

Protect Biotechnology Intellectual Property with Joint Development Agreements

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February 15, 2008 – Williamsburg, Va. – With the rise in outsourcing new drug and biologic development to overseas laboratories, how are biopharmaceutical executives protecting their intellectual property from insider theft?

Drug and biotech co-development projects are increasingly common as firms seek to increase their product pipelines and speed time to market. Smaller firms are at a distinct disadvantage when it comes to negotiating agreements that protect their current intellectual property and their long-term creative potential.

Outside of the FDA regulated marketplace, one successful strategy to place co-development partners on equal footing and protect both partners' intellectual property has been the creation of a *Joint Development Agreement* (JDA). Such a document can be created either during the initial negotiations or as a follow-on guiding set of principles incorporated as a contract amendment.

Tip #1: Intellectual Property Ownership

If the contract between product development organizations does not specify ownership rights of various components of intellectual property, the JDA is the place to summarize these.

There are three areas of intellectual property (IP) ownership the joint development agreement must specify:

- Initial IP brought to the collaboration by each partner;
- Ownership of the new IP that results from the partnership; and
- Rules for negotiation around any IP outgrowths that are not necessarily part of the **partnership's goals, but that develop as natural offshoots of the partnership's work.**

As a best practice, consider creating an IP fact sheet as an addendum to the JDA that reviews the basic types of intellectual property as well as the essentials of IP ownership and rights.

Even if the partnership contract specifies some components of IP ownership, consider using the joint development agreement to further elaborate on ambiguous points. In such a case, the goal is to ensure that the scientists and engineers involved clearly understand the expectations of their executive team.

Tip #2: Knowledge Flow Management

The flow of information and knowledge between collaborating organizations is one of the main thrusts of a joint development agreement.

Key components to address include: communication, issue resolution, project reviews and stage

gate responsibilities, roles of each team member, checkpoints to ensure tangents are minimized yet still allowed, storage of information and security protocols. The goal of such efforts is to ensure that information exchanges and decision-making expectations are aligned among the collaborating organizations.

Tip #3: IP Storage and Security

To achieve this, involve personnel from records management and information technology groups. Records management must clarify the appropriate records retention rules around information generated during the co-development project and may need to bring in legal counsel to provide advice on certain aspects to minimize risk and liability in the worst case event of future litigation and information discovery motions.

Information technology (IT) professionals will be required to understand the necessary levels of security expected and provide recommendations. Consider having the project manager or other non-IT executive approve the various levels of electronic security; leaving the security of developing intellectual property in the hands of your computer department risks an imbalance of security versus access.

I frequently advise my clients to avoid situations wherein five or more individuals who are in constant contact with each other have the exact same levels of access to intellectual property. Drawing on historical patterns seen in financial fraud, five is the trigger number of people required for theft of intellectual property without alarm bells sounding until it is too late.

Without careful consideration of options and techniques, the five-person trigger point may seem an unnecessary burden by project managers and information technology personnel. Consider asking your outside counsel, an independent consultant or even your alliance partner for help in implementing this control.

Place all joint project documents, schedules, meeting summaries and so forth, in a central repository where they become the property of all parties involved in the collaboration. Note that storing the information in a central location does not imply across-the-board access.

Many of the documents in the repository will be “read-only” (or may not even be visible), depending upon each individual’s role within the collaboration. In addition, having the information technology department of each organization provide a regular electronic back-up, as well as periodic snapshots of the repository for long-term archival, will provide each partner protection and proof for its claims of intellectual property ownership and project effort.

Final Thoughts

While the joint development agreement is not a legally binding document until it is made into a contract amendment or otherwise incorporated contractually, the JDA is a set of operating **principles and guidelines agreed upon between the collaborating organizations’ executives** and project teams.

Review the JDA on an annual basis. Are the controls still working as intended? Are there any

further areas of work undertaken together that need to be incorporated into the JDA? Are there new intellectual property aspects that need to be captured? Have all team members and senior executives reviewed the agreement? Do they understand their roles and accountabilities?

If executives are uncomfortable asking these questions, recognize this as a warning flag. Consider bringing in an outside facilitator to help with an unbiased review and set of recommendations.

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For a complete copy of the article, "Trade Secrets," visit the published articles section of Cerulean's Resource Library at <http://www.ceruleanllc.com>. For further information and recommendations to prevent intellectual property, send an email to info@ceruleanllc.com.

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