IP due diligence: key areas of analysis in biotech and pharma transactions

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The principal issues in IP due diligence are whether an acquiring party can market products or services free of third-party infringement claims, and to what extent IP can prevent copying. In pharmaceutical and biotechnology transactions, while third-party infringement risks are critical, the ability of IP to exclude others from the market for as long as possible may be of equal importance due to, among other factors, the high costs of research and development and obtaining regulatory approval. Obtaining unfettered exclusive IP rights allows companies to recover their investments. This is in contrast to other technology sectors, where development time and product life cycles are shorter, making the first issue (i.e., freedom to operate) sometimes of greater importance.

Thus, as part of the IP due diligence process, third-party rights and restrictions in such IP should be identified and their impact assessed. The use of federal funds and collaboration between companies and institutions and the government in the development of pharmaceutical and biotechnology IP broadens the scope of issues that may have a direct impact on the exclusivity and the ability for the IP at issue to prevent copying. Below we discuss some of the due diligence concerns raised in these situations.

In the pharmaceutical and biotechnology industries, oftentimes small companies and universities receive federal government funding for R&D. Statutory requirements under the Bayh-Dole Act and agreements between the government and companies and institutions create obligations and grant rights associated with IP arising out of such collaborative work.

Disposition of rights to IP
Under the Bayh-Dole Act, a small company or non-profit entity, or ‘contractor’, which receives federal funds for R&D under a ‘funding agreement’ must disclose within a reasonable time inventions developed using these funds to the relevant federal agency, e.g., National Institute of Health (NIH). Title to rights in undisclosed inventions developed using federal funds may transfer to the federal government.

Even if the disclosure requirements are satisfied, the contractor still must elect to retain title within two years of disclosure. Failure to do so provides yet another instance in which the federal government may receive title. The terms of funding agreements may vary. They may even contract out of certain Bayh-Dole Act provisions. Funding agreements should be reviewed to determine potential claims by the federal government. In the context of M&A transactions, a target’s actions should also be reviewed for compliance with terms of such agreements.

In the pharmaceutical and biotechnology industry, it is not uncommon for researchers employed by universities to engage in outside consulting with companies. If this occurs while the university is accepting federal funding, the ownership issues may become complicated. Understanding the IP obligations the researchers may have entered into and the timing of events is thus important to determine if there are any issues in regard to title, which may also flow down to any corporate licensees.

Grant to US government
Under the Bayh-Dole Act, if a small business or non-profit entity elects to receive title to an invention, the federal government shall have a non-exclusive, non-transferable, irrevocable, paid-up licence to practice or have practiced on behalf of the US any ‘subject invention’ throughout the world.

Accordingly, the extent to which third-parties may be engaged by the government and thereby allowed to compete with the potential acquirer or partner should be assessed in any due diligence situation.

March-in rights
Another right exchanged for federal funding under the Bayh-Doyle Act is known as a ‘march-in right’. March-in rights allow the relevant federal agency to require a grant of a licence, exclusive or non-exclusive, in any field to a ‘responsible applicant’ (including a competitor of the acquiring party), if one of four situations arises: (i) the contractor or assignee has not taken effective steps to achieve practical application; (ii) it is necessary to alleviate health or safety needs that are not reasonably satisfied by the contractor, assigns or their licensees; (iii) action is needed to meet public use requirements specified by Federal regulations that are not reasonably satisfied by the contractor, assigns or their licensees; or (iv) the preference for US industry has not been obtained or waived, or because a licensee having the exclusive right to use or sell in the United States is in breach of its agreement obtained pursuant to the preference for United States industry. March-in rights may also be conferred via collaboration agreements between the government and a non-government party.

While to date the federal government has yet to exercise march-in
rights, petitions for them have been filed from time to time for pharmaceutical and biotechnology inventions. In particular, petitions for march-in rights have been submitted to the NIH on the following grounds: for failure of a patentee to commercialise a biomedical device; the need to alleviate health or safety concerns; the price of a drug was higher in the United States than in other countries; the increase in the price of a drug was asserted to be anti-competitive; and the shortage of a drug was allegedly leading to rationing and a possible life threatening condition. In view of such petitions, it may be prudent to investigate the target company to determine if it is at risk under march-in rights in the case of any federally-funded inventions.

Preference for US industry
Another statutory requirement under the Bayh-Doyle Act is the requirement that a grantee, and its assignee, shall not grant an exclusive right to use or sell in the US a subject invention to a person unless the person agrees that the products embodying the subject invention or produced using it will be manufactured substantially in the US. There are certain instances in which this requirement can be waived.

For many pharmaceutical companies, whose manufacturing capabilities are based overseas, this requirement, should it apply, may significantly devalue the target company and its IP, and possibly serve as a competitive disadvantage for the acquirer.

Cooperative Research and Development Agreements
Another example of an agreement entered into between pharmaceutical and biotechnology companies and the government is a Cooperative Research and Development Agreement (CRADA). A CRADA allows any entity to collaborate with a federal organisation. There are no statutory disclosure or election requirements, as required by the Bayh-Dole Act, because there is no transfer of federal funds in a CRADA.

The IP provisions of a CRADA agreement involving a pharmaceutical or biotechnology company may, however, still provide requirements equal to the Bayh-Dole Act or provide additional restrictions. For example, if a party fails to file a patent application, or fails to maintain any patent or application, the government may take title. Due to these variations, CRADA or similar agreements should be reviewed to determine the presence of third-party rights and restrictions on the jointly developed IP.

When peeling away the layers of a pharmaceutical or biotech company’s IP during due diligence, the impact of any federal funding and collaborative agreements with the government should be assessed to inform the potential acquirer or partner as to any undesirable grant and restrictions they may impose. The actions of the target company also should be assessed to determine whether it has met its statutory and contractual obligations. These matters may have a critical impact on the target’s ability to prevent others from copying.

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