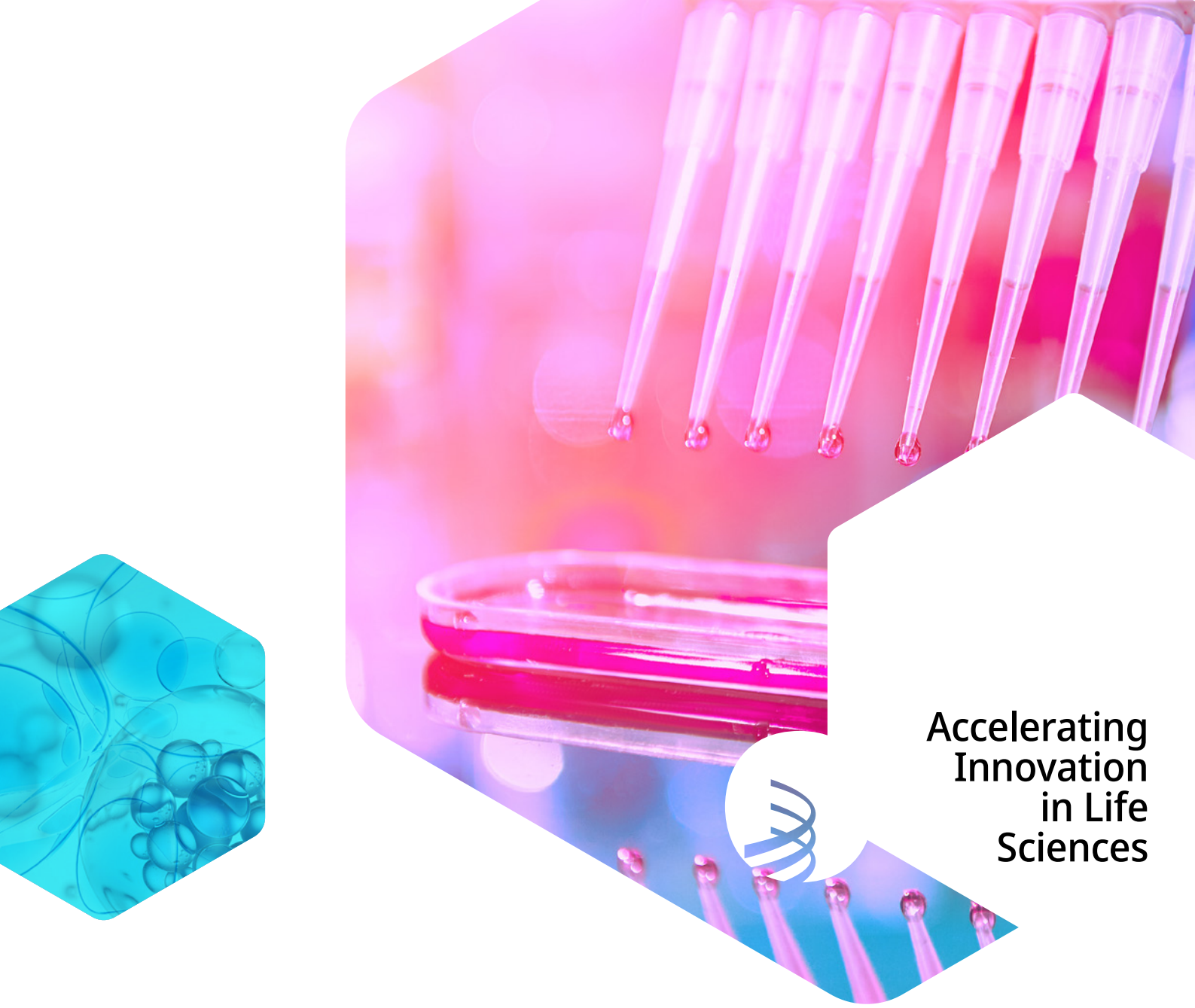

Accelerating Innovation in Life Sciences

Patenting Healthcare-related Inventions

A Guide for IP advisers and managers

WIPO

Patenting Healthcare-related Inventions

A Guide for IP advisers and managers

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Contents

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Introduction

Key points

- The main innovation trends within the life sciences are: processes and technologies augmented by artificial intelligence (AI); cell and gene therapy (CGT); and clustered regularly interspaced short palindromic repeats (CRISPR-) Cas technologies.
- The coronavirus disease (COVID-19) pandemic has shown that shorter development timelines are possible for life sciences innovations.

