

The Importance of Intellectual Property Due Diligence in the Life Sciences Industry When Entering into a Merger or Acquisition

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Ownership and/or adequate control of intellectual property (IP) is a requirement when running a life science business. However, many owners of new and existing life science businesses often operate without adequately owning or protecting their business's IP. In most mergers and acquisitions (M&A) transactions, parties often focus on financial considerations to the exclusion of IP rights. Even when they do consider IP rights, the potential acquiring company often assumes the IP rights will automatically transfer with the purchase of an entity or its business or assets and/or that any post-closing IP issues can be cured solely by securing strong representations and warranties. It is important to secure strong representations and warranties. However, relying on indemnification for breach of representations and warranties as the sole remedy to protect the acquired IP can result in unexpected surprises after closing that may halt or challenge intended business plans. What follows are a few major areas that life science business owners should consider when performing IP due diligence as part of an M&A transaction in the life sciences industry, with IP diligence ideally beginning based on public records evaluation by IP specialists even before a target is approached.

1. Ownership of IP Rights. A review of the ownership of a target's IP will reveal if the target owns the IP it claims or believes to own. Such review must include searches at the relevant intellectual property offices to establish that: (i) all IP capable of formal protection has been duly registered, issued, or otherwise applied for, and is up to date with the relevant office, including demonstrating proper chain of title held by the target; (ii) any transfers or changes in ownership can be traced or ascertained and where applicable, registered; (iii) there are no assignments or licenses of the IP to third parties; and (iv) there are no encumbrances that may restrict the utilization of such IP.

2. Control of IP Rights. A target may have entered into prior agreements that restrict the use of its IP. The due diligence process should include a review of such agreements and identify any restrictions that may apply to the buyer of such IP. Buyer's counsel will then advise and assist the buyer with evaluating the restrictions, including how to address such restrictions pre-acquisition and post-acquisition and whether desired business goals can even be achieved through such an acquisition including IP assets.

3. Potential Liability or Infringement Claims. The due diligence process should also include a review on whether a target may be infringing on or otherwise violating the IP rights of third parties or otherwise face exposure due to allegations of IP infringement, misappropriation, or improper title. This includes, but is not limited to, a review of any known litigation or threatened litigation. Buyer's counsel will then advise on the potential liability the target faces including evaluating potential indemnities that the buyer may require of the target. The due diligence should also include review of the target's history and procedures for obtaining or registering its IP rights to ensure that the target is not infringing on or violating the IP rights of third parties. This is typically referred to as a freedom-to-operate (FTO) search and opinion. The due diligence process should also include a

review of the target's procedures for protecting and enforcing its own IP rights against infringement or other violation by third parties.

4. Encumbrances. The target's IP assets may be encumbered and the due diligence process should reveal the extent to which such assets are encumbered. Searches at the relevant registries may show the existence of any encumbrances which could include security interests, liens or licenses. However, relying solely on such searches is not sufficient to determine whether there are any encumbrances on the target's IP. If such encumbrances exist, the buyer may opt to reprice the value of such IP or require that the target procure their release.

This list only covers a few major areas that that life science business owners should consider when performing IP due diligence as part of an M&A transaction in the life sciences industry. In such transactions , IP due diligence is a valuable tool in assisting with the buyer's evaluation of the economic value of the IP to be acquired by comparing the strength, scope, limitations, quality, and potential for follow-on IP against both parties' business objectives and post-acquisition goals.