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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

10 Considerations When Licensing AI For Drug Discovery

By **Stephanie Sharron, Annalisa Cooper and Wolfgang Schoenig** (April 25, 2023, 5:31 PM EDT)


Stephanie Sharron


Annalisa Cooper


Wolfgang Schoenig

While the traditional process of discovering a new drug is long and expensive, artificial intelligence drug development platforms can help reduce time and money by efficiently analyzing vast data sets within the drug discovery process.

Researchers can use such AI platforms for identifying new biological targets associated with a particular disease, screening known compounds for new applications and designing new therapeutic compounds, among other applications.

In this article, we explain our top 10 considerations for AI transactions involving use in drug discovery.

1. Consider the nature of the services being provided.

The agreement should clearly document the type and scope of services being provided, e.g., whether the AI company is providing an established AI platform or whether the AI company and pharmaceutical partner will be collaborating to develop a new model or even an entirely new AI platform.

The agreement also should clarify whether generative AI or a different type of AI is involved. Depending on the nature of the service and the type of AI used, each side should document their expectations in terms of the functionality and performance of the AI solution. Some specific areas that the scope of services should address in the drug development context include:

- Definition of performance measures, e.g., in the form of key performance indicators or benchmarks, in order to allow verification whether the output generated by the AI is aligned with ethical, legal and operational requirements and objectives applicable to the pharmaceutical partner, such as accuracy, maximum error rate, etc.;

- Explainability of the AI output and how it was generated, e.g., to increase the likelihood of adoption in the medical setting by allowing clinicians to understand and trust the prediction;

- Selection of data sets for training of models to mitigate against or account for bias in the output generated, e.g., to ensure that the AI solution generates output that reflects and addresses the needs of different populations of individuals, e.g., race, gender, age;

- Process for ensuring privacy compliance, especially as it relates to sensitive health data; and

- Adequate security of AI solutions, especially as applied to sensitive data.

Each party's respective contributions as well the type of AI and the intended use case will influence many of the considerations described below, including rights to input data, rights to output, exclusivity and allocation of risk.

2. Be mindful of IP ownership.

Intellectual property issues typically are a primary concern of the parties to an AI transaction. The AI company will usually need to retain ownership of the AI platform itself and any improvements to the AI platform as such.

It is similarly important for the pharmaceutical company to retain ownership of the data it contributes and to either own or have some exclusivity with respect to the output or results generated by the AI, such as newly designed chemical compound candidates.

Typical areas of contention are, however, the allocation of rights to:

- Data models; and

- Ownership versus license rights to output and results generated, including rights to the inferences, insights and other correlations used to produce the results.

Resolving these issues requires the parties to take the full context of the transaction into account, including what functionality the AI performs, the relative information and expertise contributed by each party, and any specific additional services provided.

Here the solution may not lie in allocation of ownership in the strict sense but in a clear delineation of purposes for which each party may or may not use the relevant asset.

3. Consider quality and privacy issues for training data.

The data that is used to train AI models is of paramount importance to the efficacy and accuracy of the AI solution. The parties should clearly state what data each party may bring to the partnership, the limitations and risks associated with the data sets based on the intended use case, and the scope of the data licenses granted to each party.

The parties also should keep in mind that accessing high-quality data can be challenging, given cost concerns, privacy implications, lack of incentives for sharing, and inherent biases and inequities underlying existing data sets.

Furthermore, depending on the nature of the data set, the parties should establish adequate protocols for complying with applicable privacy laws, including the Health Insurance Portability and Accountability

Act with respect to the U.S. and the General Data Protection Regulation with respect to the EU.

Data pertaining to how the AI is used by the developer or the end customer also can be valuable, especially to those developing AI solutions. Usage data can inform future enhancements to the AI solution as well as assist with maintenance and support of the AI solution.

Organizations developing AI solutions therefore will want to secure rights to collect and analyze such usage metrics in order to maintain, support and further improve their AI offerings.