Successful technology transfer in the field of life sciences is a complex challenge requiring the input of many parties: scientists and/or inventors, the technology transfer office/department professionals, patent attorneys, consultants, etc. The objective of this report is to provide a reference document for all essential stakeholders involved in patenting innovation within the life sciences sector, particularly within the technical fields of biotechnology and pharmaceuticals. Given the broad target audience, this document seeks to identify and address key themes applicable to all.

The document can also be considered as a tool to assist innovation stakeholders in steering research and technology development towards patentable outcomes, and to support business decisions that will be made as patent prosecution progresses. Moreover, the document emphasizes the pre-grant patent practice, specifically the characterization of potentially patentable research outcomes and inventions and their use as a basis for the patent application filing, and the patent prosecution that follows.

While parts of this report provides a global perspective, country- or region-specific patenting diagnostic approaches are examined for Europe, Japan and the United States of America.

To support the comparative analysis presented in this report, the study also incorporated insights from patent attorneys and technology transfer professionals in Europe, Japan and the United States of America. These perspectives were gathered through a series of expert interviews designed to complement the desk study with practical, day-to-day experiences from professionals working in these jurisdictions.

The interviews were conducted using two structured questionnaires tailored respectively to patent attorneys and to technology transfer professionals. The information collected informed the analysis presented throughout.

To encourage open and candid contributions, participants were assured that their responses would remain anonymous. Consequently, individual responses and underlying data are not disclosed and the insights are presented in aggregated or synthesized form. In total, the survey received 28 responses: 20 from life sciences patent attorneys and 8 from technology transfer professionals.

Trends within innovation in life sciences

The innovation opportunities within the life sciences field are limitless. The following three main trends that we identified through market research and literature searches are outlined below.

AI-enhanced processes and/or technology

Both AI and machine learning (ML) have become increasingly prevalent terms in the vocabulary of innovators across a range of industry sectors. AI and ML are closely related and connected terms, with ML being a subset of AI.

AI refers to the capability conferred to a computer system that allows it to mimic cognitive functions including learning and problem-solving, utilizing both mathematics and logic to process new information and make decisions. ML is the application of AI, implementing mathematical models of data that enable a computer to learn without the requirement of direct instruction; the computer therefore uses experience to learn and improve. In other words, AI allows the system to "mimic the thinking process" and perform tasks independently, and ML confers the ability to develop this intelligence.

AI for clinical trials

AI offers those within the life sciences sector wide and varied opportunities. Currently, an area of drug development that has begun to benefit from AI and ML is clinical trial design, operation and analysis. AI technologies such as ML can provide benefits from the very beginning of the clinical trial process, with data gathered during pre-clinical studies being analyzed to estimate the lowest clinically effective dosage to be used as part of the wider dosing regimen.[1]

AI also offers the ability to optimize patient recruitment and thereby increase the success of a clinical trial. Clinical trials have specific recruitment requirements with inclusion and exclusion criteria that patients must meet. Identifying suitable patients poses a significant challenge and is the major cause of delays to trials; recruitment can take up to one-third of trial duration, and 86 percent of trials fail to meet the established recruitment timeline.[2]

It is hoped that AI, when used to examine the vast data available in electronic medical records (EMR), may offer a solution to optimizing patient recruitment. The United States Food and Drug Administration (FDA) has identified the following criteria that AI could adopt:

- reducing population heterogeneity
- choosing patients most likely to have a measurable clinical endpoint
- identifying a population more capable of responding to the treatment.

AI can be used to automatically analyze EMR and identify patients that meet the eligibility criteria of various clinical trials, recommending these matches to both patients and sponsors. A pilot of such a system was successfully conducted by Mayo Clinic, IBM Watson Health and Novartis.[3]

The monitoring of ongoing clinical trials is an essential aspect of quality control mandated by regulatory bodies to ensure both the safety of participants and the integrity of the trial, and is often outsourced to specialist contract research organizations. This is time-consuming and costly, with trial site monitoring (including management of collected data and performance reviews) representing one of the top three costs across all study phases (an estimated 9–14 percent of total costs).[4] As well as the costs, the current approach lacks the ability to monitor data in real-time, hindering any prospective risk mitigation and possibly having a significant impact upon the trial results.

