Building IP Value in Bioinformatics

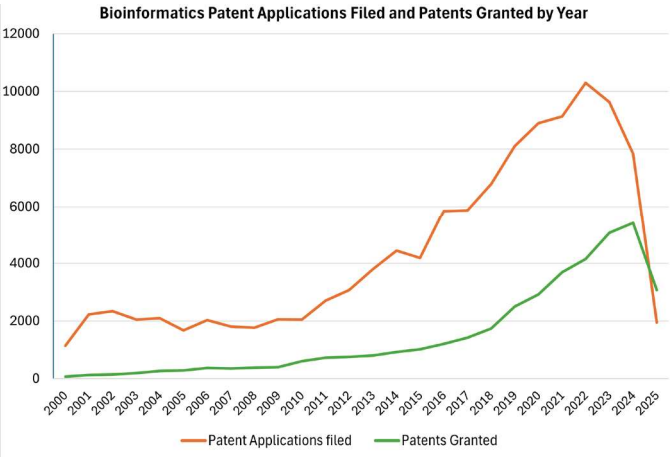
Bioinformatics sits at the convergence of computational methods, life sciences, diagnostics and data analytics. Advances in computational power and efficiencies and the increased capabilities of AI methods mean developments in genomics, diagnostics, computational biology and AI-driven drug discovery are driving forward at pace. Patenting in this field shows ever increasing activity, indicative of the commercially valuable nature of innovation in this field. However, with these emerging and rapidly developing technologies come intellectual property complexity and challenges. This article considers key patenting trends and patent protection considerations in bioinformatics.

What is Bioinformatics?

Bioinformatics is the science of using computational tools and methods to analyse biological data, particularly large datasets such as genomic sequences or protein structures. In the context of pharmacy, bioinformatics plays a vital role in drug discovery, development and personalised medicine by helping researchers identify new drug targets, predict how drugs will interact with specific genes or proteins and tailor treatments based on individual genetic profiles. As pharmaceutical research becomes increasingly data-driven, bioinformatics serves as a key bridge between laboratory science and clinical application.

Patent Filing Trends

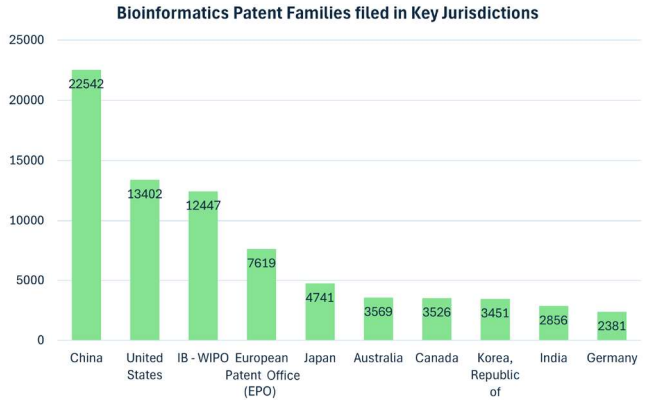
Since 2000, the number of patent filings in bioinformatics has held steady at around 2000, with an increase from around 2010, which led to around 10,000 patent filings in 2022 and 2023. Of those filings, the number of granted patents has increased at a growing rate since 2000, with around 5000 patents granted in 2024.



The data shows a decrease in filings after 2023, which is likely an artefact due to patents filed but not yet published (typically a patent is published 18 months after filing), so not contributing to the data. Also, the data shows a decrease in the number of grants after 2024 because the data was captured partway through 2025.

Looking at where bioinformatics innovations are taking place and where patent protection is being sought, the highest number of patent filings in bioinformatics are in the jurisdictions of China, the USA, the European Patent Office and Japan, with a significant number of "International" applications being filed with the World Intellectual Property Organisation, which are then entered into national/regional jurisdictions after 30 or 31 months from the initial filing date.

It is clear that bioinformatics is a rapidly developing field of increasing importance wherein patent applications are filed to obtain commercial protection for innovations. Next, we consider how patent applications filed in Europe may be examined and what to consider to ensure robust patent protection.



Patent Examination in Europe at the Convergence of Life Science and Software – Is It Technical?

To be patentable, an invention must be novel (not known anywhere publicly before the filing date of the patent application) and inventive (not obvious from what is already known). In bioinformatics (and other software-related innovation), the patent application will also be examined to determine whether the invention falls into a category of exclusion from patentability. There are two main exclusion categories to consider when drafting patent claims:

1. Under Article 52(2) of the European Patent Convention (EPC), "discoveries, mathematical methods, programs for computers, and presentations of information as such" are excluded from patentability as being non-technical. The "as such" is important because if the invention includes technical features solving a technical problem, the invention can be framed to avoid being excluded from patentability. Thus, if the invention is an algorithm that processes molecular data, this may be excluded from patentability as software per se. However, if the invention is framed as a method of taking molecular data as input from real world measurements, processing the molecular data using the algorithm and providing a technical output, such as an indication of the likelihood of a drug being suitable to treat a medical condition, the invention is more likely to avoid an objection under Article 52(2) EPC.

