I. Introduction

Conventional biopharmaceutical IP strategy, focused on tangible drug assets[1], faces disruption on several fronts. Artificial intelligence (AI)-driven drug discovery technologies continue to improve and bring candidates into trials[2], if not yet to full FDA approval. Greater awareness of the high cost and failure rate of traditionally developed drugs[3] is also bringing more attention to the early potential of AI technologies to bring drugs to market faster and with lower cost[4]. The impending patent cliff for several blockbuster drugs[5] will also lead firms to reevaluate their focus on protecting tangible drug assets with patents. In addition, the FDA has taken steps to address the use of AI technologies both internally[6] and by stakeholders[7], which may shift the line on the tradeoff between patent and trade secret protection.

This chapter will outline these disruptions as well as the current AI drug development landscape, including identifying trends in how AI-focused firms are currently allocating resources to assets, specific targets or modalities, and/or underlying AI technologies. In view of this landscape and other disruptions in the biopharmaceutical (biopharma) market, the chapter will outline actionable IP strategies for players across the landscape including academic institutions, early-stage companies, and large pharmaceutical enterprises. Specific considerations for executing on IP strategies and other approaches for establishing exclusivity around new technologies and business models will be evaluated, including guidance on the patent vs. trade secret decision and tactics to strengthen patent applications for examination and litigation success, enabling stakeholders to adapt and thrive in this evolving landscape. Put succinctly, this chapter will help answer the question, is it worth the cost and time to pursue patent protection for AI drug development technology?

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[1] "Assets" as discussed herein include drug candidates, such as molecules or biologics in preclinical or clinical development, as well as approved drug products, particularly drugs that have received regulatory approval and are being marketed. Conventional IP strategy thus typically focuses on protecting the chemical composition or formulation of assets.
[2] https://www.nature.com/articles/s41591-025-03743-2
[3] https://www.nature.com/articles/d41586-023-03172-6
[4] https://www.drugtargetreview.com/article/157270/navigating-the-ai-revolution-a-roadmap-for-pharmas-future/
[5] https://www.bcg.com/publications/2025/patent-cliff-threatens-biopharmaceutical-revenue
[6] https://www.fda.gov/news-events/press-announcements/fda-launches-agency-wide-ai-tool-optimize-performance-american-people
[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-use-artificial-intelligence-support-regulatory-decision-making-drug-and-biological

II. Overview and Objectives

A. Contextualizing AI Disruption in Biopharma

AI's potential as a disruptive force in the drug discovery and development pipeline is best understood in the context of conventional drug development challenges. For example, a 2024 study found that the "mean cost of developing a new drug from 2000 to 2018 … was $172.7 million (2018 dollars) but increased to $515.8 million when cost of failures was included and to $879.3 million when both drug development failure and capital costs were included. The ratio of R&D spending to total sales increased from 11.9% to 17.7% from 2008 to 2019.[8]" Another analysis estimated the time and cost of drug development as 10-15 years and $2.6 billion, respectively.[9] Perhaps most starkly, an "estimated 86% of drug candidates developed between 2000 and 2015 did not meet their stated endpoints.[10]"

These challenges mirror three of the key ways in which AI might be disruptive: (1) decreasing capital costs by shifting from experimentation in real-world settings, which can require significant time, labor, physical resources, and uncertainty, to simulations and other lower-cost computational approaches; (2) making data analysis tasks in R&D more cost-efficient with AI; and (3) compressing timelines by performing tasks computationally more quickly than with experimentation, studies, or process development, with the assumption that such tasks will at least achieve parity in relevant criteria such as safety and efficacy. In other words, AI can be disruptive where the cost and/or time components of drug development tasks can be shifted to lower cost and/or faster computing tasks, while still achieving target performance criteria.

B. Why are IP Strategies Essential to Navigate This Disruption?

Traditionally, patents for assets have been paramount in biopharmaceutical IP strategy because of at least the following factors: (1) the right to exclude offers a reliable mechanism to achieve a return on the nine-to-ten figure investment required to bring a drug to market; (2) they provide this right to exclude for a long enough period of time to be useful when drugs are commercially

[8] https://pmc.ncbi.nlm.nih.gov/articles/PMC11214120/
[9] https://www.patheon.com/us/en/insights-resources/blog/drug-development-phases.html
[10] https://www.nature.com/articles/s41591-023-02361-0

significant; and (3) they cannot be circumvented by reverse engineering (unlike trade secret protection).

When evaluating machine learning and AI technologies, however, the calculus changes. The rapid pace of AI development makes it more challenging to know, at the time of filing and during patent examination (that is, before filing through 3-4 years from filing), which claims might be infringed by a competitor in 5, 10, 15, and 20 years from filing. Patent applications for AI technologies are susceptible to 35 U.S.C. § 101 patent eligibility challenges, with the Federal Circuit's *Recentive v. Fox* decision indicating that merely applying machine learning to useful data may not be sufficient to achieve patentability without, for example, claim limitations that demonstrate an improved machine learning model in and of itself.[11]

These considerations support the conventional focus on patenting assets, such as the compositions of small molecule or biologic drugs, rather than underlying computational technologies. Nevertheless, as the driver of drug development value shifts from traditional approaches to include computational approaches, IP strategies must also be reconsidered.