1 Harrer, S., P. Shah, B. Antony and J. Hu (2019). Artificial intelligence for clinical trial design. *Trends in Pharmacological Sciences*, 40(8), 577–591. doi:10.1016/J.TIPS.2019.05.005.
2 Harrer, S., P. Shah, B. Antony and J. Hu (2019). Artificial intelligence for clinical trial design. *Trends in Pharmacological Sciences*, 40(8), 577–591. doi:10.1016/J.TIPS.2019.05.005.
3 Helgeson, J., M. Rammage, A. Urman, M.C. Roebuck, S. Coverdill, et al. (2018). Clinical performance pilot using cognitive computing for clinical trial matching at Mayo Clinic. *Journal of Clinical Oncology*, 36(15). doi:10.1200/JCO.2018.36.15.
4 Kolluri, S., J. Lin, R. Liu, Y. Zhang and W. Zhang (2022). Machine learning and artificial intelligence in pharmaceutical research and development: a review. Journal of the American Association of Pharmaceutical Scientists, 24(1), 19. doi:10.1208/s12248-021-00644-3.

AI tools for the monitoring of trial site performance and data quality may offer a framework to increase efficiency by predicting and detecting risks in real-time, consistent with the lean philosophy. By applying AI tools, an advanced form of risk-based monitoring may be implemented; improving risk prediction as a result of real-time analysis of clinical data being combined with predictive analytics (based upon available data from similar trials) can transform the ability of a sponsor to protect patients, reduce trial duration and lower costs.

Additionally, AI could assist in the monitoring of clinical trial participants. For successful progression through a clinical trial, it is essential that patients adhere to the trial procedures and rules throughout, and that data-points used to assess the impact of the therapy are collected both reliably and efficiently. Patient dropout, experienced by 85 percent of clinical trials, is an area of concern; in affected trials, patient dropout averages about 30 percent. Most of these dropouts are the result of a lack of adherence to the trial protocol, and have a significant impact upon costs associated with the trial. A linear increase in non-adherence rates results in an exponential increase in additional patients required to conserve the essential statistical power of the results.[5]

Reducing the adherence burden and making endpoint detection more efficient are essential to minimizing dropout. It is hoped that AI techniques, in combination with wearable technology, can offer an approach that enables mobile, real-time and personalized patient monitoring systems. Underlying deep-learning models can analyze and periodically update the measurement data tailored to the patient, and can be adaptive to changes in disease expression and patient behavior. AI can also assign a dropout risk to each patient by detecting a lack of adherence to the study protocol, alerting the trial sponsor who can reach out to the patient to assist them with protocol adherence.

AI for drug development

Advances in the high-throughput screening of compounds have significantly enhanced the discovery of potential new drugs, but the process is still laborious and time-consuming with low levels of success. It is essential that progress is made in enhancing the chances of success in the early stages of drug development, as this will enable therapeutics to be developed both faster and cheaper. AI techniques also have the ability to discover new compound candidates.

The investment bank Morgan Stanley has estimated that a 20–40 percent reduction in preclinical development costs may allow for the additional development of four to eight novel molecules across a subset of United States (US) biotech companies. This would represent a potential 15 percent increase in approved novel therapies, generating additional sources of revenue and benefiting a wider patient population.

It is hypothesized that these AI drug development platforms could realize significant revenue growth and investment within the biopharmaceutical sector. Indeed, in the period 2015–2020, equity funding of AI within the healthcare sector rapidly grew worldwide.

When combined with technological advances that have allowed for the collection of large data sources combining genomic data, patient medical records and advancements in medical imaging in projects such as United Kingdom (UK) Biobank, it is hoped that AI platforms will be able to utilize these data to identify possible therapeutic targets in the drug development phase. AI may also be able to assist in drug design by predicting the three-dimensional (3D) structure of receptors and drug–receptor interactions. This is referred to as de novo drug design (DNDD), a computational approach that results in the generation of novel molecular structures.[6] This extends beyond small-molecule drug design; by predicting T-cell epitope binding affinity, AI can establish with a high degree of certainty that a T-cell will bind one or more epitopes present on an antigen.

