Amgen Hasn't Resolved Questions on AI Medical Invention Patents

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- WilmerHale attorneys examine enablement of AI inventions
- Evolving nature of AI models presents questions after Amgen

Personalized medical intervention is in a transformative phase as artificial intelligence algorithms are increasingly deployed to tailor treatments for individual patients based on their unique characteristics.

Developers face the task of adequately protecting AI-based technologies under current US patent jurisprudence. Enablement and necessary disclosures to obtain patents related to AI are one such challenge.

Roughly a year has passed since the US Supreme Court delivered its enablement ruling in *Amgen Inc. v. Sanofi*, where the court refined the boundaries of undue experimentation. In Amgen, the challenged patent included broad functional claims to any antibody that bound to a protein and functioned a certain way.

The Supreme Court found that 26 examples of antibodies in the Amgen specification were insufficient to support claims to a broad genus functionally defined antibodies absent some enabling guidance. The ruling presents questions for the patentability of AI-related inventions in precision medicine.

Functional language may be required to secure commercially relevant claims. However, following *Amgen*, the amount of disclosure necessary to support allowance of such claims is unclear. These challenges are compounded both by the black box nature of AI-related models' work and the evolving nature of the models themselves.

Black Box Problem

AI models that employ deep learning models or complex neural networks are difficult to describe. These models may be based on a surprisingly small amount of actual software code and are instead trained using voluminous datasets. For example, an AI-based model might involve training with reams of patient information—including genetic profiles, clinical histories, and treatment outcomes—to identify patterns that inform tailored therapeutic approaches.

While the resulting outputs can be quite reliable, the model's actual operations frequently occur within a "black box" that is unknown to the operator and can be difficult to describe in retrospect.

AI systems have achieved great success in image-based front line diagnostic applications, for instance. In many of these systems, pattern recognition goes beyond merely detecting edges, volumes, and shapes—deeper layers of the network interrogate highly complex combinations of features.

Providing an enabling disclosure sufficient to support claims to the AI system or model can be challenging, particularly where the claims in a patent call upon functional terminology.

Because these models are often built through trial and error, the iterative process used to create the model may be as relevant to the function of the final model as the underlying training data. If one were to attempt to reconstruct the model without the specific sequence of failures encountered in the original build process, the reconstructed model may behave very differently from the original.

The disclosure of training data by itself may not be enough to provide the "general quality" that runs "through the class" unless it is presented alongside a blow-by-blow recounting of each specific trial and error encountered during the development of the model.

Amgen raises several questions regarding the extent of disclosure and general qualities sufficient for the enablement of AI inventions in precision medicine:

- Will training data need to be disclosed in patent specifications?
- If aspects of the training data cannot be disclosed, are there other solutions for properly enabling AI claims?
- Is the solution to shift the enablement inquiry in AI applications to overall functionality rather in lieu of requiring a detailed disclosure of the inner workings on the model?

Though the US Patent and Trademark Office is actively exploring solutions, and seeking public comment on how "patent applications for AI inventions [can] best comply with the enablement requirement," no affirmative guidance exists on the subject.

AI Models' Evolution

AI models used in personalized medicines typically aim to be dynamic and accommodate evolution over time as they're updated with new data, improved algorithms, and enhanced computational resources. This continuous development is crucial for increasing the models' accuracy, efficiency, and versatility.

Narrow AI claims allowed today may not be relevant to the models being used six months or six years later. However, it may not be trivial to provide an enabling disclosure that supports broad claims that cover the underlying concept of the model.

Unlike traditional medicines where a narrow claim to a compound would still cover the use of the compound in a later developed formulation or treatment method, AI models are more than the sum of their parts. It may not be possible to foreclose design-arounds by covering a single feature of the AI. Open questions regarding the best way to secure commercially relevant claim sets include:

- What claiming strategies are sufficient to allow AI patents to achieve commercial relevance over the life of the patent and the product?
- What types of data and other description might be necessary to support a model that evolves?
- What types of description would satisfy the Amgen requirement of a "general quality" that gives the class its "peculiar fitness" for a particular purpose?

These are largely abstract inquiries until the USPTO provides affirmative guidance and the Federal Circuit applies *Amgen* to AI claims.

How Section 112 law applies to AI claims in view of the Amgen v. Sanofi holding remains uncertain. However, patent disclosures will need to provide a detailed and clear description of the development process, including the iterative training of models, to navigate the post-Amgen landscape.

Practitioners should also consider the particular applications of their AI model and whether the technology is more suitable for trade secret protection.

The case is *Amgen Inc. v. Sanofi*, U.S., No. 21-757.

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