III. Varied Business Models Involving AI for Drug Discovery

Figure 1 below provides an overview of typical workflows around AI drug discovery technologies:

[11] https://www.cafc.uscourts.gov/opinions-orders/23-2437.OPINION.4-18-2025_2500790.pdf

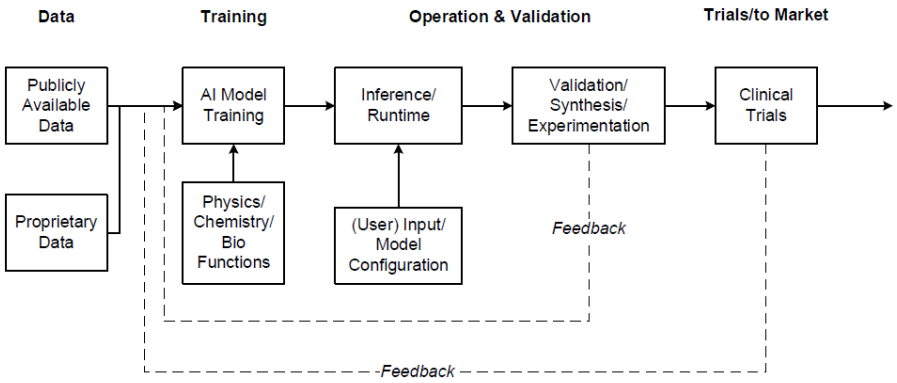

Fig. 1. Overview of AI drug discovery and development workflow.

As demonstrated in Fig. 1, a variety of business models can be implemented that rely on one or more stages of these workflows. For example, a **target-focused** AI company may apply its efforts to using its own proprietary data to identify relevant targets for certain indications and generate candidate drugs for those targets, such as if the company is aiming to move those candidate drugs into clinical programs for those indications, either independently (such as to pursue an end-to-end approach) or in a strategic partnership. Such companies may be just as invested in protecting candidates as well as the underlying AI technology that generates them.

An AI **platform** company may focus more on creating a technology solution that customers or partners can readily customize and deploy for their own targets and programs. For example, such companies may still rely on at least some proprietary data to train and validate its AI models. They may also value customer usage data and feedback as information necessary to continually improve their platform and services.

However, such companies may be less interested in retaining exclusivity over the drugs generated with their platform. Like companies that commercialize language models, which often make clear in their terms of use for commercial users that they will take no ownership in either the prompts that users provide or the outputs that are generated, AI platform companies for drug development may prefer to drive revenue generation through repeated customer use (or

milestones tied to key outcomes, where the platform is being used in more of a strategic partnership context).

More broadly, there are a wide variety of use cases for AI and machine learning throughout these workflows, including computer vision applications, such as converting medical, sensor, cell images, etc., into useful information or features for further processing and model training; and techniques for moving experimentation previously performed in physical lab settings into simulations.

A. Recent Deal Review

A number of recent deals[12] reflect the varied business models and value propositions around AI drug discovery technologies. For example, such technologies are involved in university licensing, collaborations, and industry collaborations and licensing, spanning each of the data, training, operation and validation, and trials (and to market) segments of the workflow shown above in Fig. 1. Representative transactions are introduced below and summarized in Table 1.

University IP Licensing: Bullfrog AI is a company focused on AI/ML analysis in the advancement of medicine,[13] and since 2018 has entered multiple license agreements with the Johns Hopkins University Applied Physics Laboratory. In particular, Bullfrog AI has licensed IP, including patents, from Johns Hopkins for technology used in Bullfrog's "bfLEAP" platform,[14] including in connection with a commercial contract with another partner for analysis of late-stage clinical data.[15]

Preclinical Candidate Licensing: Evaxion, which is developing vaccines using AI, entered an option agreement with Merck for Merck to exclusively license preclinical vaccine candidates.[16] Merck later exercised the license option on a candidate under this agreement.[17] The license

[12] Deals identified from keyword searches in the SEC EDGAR database for the time period between January 1, 2022 and September 30, 2025; citations in Table 1 provided to EDGAR data and/or corresponding press releases.
[13] https://www.sec.gov/Archives/edgar/data/1829247/000149315224030569/forms-3.htm
[14] *Id.*
[15] *Id.*
[16] https://www.sec.gov/Archives/edgar/data/1828253/000117184324005434/f6k_100124.htm
[17] https://evaxion.ai/?press_release_id=10586

contemplates various milestone payments, along with further development of the vaccine candidate.[18]

Strategic Collaboration: Tempus and Recursion entered a strategic collaboration in 2023 for "biomarker-driven therapeutic development with a data-first approach."[19] This data-first approach is reflected in the collaboration's division of ownership between the licensed data, which is retained by Tempus, and results generated by Recursion as an end user of Tempus's technology, which are owned by Recursion.[20]

Drug Creation Partnerships: Absci is an AI drug creation company that combines AI-guided antibody drug creation and AI-guided lead optimization with validation in lab experiments.[21] Absci states that they "structure our partnerships as drug creation agreements with options for our partners to license intellectual property rights to the biological assets we create after completion of the drug creation phase."[22] Absci also more broadly identifies IP-related advantages in AI-baesd drug creation, in that such approaches generate "broader IP for first-in-class drugs and finds new IP for fast-follower or best-in-class strategies."[23]

[18] *Id.*
[19] https://www.tempus.com/news/tempus-announces-new-strategic-collaboration-with-recursion-to-advance-therapeutic-development/
[20] https://www.sec.gov/Archives/edgar/data/1717115/000119312524142956/d221145dex1022.htm
[21] https://www.sec.gov/Archives/edgar/data/1672688/000162828024012366/absi-20231231.htm
[22] *Id.*
[23] *Id.*

Table 1. Summary of Deals.