5 Harrer, S., P. Shah, B. Antony and J. Hu (2019). Artificial intelligence for clinical trial design. *Trends in Pharmacological Sciences*, 40(8), 577–591. doi:10.1016/J.TIPS.2019.05.005.
6 Mouchlis, V.D., A. Afantitis, A. Serra, M. Fratello, A.G. Papadiamantis, V. Aidinis, et al. (2021). Advances in de novo drug design: from conventional to machine learning methods. *International Journal of Molecular Sciences*, 22(4):1676. doi:10.3390/ijms22041676.

Advantages of DNDD include the ability to examine a broader chemical space, designing compounds that are likely to constitute novel intellectual property (IP) and identifying novel therapies in a shorter period than traditionally achieved, optimizing drug design while reducing cost and time to market.[7]

AI as an inventor

AI can clearly advance research within the life sciences. However, what of the debate surrounding AI as an inventor? Could AI be listed as the inventor on patent filings? It is suspected that patent filings were secured on AI-generated inventions as long ago as during the 1980s; in such instances, it is further speculated that filers were advised to list a human as the primary inventor.

In August 2019, the World Intellectual Property Organization (WIPO) announced two Patent Cooperation Treaty (PCT) filings for AI-generated inventions in which no human was an inventor. These filings listed the AI named Device for the Autonomous Bootstrapping of Unified Sentience (DABUS), the inventor and the owner of the AI, as the patent applicant and prospective owner of any granted patents. Both the European Patent Office (EPO) and UK Intellectual Property Office (UKIPO) had evaluated the patent filings, and found that they met with the prerequisites of patentability. However, both applications were rejected by UKIPO as DABUS is not a person and therefore not eligible to be listed as an inventor under UK patent law. Appeals were dismissed by both the High Court and Court of Appeal, with the Supreme Court hearing the case in March 2023.[8]

Because there is no substantive requirement within the Patents Act that an inventor must be human but only the "actual deviser" of the invention, representatives of Dr Stephen Thaler (the creator of DABUS who submitted the patent filings) argued that specifying "no person" as the inventor of AI-generated inventions would be in keeping with the purposive interpretation of the Patents Act.

Other countries in which the patents in question were filed have also debated the issue of AI as an inventor, with all jurisdictions that operate an examination process refusing to grant a patent.[9] The Legal Board of Appeal of the EPO also confirmed that, under the European Patent Convention (EPC), the inventor within a patent application must be a human being.[10]

CGT

Healthcare is currently undergoing a revolution in our approach to the treatment of disease: personalized medicine represents a shift in our ability to tailor treatment to individual needs. Using next-generation sequencing, we can now sequence an entire human genome for a cost of less than USD 1,000, and our ability to extrapolate meaningful data and conclusions from this information is ever increasing as a result of advancements in our AI and ML capabilities and projects (e.g., UK Biobank and 100,000 Genomes).

These findings allow us to better understand the physiology of disease, revealing novel therapeutic targets for a new generation of advanced therapy medicinal products (ATMPs), also known as CGTs, that promise to prove effective against rare diseases such as retinitis pigmentosa and some blood cancers such as leukaemia and lymphoma, that have proved to be difficult, if not impossible, to treat.

Definitions and regulations of ATMPs and CGTs vary by jurisdiction. Within the United States of America and the European Union (EU), the FDA and the European Medicines Agency (EMA) regulate ATMPs and CGTs under the framework governing biological products.[11] However, to provide context for our readers, the broad definition provided by the EMA of an ATMP is a medicine for human use based on genes, tissues or cells.

7 Gupta, R., D. Srivastava, M. Sahu, S Tiwari, R.K. Ambasta and P. Kumar (2021). Artificial intelligence to deep learning: machine intelligence approach for drug discovery. *Molecular Diversity*, 25(3), 1315–1360. doi:10.1007/s11030-021-10217-3.
8 The Artificial Inventor Project. WIPO Magazine; 2019. Available at: https://www.wipo.int/wipo_magazine/en/2019/06/article_0002.html (accessed May 24, 2025).
9 The latest news on the DABUS patent case. IP STARS; 2021. Available at: https://www.ipstars.com/NewsAndAnalysis/The-latest-news-on-the-DABUS-patent-case/Index/7366 (Accessed May 24, 2025).
10 J 0008/20 (Designation of inventor/DABUS) of 21.12.2021. European Patent Office. *SSRN Electronic Journal*. Published online 2020). https://www.epo.org/en/boards-of-appeal/decisions/j200008eu1
11 Landhuis, E. (2021) The definition of gene therapy has changed. *Nature*, 325(5). doi:10.1038/d41586-021-02736-8.

