D YOUNG & CO
INTELLECTUAL
PROPERTY

IP for techbio

Patent strategies for techbio innovators

Contents

In this guide we will consider the way the techbio sector is developing and the strategies for protecting arising intellectual property (IP), which may differ from strategies used in the traditional biotechnology and technology sectors.

Techbio is defined as the interface between biotech and tech, and focuses on using cutting-edge techniques from both sectors to drive innovation. During recent years there has been a surge of interest in this evolving sector.

Broadly speaking, the techbio sector can be divided into two main areas. The first of these is the use of data to drive traditional innovation, and is largely driven by existing biotechnology, pharmaceutical and life science companies. The second area is the development of new platforms for driving innovation, and is largely driven by tech companies. The following articles address these related yet distinct areas of innovation and their respective IP challenges and solutions.

Data-driven solutions in the biotechnology, pharmaceutical & life sciences sector

Data-driven innovation

Traditionally, innovation in the biotechnology and life sciences sectors has relied heavily on wet data. Whilst this approach provides a robust system, it places a heavy burden upon the early stages of research: a time when funds may be scarce and uncertainty levels are high.

Using data-driven solutions may allow companies to focus resources upon projects having a greater chance of success, driving pipelines forward in a cost effective manner.

The traditional approach

Life science and biotechnology companies have long placed a heavy emphasis on the importance of wet data. *In vitro* studies are commonly followed by testing in an animal model, and the process culminates in an expensive and lengthy clinical trial. There are many advantages to this approach, including a deep understanding of the activity of a candidate molecule and an acknowledgment of the relevant safety considerations. However, this wet experiment focused approach requires a large investment of both time and money at an early stage of development when the outcome, and even the aims, of a project can be far from clear.

Take, for example, the development of a small molecule pharmaceutical. Initial experiments are likely to be devised on the basis of an understanding from the literature of the causes of a particular disorder or the workings of a particular pathway. From this premise a library of small molecule candidates is chosen for initial screening, probably based upon structural similarity to a component of a pathway thought to be involved in a particular disorder. These initial wet experiments are likely to be performed *in vitro*, with a large proportion of the tested compounds found to be inactive.

It is only after extensive *in vitro* testing that the most promising candidate compounds are likely to move to testing in an animal model. Animal models can be extremely useful research tools. However, by definition they are based upon the biology of an organism which is not human, which is itself a challenge for researchers looking to devise a pharmaceutical for human use. Further, it is known that many disorders do not have an adequate animal model, hampering the development of treatments for these disorders.

Finally, once data in an appropriate animal model has indicated a reasonable chance of success for a candidate compound, clinical trials are required in order to demonstrate a reasonable toxicology profile in a healthy population, as well as a suitable therapeutic efficacy. This is a lengthy and expensive process in itself, but it also comes at the end of a process which has already taken many years, a huge amount of investment and has seen a large number of candidate compounds fall by the wayside.

There will always be a role for wet experiments and clinical trials in the biotechnology and life science sectors, but what if these expensive stages of testing could be focused upon candidate compounds known to have a greater chance of success?

> *Patent newsletter subscriptions*

Articles in this guide were first published in our bi-monthly patent newsletter.

If you would like to receive our IP-related news and invitations to our webinars and events, please send your details to subscriptions@dyoung.com or visit our website www.dyoung.com/subscriptions.

This is where data-driven solutions in the techbio space can play a pivotal role.

The role of data-driven solutions

Techbio solutions offer a data-driven way in which to focus research upon candidate compounds having an increased chance of success. Taking the small molecule pharmaceutical example previously mentioned, data-driven approaches can reduce, or remove, the need for initial wet experiments. For example, a machine learning model trained based on a library of known chemical structures labelled with known therapeutic effects can be used to predict which other chemical structures are candidate compounds for the treatment of a certain medical condition.

Selecting an appropriate pathway through which a particular disorder can be treated is a challenging but vital initial stage in the traditional approach to pharmaceutical development. Performing this step manually, using wet experiments, requires an in depth knowledge of the relevant field, but also an element of good fortune to select a premise which has the potential to yield relevant candidate compounds. Using machine learning approaches to analyse the relevant data can reduce the need for good fortune, allowing the assimilation of a much larger data set and the arrival at a premise that is a more accurate reflection of the clinical situation and therefore more likely to succeed.