Deal Type /Business Model	Relevant Technology and/or Assets	Targets, Therapeutic Areas, and/or Indications	Entity Types	Example Terms
Licensing university research-based IP[24]	AI/ML platform for analysis of complex data in advancement of medicine, including evaluating pre-clinical and clinical trial data	Various applications	Licensor: Tier 1 Research University Licensee: technology-enabled drug discovery company	Equity, royalties upfront payments
Expanded collaboration to option and license agreement[25]; option later exercised[26]	Preclinical AI-based vaccine candidates; no clear indication of license to/use of underlying platform	Infectious agent	Licensor: clinical stage biotech/ "techbio[27]" Licensee: large pharmaceutical firm	Upfront payments; milestone payments; royalties
Strategic collaboration[28]	De-identified multimodal data (to support AI model development)	Biomarker-driven therapeutic development	Licensor: technology company advancing precision medicine Licensee: clinical stage techbio	Annual payments
Structuring partnerships as drug creation agreements with options for partners	Integrated drug creation platform combining data to train, AI to create,	Various applications, including dermatology,	Partners include large pharmaceutical firms	Potential milestone payments and royalties upon

[24] https://www.sec.gov/Archives/edgar/data/1829247/000149315224030569/forms-3.htm (also discussing licenses for cancer drugs and strategic data and commercialization agreements, along with "go to market with the discoveries with the ultimate goal of securing multiple revenue generating strategic partnership deals with biopharmaceutical companies.")
[25] https://investors.evaxion.ai/news-releases/news-release-details/evaxion-significantly-expands-vaccine-development-collaboration
[26] https://evaxion.ai/?press_release_id=10586
[27] "Techbio" often used by firms operating from a software/ML/AI-focus, in contrast to more traditional "biotech." *See, e.g.*, https://www.bioindustry.org/policy/technologies/techbio.html
[28] https://www.tempus.com/news/tempus-announces-new-strategic-collaboration-with-recursion-to-advance-therapeutic-development/

Deal Type /Business Model	Relevant Technology and/or Assets	Targets, Therapeutic Areas, and/or Indications	Entity Types	Example Terms
to license IP rights to AI-developed assets; developing proprietary asset pipeline[29]	and wet lab validation	oncology, and hematology		certain drug creation activities

This landscape demonstrates the critical role of IP rights, as well as significant customization of how IP rights are allocated to account for the new, evolving business models and collaboration structures. For example, across the example deals and other business models noted above, many of the key components of the workflow of Figure 1 are implicated. This includes proprietary data licensing; AI model training; and execution on and feedback from both wet lab experimentation and clinical trials. Given the diversity and creativity in these business models and transaction structures, corresponding flexibility in IP assets to support such efforts may also be expected.

IV. IP Toolkit for AI Drug Discovery and Development

As previewed above, IP strategies for technologies at the intersection of AI and biopharmaceuticals involve patents and trade secret protection, along with copyright-type protections, including open source licensing. These types of protection are outlined in the table below.[30]

Table 2. Major Types of IP Protection Applicable to AI for Drug Development Technologies

Type of Protection	What It Covers	Can Apply to AI for Drug Development?
Patent	Ideas - machine, method, article of manufacture, composition of matter; protects against independent discovery	Yes – focus on technical solution to technical problem, particularly where demonstrate improvements to the AI as opposed to better data processing
Trade Secret	Confidential information not publicly available + protected	Yes

[29] https://www.sec.gov/Archives/edgar/data/1672688/000162828024012366/absi-20231231.htm
[30] Trademarks are not discussed here as being less relevant to maintaining exclusivity over technologies themselves.

Type of Protection	What It Covers	Can Apply to AI for Drug Development?
	from disclosure; does not protect against independent discovery	
Copyright	Creative work – expression of idea as captured in a written/visual/musical form	Potentially around (creative/design aspects) of software that implements the AI/ML
Open Source	Open source licenses typically allow for public, free access to software technologies, with various requirements directing the licensee's obligations on further sharing, derivatives, and including such requirements in copies of the software	Yes

In addition, in the context of biopharma innovation, and continuing for AI drug discovery technologies, proprietary data is a critical asset[31] often maintained as a trade secret. While techniques such as federated learning may have potential for allowing multiple firms to use (and improve) the same AI platform without revealing confidential information, successfully implementing such techniques is challenging.[32] For example, in federated learning, many different firms can train a base version of a machine learning model using their own data, where such training is reflected in new model updates, such as gradients or weights; each firm can then share the model updates (which can also be aggregated and redistributed) instead of the underlying data. This allows each participant in the federation to take advantage of improved performance learned across a greater amount of useful data; however, depending on how the technology is implemented, it may be possible to still extract the underlying private data from the model updates.

As such, the "data moat" strategy may remain a key tenet of an overall IP strategy. For example, an AI drug development platform can use (proprietary) data as inputs Valuable data in the AI drug development context can include both the data used to train or fine-tune models as

[31] *See* https://www.nature.com/articles/d41586-025-00602-5.
[32] https://www.nature.com/articles/d41586-025-00602-5.

well as the outputs generated by the models. Rather than relying only on explicit IP rights tied to the models themselves, or to the eventual drug assets that might be formulated from the outputs of the models, firms may consider maintaining confidentiality over the data (both on the input or training side and on the output side). The hypotheses supporting this strategy include (1) as AI technologies overall improve, better insights can be unlocked from a given set of data; and (2) this approach is limited in time only by the usefulness of the data, not a term limit as with patent protection.

V. Factors that Drive the Patenting Decision

In the context of these options for protecting AI drug development technologies as well as various business models in this space, it is useful to understand certain factors that drive the value of different forms of IP protection. Strategies for protecting these technologies can be evaluated from a cost-benefit perspective, where any form of IP protection may have financial costs to procure protection, resource costs to establish processes for identifying innovations and maintaining trade secret programs, and time costs for the efforts required to manage these processes. The factors described below underscore the scope of protection that can be achieved through patenting, which corresponds to the benefit side of the cost-benefit equation when evaluating how to protect these technologies.

Criticality (and Design Arounds): How *critical* an invention is will indicate the likelihood that a competitor will need to practice the same invention in order to achieve commercial success. As an example, if a computational technology requires a specific filter for the input data in order to achieve performance criteria such as accuracy or speed, without which customers might not use the technology, this filtering can be critical—and thus a strong basis for choosing to patent the technology. On the other hand, if there are a number of ways to avoid using the filter while still achieving a commercially viable product—in other words, design-arounds—then the invention (at least when patent claims include the filter) would not be critical, and thus may not be worth patent protection.