The first ATMP to be approved by the EMA was ChondroCelect in 2009 (a tissue-engineered product targeted at cartilage defects), and the first to be approved by the FDA was PROVENGE™ in 2010 (somatic cell therapy for prostate cancer). As of January 2023, the EMA has approved 25 ATMPs (including those that have subsequently had market access withdrawn). Eleven of these approvals occurred from 2020, highlighting the increasing numbers of ATMPs successfully making it to market. As of July 2025, the FDA has approved 45 CGTs. In both markets the majority of approved therapies are gene therapies, defined here as one containing or consisting of recombinant nucleic acid. Gene therapies are often intended to be administered for the purpose of introducing functional genes into cells to replace missing or defective genes to correct a genetic disorder. However, with advances in precision gene editing, it is likely that this definition will continue to evolve along with the regulatory provisions that govern their development and use.[12]

Immunotherapies such as chimeric antigen receptor T (CAR-T) cells are responsible for a significant amount of the activity within the field of gene therapy. It may not seem obvious to consider CAR-T therapies as gene therapies; however, they are considered as such because the T cells are modified with a recombinant nucleic acid encoding a chimeric antigen receptor. It is the CAR that redirects the action of the T cell through binding to target antigens, resulting in the activation of the T cell. Since their initial development in 1989, multiple generations of CAR design have improved CAR-T therapies.[13]

CAR-T therapies can be either autologous (obtained from the same individual) or allogeneic (sourced from a donor) by design. The benefits of having an off-the-shelf allogeneic therapy is that it may (i) reduce the cost and (ii) improve access to the therapy as a result of economies of scale and not requiring specialized local expertise. Researchers have also considered alternative lymphocytes to T cells such as natural killer cells (NK), resulting in CAR-NK therapies. It is hoped that these may provide a truly allogeneic therapy as they do not have to be donor matched.

CAR-T immunotherapies have had significant success in the treatment of B cell leukemia and lymphoma but have shown limited therapeutic effect in solid tumors and hematological malignancies. CAR-T therapies are limited in their ability to infiltrate solid tumors, suffer from antigen escape and are highly susceptible to environmental conditions within the tumor microenvironment.[14] There is therefore a need for continued innovation to overcome some of the current limitations of CAR-T therapies.

The ATMP industry is in clear need of IP guidance and support, including professional IP services that can clearly articulate to innovators what can be protected, the value of protection and the effective exploitation of IP assets related to all aspects of the ATMP industry.

CRISPR/Cas

One of the most significant discoveries in modern times, CRISPR and their associated Cas proteins have been evolved by prokaryotes to provide an innate immune mechanism to combat attack from bacteriophages. The CRISPR-Cas mechanism of immunity incorporates short fragments of DNA excised from the invading bacteriophage within the host genome. Post-transcription, it is these fragments that guide protein complexes to foreign DNA sequences targeted for degradation.

The CRISPR locus is preceded by an adenine- and thymine-rich sequence and flanked by genes encoding the Cas proteins. CRISPR-Cas systems can be divided into two primary classes, further divided into six types and again into various subtypes, with the classification determined by the action of the Cas proteins in the cleavage of foreign DNA. The effector module comprises a multi-protein complex in class 1 (types I, III and IV) systems, as opposed to a single effector protein in class 2 (types II, V and VI) systems.[15] Furthermore, types I, II and V can recognize and

12 Landhuis, E. (2021) The definition of gene therapy has changed. *Nature*, 325(5). doi:10.1038/d41586-021-02736-8.
13 Zhang, C., J. Liu, J.F. Zhong and X. Zhang (2017). Engineering CAR-T cells. *Biomarker Research*, 5(1), 22. doi:10.1186/s40364-017-0102-y.
14 Sterner, R.C. and R.M. Sterner (2021). CAR-T cell therapy: current limitations and potential strategies. *Blood Cancer Journal*, 11(4), 69. doi:10.1038/s41408-021-00459-7.
15 Hille, F. and E. Charpentier (2016). CRISPR-Cas: biology, mechanisms and relevance. *Philosophical Transactions of the Royal Society of London B: Biological Sciences*, 371(1707). doi:10.1098/RSTB.2015.0496.

cleave DNA, type VI can edit RNA and type III edits both DNA and RNA. The effect of type IV on DNA or RNA has yet to be established.[16]

The mechanism of CRISPR-Cas defense can be broken down into three stages: adaptation, crRNA (CRISPR RNA) processing and interference.