The use of data-driven solutions within a biotech process does not need to end once a relevant premise or pathway has been

established. Rather, computer modelling can be used to determine the candidate compounds most likely to interact at an appropriate point in the selected pathway. This has a greater chance of success than basing decisions on the structural similarity of a candidate compound to a component of a pathway alone because it allows additional parameters such as steric interactions and affinity to be accurately modelled.

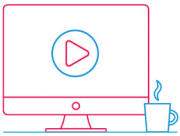
Taken together, these and other techbio approaches to pharmaceutical innovation can reduce the risks associated with early stage drug development, reducing upfront costs and allowing companies to take viable candidates into the clinic at a fraction of the cost of candidates arrived at through traditional approaches alone, for which the candidate atrophy rate will have been much higher.

Available IP

Within the traditional approach to pharmaceutical development there are a number of possibilities for arising IP, including patent protection, know-how and trade secrets.

Highly prized candidate compounds are almost always patent protected and these patents, and associated supplementary protection certificates (SPCs), can be extremely valuable. Primary patent protection is likely to focus upon the structure of a candidate compound, which may be defined chemically or through the nucleic acid or amino acid sequence of a biologic in a composition of matter patent. Follow on patents are also available for novel and inventive formulations, second generation molecules, methods of treatment, and dosage regimens, amongst other things.

> *Related webinar*



Our webinar "Protecting innovation in the techbio sector" is now available on demand at: dycip.com/web-techbio-innovation

Ancillary inventions may relate to proprietary assays and laboratory techniques involved in the selection of candidate compounds, but these do not form the core assets of a biotech company and are often protected as trade secrets or kept as know-how rather than being the subject of patent protection. An evolved IP strategy will include preferred options for protecting this innovation whilst focusing costs upon the core assets of the company.

It is likely that the IP position for companies using techbio solutions within traditional methodologies will be similar to a traditional IP strategy approach, with patent protection sought for candidate compounds and follow on inventions, and trade secrets and know-how used to provide additional protection for associated innovations.

Taking the pharmaceutical development example introduced earlier, small molecule candidates selected using data-driven solutions will initially be protected under a composition of matter patent, with additional patents available for novel and inventive formulations, second generation molecules, methods of treatment, and dosage regimens, irrespective of whether these innovations were arrived at using data-driven solutions or traditional wet experimental techniques. As for companies developing candidate compounds using traditional approaches, the primary focus, and therefore value, surrounding this area of the techbio sector resides in the compounds themselves.

Methodologies surrounding the generation of candidate compounds are likely to be of secondary importance to biotechnology companies as they look to assimilate data-driven solutions into their standard experimental toolkit. These will often therefore be protected as know-how or confidential information, at least in the first instance. Biotech companies relying on data-driven approaches should also take care to protect their data sets, which may have taken considerable investment to develop and can be of significant commercial value. Although unregistered IP rights such as database rights may be available in certain countries, it is also advisable to implement IT security measures for protecting access to the data, and review contractual provisions in contracts with employees, contractors, commercial partners and customers restricting use and dissemination of such data sets.

In contrast, techbio companies developing new platforms for driving innovation will have such methodologies at the core of their business and will increasingly look to protect these platforms per se rather than merely the products thereof. Protection for the data processing platforms may also be of interest for companies developing diagnostic tools, for example, a machine learning model which processes biomarkers or genetic sequence data from a patient to generate a prediction of whether the patient suffers from a particular health condition. We will focus on these aspects of the techbio sector in the following article.

IP protection for platform innovation in the techbio field

In this article we will assess the forms of protection available for platform innovation within the techbio field, which may differ from the forms of protection available for innovation arising from using techbio solutions within the biotechnology and life sciences fields.

IP protection for data-driven innovation in the life sciences field

Techbio is fast emerging as a technical sector of interest, focusing on the application of "big data" techniques to drive innovation in the biotech and life sciences fields. Data-driven analysis can reduce the amount of wet lab experimental research needed to identify relevant biological pathways and screen candidate compounds for the treatment of particular diseases. Patent protection can, in principle, be available for compounds or methods of treatment arrived at using computational methods, with the claims of the patents covering the compounds or methods of treatment themselves (rather than the methods used to develop them) in the same way as those obtained through traditional wet lab methods.