Patentability is often used as an umbrella for the substantive requirements for claims, namely that they be patent eligible under 35 U.S.C. § 101 (as discussed above), novel under 35 U.S.C. § 102, and non-obvious under 35 U.S.C. § 103. Patentability can be analyzed as a

discrete factor—is the technology patentable or not—or, more effectively, on a spectrum—how much effort, for example, rounds of prosecution with the USPTO, will be required to achieve a granted patent of useful claim scope. This factor may be evaluated both before a non-provisional application is filed, such as based on prior understanding of the art as well as specific prior art results identified through searching, as well as during the examination process as rejections are received and considered. Patentability is grounded in a sliding scale tied to the scope of the claims[33], where more useful (typically "broader") claims, all else being equal, are more difficult to patent than "narrower" claims that may be less likely to be infringed, or more easily designed around. The question of patentability is further complicated by the multiple venues in which patents can be challenged after grant, such as the Patent Trial and Appeal Board and district court (and appeals court) litigation, where greater resources applied by patent challenges (and substantive and/or procedural standards) can lead to invalidation of claims previously deemed patentable by the USPTO.

Commented [A1]: To address comment about explaining what "example claims" are later in the document, in reference to the USPTO subject matter eligibility guidance, a brief footnote definition of claims is suggested here (assuming the overall book will not have a standard definition)

Detectability: Enforcing a patent depends on *detecting* that the patent has (potentially) been infringed in the first place. The patent exclusionary right cannot be enforced without awareness of the claimed technology being practiced by another party. While this is typically not an issue for some technologies, such as mechanical/structural inventions where infringement can be confirmed based on visual inspection, it is more challenging to determine that software-based technologies infringe a patent. Patents for AI technologies often rely on algorithmic details that may only be apparent at the source code level. While some companies may publish marketing materials or technical documents that reveal software functionality in sufficient detail to demonstrate infringement, in other instances such information may not be publicly available.

Detectability is also directly related to meeting the standard for pleading patent infringement. Although "patentees are not required to plead infringement on an element-by-element basis,[34]" there must be "some factual allegations that, when taken as true, articulate why it is plausible that

[33] Every granted patent has one or more claims that define what the patent owner can prevent others from exploiting, generally structured as a list of required features where, if each required feature is present in a product or service, the patent may be enforceable against the product or service.
[34] Bot M8 LLC v. Sony Corp. of Am., 4 F.4th 1342 (Fed. Cir. July 13, 2021) at 1352.

the accused product infringes the patent claim;" a conclusory statement that a product infringes a patent is insufficient.[35]

Thus for AI technologies, properly pleading patent infringement is likely to require at least some factual articulation that the product has specifically claimed data processing steps or model architecture features, which may not be explicitly described in publicly available information for the product. As such, and in tandem with the patentability factor, there may be lesser incentive to patent technologies that need to be claimed at a level of detail that is challenging to detect.

Ability to Reverse Engineer: The ease of *reverse engineering* a technology is a significant factor in focusing on patent or trade secret protection. Generally, technologies that are easier to reverse engineer are more effectively protected with patents rather than trade secrets, since (later) independent discovery of a technology has no bearing on patent infringement, while it allows for trade secret protection to be circumvented. Conversely, trade secret protection will generally be stronger for inventions that are challenging to reverse engineer, as it becomes more likely that the technology can be successfully maintained as secret for long periods of time. For AI technologies, the reverse engineering question can be highly dependent on where the commercially valuable aspects of the technology lie: certain aspects, such as data used for the model, may be more public than others, such as specific model architecture features or thresholds for triggering actions.

Ability to Keep Secret: Related to reverse engineering—and the trade secret question more generally, is how easily a technology can be *kept secret*. For example, techniques such as dividing the technology across personnel and security barriers can be more effective for software platforms that have distinct modular components, while other technologies may not be as easily kept secret.

Infringement Targeting: Direct patent infringement, where all elements of the patented invention are practiced by a (single) infringing entity, is generally preferable to other, indirect infringement theories that have additional requirements (such as inducement or knowledge) in order to

[35] *Id.* at 1351.

successfully prove infringement.[36] Such requirements can increase both the cost and difficulty of proving infringement.

VI. Applying the Patentability Factors to Technologies in AI Drug Development Business Models

As explained above, the AI drug development field has a variety of business models. The product or service that a company sells may remain in the computational domain, such as an electronic representation of an asset or an electronic process performed using customer data. The product or service may involve real-world synthesis of an asset or real-world processes performed on assets, or may cross over between both electronic and real-world domains.

These considerations are fundamental to properly crafting patent claims. For example, if an AI drug discovery company provides a platform for customers to generate drug candidates based on customer data, and does not perform any real-world drug synthesis, it will not be useful to limit claims to synthesis steps. There may be nuances to such distinctions depending on whether the AI technology is a general platform that customers can use to address any number of therapeutic targets, or more specifically tailored to a target, as this may affect whether there is a "substantial noninfringing use" that would allow for contributory infringement.[37] At the same time, claims are more likely to be eligible under 35 U.S.C. § 101 if they recite a real-world action like synthesizing an asset or administering the asset to a patient. As such, there is significant tension between drafting AI drug discovery claims that have direct infringers and that are patentable.

To summarize, strong patent claims can (1) easily be mapped to a single competitor; and (2) have (a) sufficient detail to overcome patent eligibility and prior art-based challenges without sacrificing (b) detectability or (c) criticality. The tension amongst these factors, along with difficulties in predicting what technologies will be commercially valuable over the 20-year patent term, make it challenging to pursue patent claims that can be confidently considered valuable. For example, a patent claim that includes both generating a candidate small molecule drug with AI and synthesizing the drug can more easily overcome the subject matter eligibility hurdle, but will be limited in enforceability to competitors that also perform both of these steps—

[36] *See* 35 U.S.C. §§ 271(a), 271(b), 271(c).
[37] *See* 35 U.S.C. § 271(c).

and thus will be difficult to enforce, without a strong contributory infringement position, against competitors that only commercialize the AI technology without actually synthesizing drugs. On the other hand, a claim that covers an AI technology that processes customer data to predict drug candidates may avoid the contributory infringement issue, but will have difficult examination (or be susceptible to invalidation after grant) without including key technical details, or will be less detectable and, likely, have less criticality if such details are claimed. Firms may thus pursue portfolio development in a manner more akin to technology companies than biopharma companies, seeking to build out a portfolio of a large number of less critical, low-cost patents: each patent individually may not provide broad exclusivity for a target, indication, or general business model, but together the patents can cover many different technologies and thus can still be effective for holding off competition.

