of an agreement, by which one or more undertakings acquire direct or indirect control of one or more previously independent undertakings or parts of them.

STRUCTURING THE DEAL AND TRANSACTION AGREEMENTS

Structuring the deal

Generally, the structure of a sale of a Swiss life sciences company follows the same basic framework as any M&A transaction. However, the nature of the underlying business makes it different from transactions in other industry sectors.

Share deal or asset deal. In the past, acquisitions of Swiss life sciences companies have most often been made by a share purchase, in cross-border transactions often through a Swiss holding company or a local trading subsidiary. However, there may be particular circumstances that make an asset purchase, which can be conducted traditionally by individual transfers of the relevant assets and liabilities or by a transfer of assets and liabilities under the Swiss Merger Act (*Vermögensübertragung*), more appropriate.

The decision on share or asset purchase depends in particular on whether:

- The target is organised as a corporation.
- The buyer wants to purchase the entire business.
- The assets are easily transferable.
- There is a risk of hidden liabilities.
- Tax and accounting considerations favour one approach over the other.
- Assets must be pledged in order to finance the transaction.

One of the major advantages of share deals is simplicity. Subject to agreements or permits with change of control provisions, the entire business is transferred. This is of particular importance in the life sciences sector as a regulated sector, since the business of life sciences companies generally entails a variety of licences, permissions and consents which are not readily transferable.

Assets deals, if performed the traditional way, require that assets and liabilities to be transferred have to be identified and individually transferred and third party consents and approvals are usually required. If an asset purchase is performed through a transfer of assets and liabilities (*Vermögensübertragung*), all relevant assets and liabilities are transferred by operation of law. However, there are other disadvantages (like disclosure obligations which make the transaction transparent) and uncertainties (it is unclear whether agreements transfer by operation of law, that is, without third party consents).

Asset deals may be an interesting option if only some of the assets of a company are sold, namely products or technologies. The buyer can pick and choose the assets that it wishes to acquire and the liabilities generally remain with the seller. This also protects the buyer to a certain extent from hidden liabilities.

Alternative deal structures. Apart from traditional M&A deal structures, other structures might be worth considering, namely in deadlock situations. In particular, licensing deals, co-promotions, co-marketing and joint ventures may be attractive alternatives, depending on the specific circumstances.

Among others, licensing might facilitate a deal if early stage (for example, biotech) companies are targets of large pharma companies, and can help to bridge gaps in valuation. Due to the inherent high risk profile of such companies, licensing is often perceived as a more effective way to share risks. Further, the investment for licensing may be segmented, so that more cash is paid only when there is a higher certainty that a product or technology is feasible. In contrast, direct acquisitions require much larger upfront payments with considerably higher associated risks.

Pre-transaction agreements

Letter of intent. Letters of intent are an important element in life sciences M&A transactions. Given their complexity in general, the entering into of a letter of intent is crucial, as it helps to identify any irreconcilable differences on key points of a transaction. Time-consuming and costly processes (in particular due diligence processes) can be saved and disclosure issues avoided. Letters of intent should address the following key points:

- Transaction description and common objective.
- Description of the main terms and conditions.
- Rules regarding the conduct of a due diligence.
- Confidentiality (if not regulated in a separate and surviving confidentiality agreement; *see below, Confidentiality agreements*).
- Possibly an agreement providing for exclusivity for the potential buyer during a certain period of time (*see below, Exclusivity agreements and break-up fees*).
- Clause specifying which provisions are binding and which are non-binding for the parties.
- Provision regarding costs.
- Applicable law and jurisdiction/arbitration.

Generally, the first three points above are non-binding, as they are subject to further analysis, negotiations and documentation of the parties. The remaining points are usually binding provisions.

Confidentiality agreements. The buyer's need for a thorough due diligence investigation of often detailed and highly confidential information is a key element of M&A in the life sciences sector. Therefore, solid confidentiality agreements are a prerequisite to protect the seller and the target. Confidentiality agreements should be concluded at the very beginning of a transaction, and can then be replaced by a confidentiality clause in the letter of intent and later in the acquisition agreement.

It is recommended to include further issues in confidentiality agreements, such as clauses relating to the non-solicitation of employees and protection of IPR.

Exclusivity agreements and break-up fees. Since from the buyer's perspective due diligence investigations are generally costly and time consuming, the buyer often tries to seek either:

- Exclusivity undertakings, by which the seller agrees not to sell or solicit other buyers, for a certain period.
- Break-up fee commitments, by which the seller promises to pay a certain amount to the buyer if the transaction does not proceed due to the seller's fault.

Disagreement between the parties may be bridged through a two-stage due diligence process (which is a rather seller-friendly approach), with initially limited due diligence by the buyer with restricted access to the target information, upon which the buyer has to submit a purchase price generally only subject to findings in the second part of the due diligence. Provided that the submitted purchase price is acceptable to the seller, the buyer is then granted access to sensitive information (quite often combined with exclusivity undertakings).