Machine learning based diagnostic tools

Techbio innovation may also lie in the provision of a machine learning based diagnostic tool, for example, a machine learning model trained to predict, based on biomarker data or scan images from a patient, whether a patient has a particular medical condition.

Patent protection can be available for such diagnostic tools. However, the patent application should be drafted carefully to ensure commercial relevance of the claims, and to ensure that the specification provides a sufficient disclosure of the machine learning model and how it was trained, in order to permit arguments for the presence of an inventive step to be made during prosecution.

Care must also be taken when drafting the patent application to avoid restrictions on the patentability of diagnostic methods, which exist in many jurisdictions. Our article about practical considerations for patenting AI provides more detailed tips on drafting patent applications in the field of machine learning (see *dycip.com/patentingai*).

What intellectual property is available for techbio platform providers?

Some life science and biotechnology companies may wish to use computational approaches to further their research, but may not have the expertise to develop their own data-driven research tools. Therefore, an emerging class of techbio companies, which develop generic computation platforms that can be licensed for use by others and applied to a wide range of life science problems, are coming to the fore. For example, the platform may provide a generic machine learning framework, and users of the tool may provide their own data sets for training this tool to handle a specific task. Developers of such a techbio platform may wish to protect their investment using IP. What options are available?

Protection using unregistered rights (for example, copyright and trade secrets)

Copyright will automatically subsist in the software underpinning the platform and can be useful in supporting licensing of the software

> *Related article*
Practical considerations for patenting AI:
http://dycip.com/patentingai

to customers, but will only protect the specific code and not the underlying functions. Care should be taken in agreeing terms on ownership of the copyright when engaging contractors for software development work. Confidential know-how associated with the working of the techbio platform may also be protected as a trade secret. However, such unregistered forms of IP will not protect against a competitor independently producing a competing platform without any copying of your innovation.

Patent protection

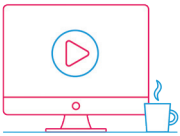
In view of the limitations of unregistered rights, patents may provide stronger protection of the technical functionality of the techbio platform. Patents can provide a monopoly right which can be enforced against others even if there is no evidence of copying. However, for generic platform providers, it can be challenging to obtain strong patent protection, as most patent offices have restrictions on the patentability of abstract mathematical methods defined generically without a specific real world use case, and overcoming these restrictions may require the patent to be relatively narrow in scope.

For example, in Europe patentability requires a claimed invention to provide a technical contribution. As with other types of mathematical methods, the European Patent Office (EPO) considers claims to machine learning based methods to be excluded from patentability unless either:

- The claim specifies a specific technical purpose for which the method is used (for example, application of the computational platform to development of a treatment for a particular disease); or

- The claim defines a specific technical implementation of the method, and the method is particularly adapted for that implementation, in that its design is motivated by technical considerations of the internal functioning of the computer (for example, this could apply if the machine learning model includes processing steps adapted for particularly efficient use of memory or network bandwidth).

> *Related webinar*



Our webinar "Protecting innovation in the techbio sector" is now available on demand at: dycip.com/web-techbio-innovation

For a generic platform provider the use case may be defined by the customer, not inherent to the platform itself, and so it may be a challenge to define a specific technical purpose, which could meet the EPO's requirements, while still being generic enough to cover all likely uses.

If a patent is to be granted, it may be that the patentee needs to accept a compromise where the patent is limited to a particular use or class of uses (for example, prediction of a compound for treatment of a specific class of medical conditions), rather than being defined for generic application.

For an inventive step to be present, it may also be that the claim needs to be limited to specific features of the computational processing adapted for the claimed use that make the processing work better for that use.

A claim directed to a specific technical implementation might be relatively narrow in scope, and it may be that others producing similar competing techbio tools might not adopt the same technical implementation, or it might be difficult to check whether a competitor's platform uses that technical implementation. Nevertheless, if there are any inventive features which make the platform use hardware resources of a computer more efficiently, this could provide a route to patentability that might not be limited to a particular use.