Commented [A2]: These updates, including emphasizing the potential "low cost" nature of such patents as well as their combination into a comprehensive portfolio, is intended to address the comment: "Page 11: "Firms may thus pursue portfolio development in a manner more akin to technology companies than biopharma companies": This sentence is not clearly supported by the previous language in this paragraph, which seems to describe how certain factors in general can disfavor using patenting as a monetization/appropriation strategy. Consider reworking previous language in paragraph to more clearly support this concluding statement, specifically by showing how factors that tend to disfavor patentability are salient for certain AI technologies being used in the biopharma space."

VII. Further Considerations for AI Patent Eligibility in US, Europe, and China

Firms seeking to establish global footprints for pharmaceutical development will also consider patent law in various jurisdictions in addition to the US, including Europe (specifically, with the European Patent Office (EPO)) and China. Each of these jurisdictions continues to develop their criteria for patent eligibility of AI-related inventions.

EPO Guidelines

The EPO examination guidelines, most recently updated in April 2025, focus on identifying a technical character for patent eligibility, in contrast to merely abstract ideas[38]. For example, the EPO explains that "AI is based on computational models and mathematical algorithms which are *per se* of an abstract nature. Nevertheless, patents may be granted when AI leaves the abstract realm by applying it to solve a technical problem in a field of technology. For example, the use of a neural network in a heart-monitoring apparatus for the purpose of identifying irregular heartbeats makes a technical contribution.[39]" This technical contribution standard is thus similar to US requirements, allowing for a harmonized claim strategy across the US and EPO.

[38] Guidelines for Examination in the EPO, G-II, 3.3.1 Artificial intelligence and machine learning.
[39] https://www.epo.org/en/news-events/in-focus/ict/artificial-intelligence

Additional patent eligible examples that the EPO provides, which may be relevant to AI drug discovery technologies, include "providing a genotype estimate based on an analysis of DNA samples, as well as providing a confidence interval for this estimate so as to quantify its reliability" and "providing a medical diagnosis by an automated system processing physiological measurements." However, these life science-related examples each require a clear recitation of at least real-world inputs (DNA samples; physiological measurements). Another example that may be useful for AI drug development that does not directly rely on real-world measurements includes "digital audio, image or video enhancement or analysis, such as de-noising, detecting persons in a digital image, estimating the quality of a transmitted digital audio signal."

CNIPA Guidelines

The China National Intellectual Property Administration (CNIPA) issued Guidelines for Patent Applications for Artificial Intelligence ("AI") Related Inventions on December 31, 2024[40]. These guidelines, distinct from the EPO guidelines and US criteria (discussed further below), explicitly categorize AI-related inventions into four categories:

a) AI algorithms or models themselves;
b) functions or field applications based on AI algorithms or models;
c) inventions made with AI assistance (with substantial human contribution); and
d) AI-generated inventions.

AI technologies from drug development would likely fall into one of the first two categories (with the fourth category likely being ineligible).

In addition, patent eligibility for AI inventions in China involves a determination that the "solution of the claim should reflect the use of technical means that follow the laws of nature to solve technical problems and achieve technical effects."[41] Suggested patent eligible examples include processing image features in a manner closely related to classifying objects, or "the specific technical connection between the artificial intelligence algorithm or model and the

[40] https://www.chinaiplawupdate.com/2025/01/chinas-national-intellectual-property-administration-issues-guidelines-for-patent-applications-for-ai-related-inventions/
[41] *Id.*

internal structure of the computer system," such as to solve technical problems relating to computing speed or data storage reduction. [42]

USPTO and Federal Circuit Guidelines

The threshold for patent eligibility in the US is also in flux across both the USPTO and Federal Circuit jurisprudence. Four distinct guide posts have emerged since July 2024, several in the last few months potentially indicating a swing towards more opportunities for patent eligibility.

a) USPTO Subject Matter Eligibility Examples

The USPTO provides guidance on subject matter eligibility with a number of example claims that are patent-eligible or ineligible, including both examples from court decisions as well as toy examples.[43] The most recent guidance notes that a "key point of distinction to be made for AI inventions is between a claim that reflects an improvement to a computer or other technology described in the specification (which is eligible) and a claim in which the additional elements amount to no more than (1) a recitation of the words "apply it" (or an equivalent) or are no more than instructions to implement a judicial exception on a computer, or (2) a general linking of the use of a judicial exception to a particular technological environment or field of use (which is ineligible)..[44] For example, this guidance includes example claims relating to using an artificial neural network (ANN) to detect anomalies; using a deep neural network (DNN) to separate speech from different sources; and an AI model designed to assist in personalizing medical treatment to the individual characteristics of a particular patient.[45]

Notably, for the example claims relating to the last of these three concepts, the key to patent eligibility was a claim limitation for administering a particular treatment determined through use of the AI model.[46] Thus while this example provides a basis for patent eligibility where AI is used to address a particular problem, it also relies on both use of the model (which may be sold or controlled by one entity, such as a technology developer) as well as administration of a