Transaction agreements

Negotiations. Generally, the elements dealt with in life sciences transaction agreements are the same as in other M&A transactions. How parties approach the terms of a definitive acquisition agreement in a life sciences transaction depends on industry-specific sensitivities, the buyer's findings in its due diligence process, and the structure of the transaction and consideration. The characteristics of life sciences businesses, regularly focusing on and involving numerous intangible assets, in particular IPR, and being exposed to a highly-regulated environment, impact several aspects of the acquisition agreement for a life sciences deal.

Purchase price provisions. As in any transaction, the provisions regarding the calculation of the purchase price and the terms of payment should be drafted carefully, to minimise the risk of differing interpretations of elements such as price adjustments or earn-out calculations. Among other things, the following should be taken into consideration:

- **Purchase price adjustments.** Purchase price adjustments triggered by deviation in the working capital are among the most common sources of disputes in M&A deals. Particular attention should be paid to how inventory is to be treated and how discounts, allowances, rebates, refunds and chargebacks are to be taken into account, as these items often play a significant role in the promotion and sale of the products of life sciences companies. Where possible, specific guidelines and examples should be included in an annex to the acquisition agreement.
- **Deferred consideration.** Deferred consideration provisions are another common source of disputes in M&A deals. To the extent that the transaction structure provides for an earn-out or other deferred consideration tied to milestones and based on ongoing net sales or other performance, the parties will typically have lengthy discussions on provisions relating to the triggers for deferred consideration payments and their calculation. The more precise potential variables and contingencies (including definition of terms) are drafted in the acquisition agreement, the better the chances for the parties to avoid subsequent disputes. Deferred consideration aspects are also often dealt with in covenants. Such provisions aim to ensure, among other things, that the buyer maximises the potential of the business or product(s) involved in the deferred consideration calculation and/or to prohibit the buyer from selling or otherwise deriving

benefit from products that are in competition with acquired product(s).

- **Set-off.** A common issue in transactions involving deferred consideration is whether the buyer will be entitled to offset indemnification claims against such future payment obligations. It is primarily a question of negotiation power whether a set-off will be permitted. It has to be noted, however, that under Swiss law a set-off of such claims is generally permitted if not contractually excluded.

Representations and warranties. In life sciences acquisition agreements, some of the seller's representations and warranties have a greater importance and are the subject of more extensive negotiations than in other industry sectors. These relate to the areas that buyers commonly focus on in their due diligence and are usually subject to typical negotiations regarding limitations, such as knowledge, materiality qualifiers and the length of look back period, namely:

- **IPR.** Representations and warranties regarding IPR typically address numerous aspects that affect, among other things:
  - disclosure of all relevant registered and unregistered IPR;
  - the target's rights in its IPR and the validity of such IPR;
  - absence of third party rights in respect of the target's IPR;
  - absence of any infringement, misappropriation or other violation of the target's IPR by third parties; and
  - absence of any infringement, misappropriation or other violation of third parties' IPR by the target's activities.
- **Product approvals.** The buyer should seek representations confirming the disclosure of all regulatory authorisations relating to the target's products and products in development, and representations regarding the status of such authorisations and confirming the absence of misstatements in the applications for authorisation.
- **Compliance with all laws and regulations.** It is common practice that the seller warrants compliance with all laws and regulations applicable to its business. Further, the buyer might require more specific representations and warranties regarding certain conducts prohibited or required under key compliance regimes (for instance GCP, GDP or GMP or data protection laws), particularly in cases where prior non-compliance has been identified. Compliance representations and warranties will also commonly focus on the absence of competition law and anti-bribery law issues.
- **Inventory.** The buyer should request representations and warranties relating to the target's inventories of products, active ingredients or other product components that cover the quality of the inventory, that is, conformity with specifications, manufacturing and handling in accordance with current GMP and other regulatory requirements and, in case of products with a specified shelf life, its age. If necessary, buyers should also seek representations regarding the quantities of inventory in stock at signing and/or closing.
- **Product liability.** Any life sciences acquisition agreement should include the seller's representations and warranties regarding product liability. These provisions typically include representations as to any known claims or bases for claims. The buyer may also insist on representations relating to the completeness of the target's adverse event reporting and the extent of its product liability insurance coverage.
- **Survival period.** As a matter of risk protection, buyers of life sciences companies or assets often seek longer survival periods for representations and warranties covering matters of particular importance in the life sciences business (for example, IPR, regulatory compliance and product liability).

Closing conditions. Generally, the closing conditions in life sciences M&A transaction agreements do not differ much from transactions in other industries, for example, accuracy of representations and warranties, compliance with covenants, no material adverse effect, and so on.

Life sciences-specific considerations may lead buyers to also seek additional closing conditions, such as:

- Third-party consents/waivers relating to third party contracts, for example, a licensing agreement with a change of control-clause, that are critical to the viability of certain aspects of the target's business.
- Non-occurrence of any competitor filings or launches of generics of key products.