Timescales and disclosure

Another factor to consider when considering patent protection for data driven techbio platforms is that patent applications are generally published 18 months after the first filing.

To meet the requirement of sufficient disclosure of the invention, most patent offices expect to see detailed disclosures of implementation methods for a machine learning platform, so the publication of the patent application may give away information to others which might have been hard to reverse engineer from the product itself. Companies may wish to balance this against the chances of success of obtaining adequate patent protection, when considering whether to file a patent application.

However, one strategy can be to file a patent application initially to allow for any non-confidential discussions of the technology with potential investors or commercial partners, and to then decide in good time before the 18-month publication date whether to allow the application to publish, and continue efforts to prosecute the patent to grant, or withdraw the patent application to prevent publication of its contents. This decision could be based on the patent office search opinion, which will often be received in the first 12 months after filing, and/or based on any feedback from investors or commercial partners.

Therefore, there can be a complex set of considerations to take into account when assessing what steps to take, which will vary depending on the specific technology at issue. With close collaboration from attorneys in D Young & Co's life sciences and computing groups, our team can review your specific needs and help you decide how to proceed.

This collection of articles has been authored by D Young & Co partners Robbie Berryman and Jennifer O'Farrell. With extensive experience in drafting and prosecuting patent applications directly at the UK Intellectual Property Office (UKIPO) and European Patent Office (EPO) and providing portfolio strategic advice for a broad range of clients across the physics, digital electronics, computing, biotechnology and life sciences sectors, Robbie and Jennifer are able to provide a uniquely harmonised and focused perspective to this popular topic.

Partner, Patent Attorney
Robbie Berryman
rjb@dyoung.com
www.dyoung.com/robbieberryman

Partner, Patent Attorney
Jennifer O'Farrell
jmo@dyoung.com
www.dyoung.com/jenniferofarrell

Robbie's areas of expertise include physics, electronics, microprocessor technology and computing (including hardware and software). He is a registered representative before the Unified Patent Court, a Chartered Patent Attorney and European Patent Attorney. Robbie's client base is diverse, ranging from start-ups and SMEs to universities and tech giants. He is particularly active in the fields of instruction set architecture, processor micro-architecture and system-on-chip design and has drafted many of Arm's key architectural patents which protect the instruction set architecture and processor designs used in the vast majority of smartphones on the market today. Robbie also works on patent applications relating to artificial intelligence (AI) and machine learning (ML), imaging devices, telecommunications, medical devices, techbio and 3D printing.

Jennifer's expertise focuses on immunology, molecular biology, biotechnology and biochemistry. She is a registered representative before the Unified Patent Court, a Chartered Patent Attorney and European Patent Attorney. is a member of the UK BioIndustry Association's (BIA) Cell & Gene Therapy Advisory Committee and regularly speaks at both biotech industry and patent events. IAM Patent 1000 has described Jennifer as "a fantastic IP communicator who pairs her elite EPO oppositions practice with appearances at a variety of industry lectures and events" and confirms that her ability "to liaise with inventors and capture the essence of new technologies in clear, concise language is very impressive".

TechBio UK 2023

Jennifer and Robbie are hosting the Innovation Showcase session, where they will discuss the technological advances and related IP needs of four innovative companies in the sector. Robbie and Jennifer are joined by European Patent Attorneys Anton Baker and Rebecca Price at the TechBio UK 2023 conference. Anton specialises in computer-implemented inventions and has successfully represented clients patenting innovations across a broad range of key technologies in today's high-tech sector, including semiconductors, lasers, photovoltaics and detection techniques. Rebecca has a strong background in biochemistry and works with a variety of clients including multinational companies, SMEs and academic institutions

Partner, Patent Attorney
Anton Baker
amb@dyoung.com
www.dyoung.com/antonbaker

Associate, Patent Attorney
Rebecca Price
rlp@dyoung.com
www.dyoung.com/rebeccaprice

Contact us

London
Munich
Southampton

T +44 (0)20 7269 8550
F +44 (0)20 7269 8555

mail@dyoung.com
www.dyoung.com

IP for techbio
Published September 2023.