[42] *Id.*
[43] https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility
[44] https://www.federalregister.gov/documents/2024/07/17/2024-15377/2024-guidance-update-on-patent-subject-matter-eligibility-including-on-artificial-intelligence
[45] https://www.uspto.gov/sites/default/files/documents/2024-AI-SMEUpdateExamples47-49.pdf
[46] *Id.*

treatment (which may be performed by another entity, such as a medical professional), leading to the divided infringement issues noted above.

b) August 4th Memo

In a memorandum[47] directed to certain Technology Centers that review a high volume of AI-related patent applications, the USPTO also recently clarified its standards for evaluating AI-related claims under 35 U.S.C. § 101. In particular, the USPTO emphasized limits on categorizing AI technologies as abstract ideas that can be "performed in the human mind." For example, the USPTO explained that there is a difference between claims that might involve AI technologies, such as training a machine learning model, and those that actually delve into specific mathematical operations.[48] This guidance thus suggests that claims that attempt to build exclusionary rights around fundamental mathematical concepts are more likely to be subject to 35 U.S.C. § 101 rejections than those that use or improve AI in the context of specific applications.[49]

c) *Ex parte Desjardins*

In *Ex parte Desjardins*[50], a USPTO Appeals Review Panel (ARP) withdrew a 35 U.S.C. § 101 rejection for a technology for training machine learning models to be capable of learning to perform well across multiple tasks. The ARP emphasized that "much of the advancement made in computer technology consists of improvements to software that, by their very nature, may not be defined by particular physical features but rather by logical structures and processes.[51]" From this point, and based on (1) an assertion in the patent application of how the described technology leads to the ability of the AI system to learn new tasks while using less storage capacity and having reduced system complexity and (2) that the claims reflected such an improvement, the ARP concluded that the claims were patent eligible.

d) Recentive v. Fox

[47] https://www.uspto.gov/sites/default/files/documents/memo-101-20250804.pdf
[48] *Id.* at 3.
[49] *See id.* at 4.
[50] https://www.uspto.gov/sites/default/files/documents/202400567-arp-rehearing-decision-20250926.pdf
[51] *Id.* at 8 (citing *Enfish, LLC v. Microsoft Corp.*, 822 F. 3d 1327, 1339 (Fed. Cir. 2016)).

At the Federal Circuit level, the 2025 *Recentive v. Fox* decision moved the patent eligibility line further from any use of AI/ML and the straightforward improvements these technologies enable, such as previously unattainable results or operating faster than a human could. Specifically, the *Recentive* court may have moved the line potentially to a requirement for improvements in the AI/ML itself, if not clear improvements resulting from different ways that a computer operates.[52] For example, *Recentive* concluded that "Machine learning is a burgeoning and increasingly important field and may lead to patent eligible improvements in technology. Today, we hold only that patents that do no more than claim the application of generic machine learning to new data environments, without disclosing improvements to the machine learning models to be applied, are patent ineligible under § 101.[53]" For example, "the claimed methods are not rendered patent eligible by the fact that (using existing machine learning technology) they perform a task previously undertaken by humans with greater speed and efficiency than could previously be achieved.[54]" In other words, going forward, patent eligible claims for AI technologies, including for drug discovery applications, will likely require some demonstration that the AI technology is being used for more than its well-understood benefits, such as by demonstrating a new solution to a new problem, an improvement in how a computer operates through the use of the AI technology, an improvement relative to another computer technology, and/or an unconventional structure or arrangement of operations in the algorithm.[55]

Taken together, these guideposts suggest that at least in the short term, AI drug development inventions that tie the use of AI to clear improvements in the AI itself, or to the field of computational techniques for drug development more generally, will likely be patent eligible under 35 U.S.C. § 101. At the same time, firms should be mindful of the standard set forth in *Recentive*, and thus include robust explanation of these improvements in their applications in order to survive any challenges if the eventually granted patents are challenged in litigation.

For example, firms seeking to build a strong, global patent portfolio to support their business models around AI for drug discovery thus need to be mindful of both (1) the "improvement"-

[52] https://www.cafc.uscourts.gov/opinions-orders/23-2437.OPINION.4-18-2025_2500790.pdf
[53] *Id.*
[54] *Id.*
[55] *Compare* the discussion in *Recentive* with Step 2B of the *Alice/Mayo* test, such as discussed in BASCOM Global Internet v. AT&T Mobility LLC, 827 F.3d 1341, 1350-51, 119 USPQ2d 1236, 1243 (Fed. Cir. 2016); *see also Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 573 U.S. 208, 225, 110 USPQ2d at 1984 (2014).

focused themes across multiple jurisdictions and (2) the potentially divergent standards for patent eligibility applied in patent office examination and in litigation. For example, patent applications should clearly articulate how the AI used in drug discovery not only achieves previously unattainable results, such as proposing more drug candidates over time than may have been possible through manual efforts, but also (a) any computer technology-specific improvements such as more efficient memory or processor usage, as well as (b) any AI drug discovery technology-specific improvements, such as improved precision, accuracy, and/or recall, or other novel metrics that can be validated by test data, relative to conventional computational drug discovery technologies.

VIII. Example Patent Claims

In view of these considerations, the following toy example claims are provided to compare and contrast the range of AI drug discovery patenting strategies in the context of subject matter eligibility and other factors explained above. This analysis also highlights where issues may arise that could potentially suggest, at least under a cost-benefit analysis, where trade secret protection may be preferred to patent protection in order to achieve meaningful exclusivity. The claims are broken down into input, output, and processing steps to facilitate evaluation. Example 1 is generally designed to have a greater likelihood of patentability than Example 2, while Example 2 is generally designed to have a greater likelihood of detectability and criticality than Example 1. More realistic versions of these claims could potentially focus more specifically on certain targets or therapeutic areas, if consistent with a firm's business strategy (though simply tying the claims to a particular focus may not be helpful for patent eligibility, even if useful for novelty and nonobviousness).