4. Consider exclusivity.

If strict allocation of ownership of certain assets proves difficult to negotiate, one party — usually the pharmaceutical company — may seek to bind the other party, usually the AI company, to exclusivity obligations.

If a pharmaceutical company, for example, is heavily involved in the development of an AI model, then the pharmaceutical company will likely want exclusive use of such AI model, relative to the AI company as well as to any third-party customers or business partners of the AI company.

More nuanced exclusivity terms may be warranted when addressing correlations of the data that are critical to training AI models so as to avoid precluding the AI company from using these correlations to improve its AI solution for other partners.

5. Account for infringement risk.

Both the input and the output of the AI have the potential to infringe copyright or misappropriate trade secrets.

If all or a portion of the input constitutes copyrightable subject matter and the copyrightable subject matter is copied in the course of training the AI, the training of data models could possibly in and of itself constitute copyright infringement in the absence of an effective defense.

In the EU and potentially other non-U.S. jurisdictions, if the AI is trained with data sets from structured databases, ancillary copyrights of the database owner may be affected.

Trade secret misappropriation could also arise if the input includes third-party confidential information or trade secrets, in the absence of terms that allow for the contemplated processing of such information by the AI. Accordingly, it is important to understand from whom input data is obtained and under what terms to assess risk.

A number of other factors might reduce risk of violating third-party intellectual property rights by input. Not all input, for example, constitutes copyrightable subject matter and not all training of models requires copying of copyrightable elements.

Moreover, in the U.S., fair use defenses may exist, depending on how the AI functions and what output is generated.

Under certain circumstances and subject to the member states' transposition into national law, Articles 3 and 4 of the Digital Single Market Directive in the EU allow the generating of new information in the

form of patterns, trends and correlations from publicly available data, if the rights holder has not expressly excluded such use in its terms of use, under text and data mining exceptions, which is very useful for many AI providers.

Contracts may permit processing of confidential information or trade secrets, including less restrictive terms that may allow for use in training AI.

Additionally, separate from the issues of whether activities with regard to input infringes or misappropriates third-party rights, the nature of the output might influence whether or not a finding of infringement of third-party rights occurs.

While case law is sparse, it is reasonable to expect that the risk of a finding of infringement likely increases the more the output resembles copyrightable elements of the input.

Aside from concerns with input and output, AI solutions also often use open-source software and other third-party technology. The contracting parties should therefore review third-party license terms to ensure they do not conflict with the terms of the agreement for the business partnership or introduce new concerns for the parties to consider.

6. Be reasonable with royalties.

The drug discovery process occurs early in the overall cycle of drug development, preceding the preclinical and clinical stages.

Given that significant research and other work usually occurs between the initial screening process and release to market, it may be difficult to determine the value of the AI's contribution to the final product.

Royalties may or may not be the appropriate form of compensation. In instances where the AI recommends a newly designed compound, the application of royalties to such compound may depend, for example, on how closely it relates to the active ingredient of the final product.

However, if the active ingredient recommended closely corresponds to a prompt or query created and submitted to the AI solution by the pharmaceutical company, or the AI is used as a tool to screen for counterindications among a subset of preidentified drug candidates, as opposed to a means for identifying the active ingredient in the first instance for a particular indication, arguments against royalties or for lower royalties might apply.

7. Evaluate confidentiality and competitive use.

AI companies should consider obligations to disclose sensitive information about the AI solution, such as disclosure of the details of the algorithms involved or the source code for the AI model itself, except under the most stringent of confidentiality protections.

While the pharmaceutical partner may want to ensure that any viable targets generated by the AI platform are considered the confidential information of the pharmaceutical partner, the AI company will want to ensure that any such confidentiality obligations will not restrict its ability to enable other customers and business partners to use the AI solution to generate output or results that include the same targets as, or similar targets to, the pharmaceutical partner's targets.

AI companies also may seek rights to use input provided by the pharmaceutical partner or even results generated from their AI solutions for purposes other than performing services for the pharmaceutical partner.