Ancillary agreements/transition. Depending on the transaction at hand, in particular if not all of a life sciences enterprise is sold, the buyer might require services from the seller for a certain period following closing. The seller and the buyer may therefore agree on transitional agreements regarding the provision of support services or consulting services (for example, reporting of adverse events, complaints and inquiries). Often, the parties will also conclude agreements regarding the manufacture, supply or distribution of the product to enable the buyer to continue operating the business. This is particularly important in life sciences M&A, as it may take some time for the buyer to obtain all necessary regulatory authorisations.

Frequently, the buyer will also be interested in employing the target's key employees to ensure know-how transfer which is a prerequisite for the successful integration. The buyer may also require the seller to sign a non-competition or non-solicitation agreement for a certain time.

CONCLUSIONS

Doing deals in the life sciences sector involves a wide range of challenges and opportunities. Due to the high complexity of life sciences businesses, it is of paramount importance to carry out a comprehensive due diligence, enabling the buyer to assess both the value and price of the transaction, as well as to identify potential risks.

The specific risks of a life sciences transaction should be reflected in the transaction agreements by setting up, among others, adequate purchase price provisions and tailored representations and warranties clauses.

Understanding of the various legal, regulatory and practical issues at stake in life sciences transactions, as well as evaluating and understanding a life sciences target and its products, is critical for M&A practitioners to assist clients in effectively assessing value, risk and appropriate deal structures, and to be able to draft and negotiate adequate terms and document a successful life sciences deal.

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Recent transactions

- Advising a private equity fund regarding the acquisition of an equity stake in a Swiss based medical diagnosis company.
- Advising a multinational South American pharma group regarding the sale of its European business to a listed Italian company.
- Advising the shareholders on the sale of a hospital and special-care home.
- Advising an online healthcare provider regarding the operation of an online pharmacy.
- Advising the shareholders of a cosmetics group regarding the sale of the Group, including subsidiaries in Switzerland, France and the US, to a listed Swiss flavours and fragrances group.
- Advising a global healthcare investment firm regarding a major investment in a Swiss based pharmaceutical company.

Languages. German, English, French, Italian.

Professional associations/memberships. Zurich Bar Association (ZAV); Swiss Bar Association (SBA); International Bar Association (IBA); SMB next (KMU next).

Publications

- *LexisNexis Mergers & Acquisitions Law Guide 2017, Jurisdictional Q&A - Switzerland (Oliver Künzler/Marc Nater/Martina Braun/Eva Schott), pp. 107-117.*
- *The life sciences, drugs and healthcare industry in 2016 and beyond: trends and predictions, Edited by Thomson Reuters, Practical Law, London (June 2016).*
- *New Challenges with respect to shareholder loans and cash pools* (in German), *in: CH-D Wirtschaft 3/2015.*
- *What entrepreneurs should know about M&A* (in German), in: *KMU Magazin Nr. 3, March 2013.*
- *How to avoid unnecessary litigation* (in German), in: *Zürcher Wirtschaft, 15th March 2012, p. 16.*
- *Intra-group reorganisations under Private and Tax law* (in German), *Schriften zum Steuerrecht Nr. 17, 2006.*

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Professional qualifications. Lic.iur., University of Lausanne, Switzerland, 2005; Dr.iur., University of Lausanne, 2010; admitted to the Bar in Switzerland, 2011.

Areas of practice. Intellectual property (IP) and technology law (ICT); data protection; life sciences and health law.

Recent transactions

- Advising a medical laboratory regarding the processing of personal data.
- Drafting and negotiating licence and supply agreements for a Swiss pharmaceutical company.
- Advising an online healthcare provider regarding the operation of an online pharmacy.
- Advising pharmaceutical companies regarding various regulatory issues, in particular concerning reimbursement and price decreases.
- Advising an international healthcare company regarding data protection.

Languages. German, French, English.

Professional associations/memberships. Swiss Bar Association (SBA); Zurich Bar Association (ZAV); Institute for the Protection of Industrial Property (INGRES); Center of Commercial Law (CEDIDAC); Data Protection Forum Switzerland (Datenschutz-Forum Schweiz).

Publications

- *The Intellectual Property Review, Chapter 25 Switzerland (Thomas Schär/Martina Braun/Brigitte Bieler/Nicolas Gut), 5th ed., London 2016, pp. 304-315.*
- *LexisNexis Mergers & Acquisitions Law Guide 2017, Jurisdictional Q&A - Switzerland (Oliver Künzler/Marc Nater/Martina Braun/Eva Schott), pp. 107-117.*
- *Moral rights of performers, Berne 2010* (in French).
- *Recent developments in contract law* (Editor), Lausanne 2008 (in French).
- *E-banking and e-trading, Online banking activities and securities trading* (Editor), Lausanne 2007 (in French).