Table 3. Example Claims for AI Drug Discovery Technologies

A system, comprising:

one or more processors to:

Steps	Example 1	Example 2
Input	- receive training data comprising a plurality of training data elements, each training data element comprising a protein sequence	- retrieve a representation of a biological target

Steps	Example 1	Example 2
	and a metric for the protein sequence with respect to interaction with a corresponding target;	
Processing	- cause an encoder to encode the protein sequence of each training data element of the plurality of training data elements into a latent representation of the protein sequence for each training data element; - apply, as input to a neural network, the latent representation of the protein sequence for each training data element, to cause the neural network to generate an output corresponding to each protein sequence; - update the neural network, based on each output and each metric for the protein sequence, to generate an updated neural network; and	- apply the representation as input to a machine learning model to cause the machine learning model to generate a plurality of candidate protein sequences corresponding to the biological target; - apply each candidate protein sequence of the plurality of candidate protein sequences as input to a target interaction function to generate a metric for interacting between candidate protein sequence and the biological target; - select, based on the metric generated for each candidate protein sequence, a subset of the candidate protein sequences; and
Output	- output a representation of the updated diffusion model	- output a representation of the label and the one or more conditions.
Evaluation Factors		
Patentability	Example 1 highlights the use of an encoder to allow the model to be trained in a latent space, which may provide computational improvements (and is intended to reflect a presumably novel approach)	Example 2 focuses more on an input-output perspective for the model, which may have patentability challenges without a clear tie between a technical improvement and certain claim limitations
Criticality	Example 1 may potentially have criticality if the claimed encoder implementation provides a significant performance improvement such that competitors would need to pursue such an approach in order to realize that improvement as well. On the other hand, if alternative approaches are still useful, it may be necessary to either	Example 2 appears to have criticality by focusing broadly on how the AI model is used to evaluate and select drug candidates.

Steps	Example 1	Example 2
	concede criticality or pursue more applications for those approaches.	
Detectability, Ability to Reverse Engineer, Ability to Keep Secret	This claim may have detectability challenges if competitors do not openly tout the use of this type of model, or the benefits that can be expected for it; on the other hand, if that holds true, it may similarly be difficult to reverse engineer (and/or easier to keep secret)	Given the level of generality of this claim, it may be fairly easy to detect, and similarly easy to reverse engineer (and difficult to keep secret).
Infringement Targeting	Both Example 1 and Example 2 can be expected to be useful in targeting a single entity, and thus avoid divided infringement issues. As discussed above, at least one AI drug discovery firm is pursuing business models in which they both use AI to develop a drug candidate and synthesize the drug candidate before licensing, which indicates it may still be possible to have claims that include synthesizing an asset without necessarily triggering divided infringement issues.	See to left.

These claims provide useful examples for testing the patentability and patent strategy analyses. It should be expected that as the AI drug development field evolves, the patent landscape will become more crowded, and thus novelty and non-obviousness challenges will increase.

IX. How Have AI Drug Development Technologies Been Protected to Date?

This section reviews the patent landscape for AI in drug development. In particular, 800+ US patent assets (published applications and granted patents publicly available as of May 15, 2025) owned by a number of key firms in the space were identified to define a representative sample of

patent assets to review.[56] The number of patent assets owned by each firm ranged from less than 10 to over 150, and were primarily filed in the last ten years.

Table 4 gives a high-level categorization of the identified patent assets into AI/ML/computational-focused or conventional technology-focused. In particular, patent assets were classified as being directed to AI/ML if such technologies were referenced in the title, abstract, or independent claims, otherwise as conventional (even if some discussion of computational methods was present in the description – but not the claims).

Table 4. Categorization of patent assets of identified firms.

AI/ML Focus	Asset-Only/Conventional Focus
180	530

Based on this high-level categorization, firms currently[57] tend to focus more on pursuing patent protection for assets rather than for AI/ML platforms.

Focusing further on patent examination strategy, it can be useful to review the USPTO Technology Centers (and art units) that the AI/ML patent assets are assigned to. Technology Centers include teams of examiners at the USPTO generally organized according to subject matter expertise[58] (further refined to specific art units); they may have varying allowance rates and other indices of examination difficulty (and cost) for otherwise similar subject matter. At the same time, applications may vary in the Technology Centers that they are assigned to based on information in applications that is used to classify them.[59]

[56] Companies were identified from previous reviews including "Expert Q&A on AI-Assisted Drug Development and Patents," https://us.practicallaw.thomsonreuters.com/w-042-2767, and https://www.biopharmatrend.com/ai-drug-discovery-pipeline/.
[57] Recognizing that there is typically an 18-month publication lag from when an application is filed to when it is made publicly available, and thus information regarding applications filed in the most recent 18 months is generally unavailable.
[58] https://www.uspto.gov/patents/contact-patents/patent-technology-centers-management
[59] *See* https://www.uspto.gov/patents/search/understanding-patent-classifications/classes-arranged-123

As such, applicants may gain advantages by preparing applications in a manner that can increase the likelihood that the applications will be directed towards Technology Centers expected to have smoother examination.

Table 5 below identifies the Technology Centers that the AI/ML applications were assigned to[60], along with corresponding allowance rates and, as a measure of examination ease and cost, the average duration of examination (from receipt of first Office Action to receipt of a Notice of Allowance) for the Technology Centers:

Technology Center	**Total Patent Assets**	**Allowance Rate (percent)[61]**	**Average Duration of Examination[62]**
1600 (Biotechnology and Organic)	47	57	1 year, 5 months
2600 (Communications)	39	80	1 year
2100 (Computer Architecture Software and Information Security)	31	76	1 year, 3 months
2800 (Semiconductors, Electrical and Optical Systems and Components)	15	83	10 months
3600 (Transportation, Electronic Commerce, Construction, Agriculture)	6	68	1 year, 1 month
1700 (Chemistry and Materials Engineering)	6	65	1 year, 3 months
2400 (Computer Networks, Multiplex, Cable and Cryptography/Security)	4	79	1 year, 3 months

As indicated above, applications for these technologies are generally assigned to Technology Center 1600 (biotechnology and organic). However, this Technology Center has the lowest allowance rate and longest duration of examination. At the same time, many applications are

[60] A number of the identified assets have not yet been assigned to Technology Centers.
[61] For all applications assigned to Technology Center.
[62] For all applications assigned to Technology Centre.

assigned to more computer technology-focused art units, which have significantly higher allowance rates and faster examination.