When such rights are sought, the contract should address concerns about protection of the pharmaceutical partner's sensitive confidential information as well as use of such input in ways that compete directly with the pharmaceutical company.

8. Plan for uncertainty.

As with all drug collaborations, the length of the drug discovery process frequently makes it is often challenging to finalize all terms upfront to enable full commercialization of drug candidates identified using an AI solution.

While contracting in phases or granting options for future negotiation are possible, one downside to deferring agreement to future negotiation is that there is not typically a remedy if the parties fail to reach agreement.

As a result, the parties could end up investing significant time and resources in an effort to identify drug candidates only to find out that there is no meeting of the minds with regard to royalties or other terms.

It is therefore often advisable to incorporate governance mechanisms, e.g., final decision-making authority allocated to one party or the other on designated issues, termination remedies, and alternative dispute resolution provisions that provide some certainty as to outcome in the event of failure to reach agreement.

9. Scrutinize contractual risk allocation.

A drug that is identified or designed by an AI solution could cause harm leading to product liability.

It is not clear in the absence of a contractual allocation of risk, what liability the company providing the AI tools and services may bear for such harm. The parties therefore should allocate responsibility for that liability — including possible contractual indemnification — in their contract.

While contractual limits on liability are common in technology license and services agreements, it is worth noting that liability cannot be restricted for death or personal injury.

What risk allocation is appropriate will depend on the contributions made by each of the parties. If an AI company provides a means for exploring different drug designs, but the customer designs the drug using the AI as a tool, holding that AI company responsible for any drug the customer develops using the tool might be problematic.

In contrast, if an AI company is being engaged specifically for that company's ability to design drugs for a customer and happens to use AI solutions to perform such development, it might be more appropriate to allocate some risk back to the AI company performing drug development services. These decisions should therefore take into account the full context of the business relationship.

10. Beware of an evolving regulatory landscape.

There is still uncertainty about the potential regulation of AI in drug development.

The U.S. Food and Drug Administration is continuing to grapple with the implications of AI in pharmaceutical manufacturing and is developing a regulatory approach to consider AI technology supporting a drug development program or marketing application.

On March 1, the FDA published a discussion paper on AI in pharmaceutical manufacturing and issued a request for information and comments regarding areas for consideration and policy development with respect to the application of AI to pharmaceutical manufacturing.

In the EU, forthcoming legislation and guidelines like the Data Governance Act, the European Health Data Space, the Pharmaceutical Strategy of Europe, and the AI Act seek to introduce a unified regulatory framework for the use of AI, including in the context of drug development.

What all initiatives have in common is a risk-benefit assessment of the AI used. The AI Act, for instance, will apply not only to providers, importers and distributors of AI systems in the EU but also to their users.

The AI Act blacklists certain AI practices that pose an unacceptable risk and provides for extensive compliance obligations with regard to high-risk AI systems, including obligations pertaining to registration, conformity assessment, human oversight, risk management, data governance and technical documentation.

Pharmaceutical companies that are themselves involved in the development of AI tools should pay attention to this upcoming regulation, because, first, regulatory compliance of AI systems used during drug discovery may also play a part in the drug approval process and, second, users of high-risk AI systems will in any event also be exposed to compliance obligations.

Stakeholders at the European Medical Agency have already published four principles that the EMA intends to use for the regulation of AI drug development tools. However, it remains to be seen how a potential regulation will play out at the end.

Conclusion

Beyond the transaction-specific issues associated with AI, organizations using AI solutions for drug discovery should consider implementing responsible AI programs and policies to ensure that they are evaluating the risks associated with their specific intended use cases and implementing appropriate risk mitigation strategies and compliance processes.

Organizations entering into business transactions involving AI will be well positioned to maximize the benefits of their AI use while mitigating the corresponding risks by both addressing the above transaction-specific risks and implementing responsible AI programs and corporate policies.

Stephanie Sharron is a partner, Annalisa Cooper is an associate and Wolfgang Schoenig is a partner at Morrison Foerster LLP.

Robert Grohmann, senior associate at the firm, contributed to this article.