2. Under Article 53(c) of the EPC, "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body" are excluded from patentability. A key to avoiding an objection under Article 53(c) EPC is to understand what constitutes a diagnostic/therapeutic method practised on the human body vs. *in vitro* methods.

To avoid a bioinformatics invention falling under one, or both, of the exclusion criteria, the invention should be tied to computing hardware; to an *in vitro* step or method; operating on real world measured or sensed data; or yielding a concrete technical result.

Once the invention is accepted as being technical (and not excluded), the examiner will consider whether the invention provides an inventive step. Only features contributing to the technical character of the invention are considered when assessing inventive step; purely mathematical or algorithmic steps are not considered for inventive step. Again, careful patent application drafting can help support the case for the inventiveness of the invention by tying the computational steps to technical effects.

Practical considerations to support technical character include:

- Explicitly reciting hardware, computing environments, sensor use, laboratory automation or data acquisition devices.
- Providing technical rationale for inventive features, such as reduced memory requirements, improved accuracy, use of real world data inputs and provision of clinically relevant diagnostic outputs.
- Detailing non-obvious algorithmic improvements and tying them to technical effects.

For example, inventions relating to "diagnosing a disease from genomic data" or "determining abnormally methylated regions via an automated pipeline" can get over the "technical" hurdles, provided they are tied to the use of technical means, computer systems or laboratory equipment, rather than being interpreted simply as a statistical inference.

Trade Secrets and Confidential Know How

Patents offer territorial protection but involve public disclosure when the patent application is published. A patent application must contain enough description and detail that someone else working in that technological space can recreate the invention.

In bioinformatics, the computational factors involved in innovations, such as algorithms, training data, parameterisation, software pipelines and computational models, allow for IP protection to be crafted around combinations of patenting and trade secrets, while retaining some valuable know-how secret within the business.

For a trade secret to exist and receive legal protection in Europe, it must meet three key requirements:

1. The information must be secret. The information should not be publicly available or easily obtainable through legitimate means.
2. The information must have commercial value because it is secret.
3. The person lawfully in control of the information must have taken reasonable steps under the circumstances to keep it secret.

While the patent must disclose enough detail to allow someone else to implement the invention, it is typically not necessary to provide full disclosure of features of the innovation which themselves provide a competitive advantage. For example, while a predictive model for drug discovery must be described in enough detail in a patent application to allow someone else to implement the model, the actual training data set used need not be disclosed (though the overall characteristics of the training data set may be required if that leads to the technical advantage the invention provides). Similarly, while a regression algorithm may be used, the specific weighting parameters in the model may not need to be included in the patent application. In this way, the know-how involving your time and effort in determining particularly effective parameters and trained models may be retained in the business as a trade secret and add value, particularly if those details are difficult to reverse engineer.

Therefore, often a hybrid approach can be an effective way to protect bioinformatics innovations, patenting the overall technical method (e.g. an algorithm implemented in a diagnostic pipeline), while retaining the detailed model weights or data curation pipeline as trade secrets.

Strategic Framework: Deciding Patent vs Trade Secret

The following table summarises some factors to consider whether patenting or retaining a trade secret can be an appropriate form of IP protection for your bioinformatics invention:

Factor	Patent Strategy	Trade Secret Strategy
Disclosure level	Full public disclosure	Confidential, not publicly revealed
Legal exclusivity	Territorial, 20 years	Potentially indefinite, but only if kept secret
Technical disclosure risk	Opponents can learn design	Rivals may reverse engineer or independently develop
Enforcement	Infringement proceedings can be brought	Breach of confidentiality/ confidentiality agreements
Suited for	Novel technical architecture, overall functionality of algorithms	Proprietary training data, model parameters, curated datasets

Conclusion

Patenting bioinformatics inventions in Europe presents both opportunities and challenges. Many innovations in this space should be considered from the point of view of relating to excluded subject matter and mixed-type inventions of technical and non-technical features. Careful consideration of the innovation and crafting a patent claim set with potential patenting objections in mind from the outset can help ensure as robust a patent application as possible.

Alongside patenting, trade secrets can provide a powerful tool well-suited to specific details, typically which provide a

competitive edge and which are difficult to reverse engineer, such as proprietary data assets or algorithmic details giving particularly accurate or advantageous results.

By combining robust patent portfolios with well-guarded trade secrets, companies can protect and extract value from their bioinformatics innovation across diagnostics, drug discovery, precision medicine and beyond.

REFERENCES

1. https://www.wipo.int/classifications/ipc/en/ITsupport/Version20190101/transformations/ipc/20190101/en/htm/G16B.htm

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