As such, AI drug development firms may benefit from designing their patent applications to be better suited towards more computer technology-focused art units. For example, titles, claims, and abstracts can be structured to more clearly emphasize the computer operations being performed, rather than the biological results achieved. This may also help address subject matter eligibility, further expediting examination.

The vast majority of the identified references did not clearly direct an AI platform to a specific indication (such as a disease or condition) or target (a biological molecule that a drug is designed to interact with to achieve a therapeutic effect, such as to address an indication). This could be a result of any of several factors:

- Patentability for AI technologies relies primarily on improvements to the computational technologies, rather than their use for specific indications. Absent a technical problem in the computer processing realm, there is unlikely to be a benefit to constraining AI claims to a particular indication
- So far in the early development of the AI for drug development sector, many business strategies have focused on providing a platform, and thus at least having the optionality to protect the technology at a platform level, rather than specific indication level, is reflected in the patent strategy
- There can be a time lag between when an AI model is ready for patenting[63] and when it is ready to patent for a particular indication, meaning that both being first to file and potential public sale or disclosure of technology make it risky to delay filing until both the model itself and the indication are ready
- Little to no clinical data may have been available 18 months ago or earlier to validate any particular drug candidate that has arisen from an AI drug discovery process, making it more difficult to use experimental data to demonstrate technical improvements and/or unexpected results that may support patentability

[63] *See, e.g.*, Barry v. Medtronic, Inc., 914 F.3d 1310, 1326-27 (Fed. Cir. 2019).

Nevertheless, as the AI drug development sectors matures, these factors leave room for increased focus on claiming AI models in a manner directed to specific indications. For example, as more AI drug development technologies, publications, and patent applications become public, and thus become prior art against future patent filings, such patent filings will have a higher patentability burden, and thus will likely need to be more narrowly tailored in order to be granted. Future filings that describe unique improvements from directing AI technology towards specific indications may thus allow for continued patent portfolio development over time even as protection for AI platforms, generic to specific indications, may become more difficult.

X. Takeaways for Key Players in Biopharma

Based on the above analysis, IP strategies for AI drug development technologies are still evolving, consistent with the variety and advancing nature of business models built around these technologies. While asset-focused protection remains the primary focus of firms operating in this space, and subject matter eligibility may prove to be a high bar for patentability on AI/ML-focused applications, there may be plenty of opportunities for firms to develop AI/ML-focused patent coverage to establish exclusivity, including as part of a comprehensive strategy that also uses trade secrets effectively.

For example, techbio firms should clearly identify the unique value they can bring to market – whether focused on assets, AI platforms, or data moats around internally developed and/or licensed data. End-to-end developers may prioritize patents on both drug candidates and AI technologies; this can set them up for success in protecting both the AI technology used for target identification or lead optimization, as well as the wet lab validation steps that can help drive deals for licensing the drug candidates. Platform providers may rely more on trade secrets and a "data moat" for model internals and datasets, relying on contractual obligations to maintain exclusivity over the proprietary data that they may expose through the platform to customers. For example, such platform providers may focus on selectively patenting only non-obvious, hard-to-reverse-engineer advances. Where pursuing patent strategies, such firms can consider focusing on claims that emphasize efficient architectures or real-world steps to bolster eligibility, in conjunction with targeting filings towards faster, higher-allowance Technology Centers. These firms can similarly apply such tactics to efficiently developing a global portfolio.

These firms may also consider complementing patent efforts with strategic use of open-source and copyright protections (while making efforts to ensure that license compliance does not require disclosure of proprietary data). In addition, patent filings can be timed to focus on key platform advancements to secure early priority dates, with some resources directed towards later, indication-specific applications as clinical results accrue.

Larger firms considering how to integrate AI drug development into their pipelines—whether through use of AI platforms or licensing or acquisition of AI-developed assets (or entire techbio firms) can similarly strengthen their negotiating positions with an eye towards such strategies. For example, it may be helpful to devote some patenting resources towards ways in which AI drug development may support their current or future drug development roadmap. In addition, such firms may benefit from evaluating the greater variety of deal structures that AI platforms unlock. This can allow for more focused deployment of financing towards deals that provide specific value to the firms' overall strategy.

XI. Conclusion

The rise of AI-driven drug discovery is forcing a fundamental change in biopharma IP strategy. While patents on tangible assets remain critical to recouping high R&D investments, the shifting value toward computational approaches demands a more nuanced toolbox. For example, more deals and other business models are assigning value to AI drug development platforms, whether directly for the use of such platforms or data generated by such platforms, or indirectly through licensing of AI-developed assets. Early-stage firms must weigh patent protection against trade secret and other non-patent approaches, such as by evaluating factors including criticality, patentability, detectability, reverse-engineering risk, and the ability to keep inventions secret. When patents are pursued, claims should highlight genuine computer-technology improvements or real-world steps to survive eligibility challenges, and techniques to direct filings towards faster, higher-allowance art units should be considered. At the same time, strategic use of copyright and data ownership-based protections can preserve competitive advantage without over-extending limited budgets. For established pharmaceutical enterprises, integrating AI platforms or acquiring techbio innovators can mean reassessing deal structures and in-licensing terms through this same IP lens—ensuring that data, algorithms, and assets are properly

protected to expand future pipelines. Ultimately, success in the AI-powered era of drug discovery will hinge on an adaptable approach that blends traditional asset patents with targeted protection of computational breakthroughs, and evolves in tandem with technological advances, regulatory shifts, and emerging business models.