In adaptation, a short DNA sequence is extracted from the genome of the intruding bacteriophage. This sequence is then incorporated into a genomic locus of the host referred to as CRISPR, consisting of short repeat elements interspaced by unique sequences referred to as spacers. The spacers are the extracted short DNA sequences originating from the invading bacteriophage. The mechanism of integration of spacers differs between the different types.[17]

The next stage, crRNA processing or biogenesis, details the transcription of the CRISPR locus generating a crRNA precursor (pre-crRNA) that undergoes processing to produce mature crRNA, each consisting of a spacer sequence flanked by a partial repeat sequence.

In the final interference or targeting stage, this crRNA subunit is used to identify target DNA sequences with which it forms an R-loop as it hybridizes. This is followed by degradation of the target.[18]

Since the discovery of the mechanism of CRISPR-Cas, modifications of the system as well as identification of a broader spectrum of Cas proteins have positioned CRISPR-Cas as a fundamental tool of modern biological research. Beginning with its utilization as a gene-editing tool, application areas have broadened to encompass gene regulation, epigenetic editing, chromatin engineering and live-cell chromatin imaging. Future directions include utilization of CRISPR-Cas systems in gene therapy for the benefit of human health.

Other notable life sciences trends

Other identified life sciences trends include an increase in the use of wearable devices,[19] 3D bioprinting,[20] organs-on-chips devices[21] and industrial biomanufacturing.[22]

Life sciences patent attorneys and technology transfer professionals who participated in our survey reported a perceived increase in life sciences patent filings, ranked from highest to lowest as follows: cell and gene therapies, AI-driven innovations, vaccine technologies, diagnostic biomarkers, monoclonal antibodies, and cell-free technologies.

16 Liu, Z., H. Dong, Y. Cui, L. Cong and D. Zhang (2020). Application of different types of CRISPR/Cas-based systems in bacteria. *Microbial Cell Factories*, 19(1), 172. doi:10.1186/S12934-020-01431-Z.
17 Newsom, S., H.P. Parameshwaran, L. Martin and R. Rajan (2021). The CRISPR-Cas mechanism for adaptive immunity and alternate bacterial functions fuels diverse biotechnologies. *Frontiers in Cellular and Infection Microbiology*, 10, 619763. doi:10.3389/fcimb.2020.619763.
18 Wakefield, N., R. Rajan and E.J. Sontheimer (2015). Primary processing of CRISPR RNA by the endonuclease Cas6 in Staphylococcus epidermidis. *FEBS Letters*, 589(20 Pt B), 3197–204. doi:10.1016/J.FEBSLET.2015.09.005.
19 Wearable technology in health care: getting better all the time. Deloitte Insights; 2021. Available at: https://www2.deloitte.com/xe/en/insights/industry/technology/technology-media-and-telecom-predictions/2022/wearable-technology-healthcare.html (accessed May 24, 2025).
20 Panda, S., S. Hajra, K. Mistewicz, B. Nowacki, P. In-Na, A. Krushynska et al. (2022). A focused review on three-dimensional bioprinting technology for artificial organ fabrication. *Biomaterials Science,* 10(18), 5054–80. doi:10.1039/d2bm00797e.
21 Strelez, C., H.Y. Jiang and S.M. Mumenthaler (2023). Organs-on-chips: a decade of innovation. *Trends in Biotechnology*, 41(3), 278–80. doi:10.1016/j.tibtech.2023.01.004.
22 Clomburg, J.M., A.M. Crumbley and R. Gonzalez (2017). Industrial biomanufacturing: The future of chemical production. *Science*, 355(6320). doi:10.1126/science.aag0804.

The effects of COVID-19 on life sciences

The COVID-19 pandemic was a testing time globally, with lockdowns imposed on society, movement restricted and global industry severely impacted. In this section we consider the effects of the pandemic in the field of life sciences and its lasting impacts on the industry.

In a survey circulated among life scientists based in Canada, France, Germany, Italy, Spain, Turkey, the United Kingdom of Great Britain and Northern Ireland, and the United States of America, 881 responses were collected to gauge the impact of COVID-19 upon their daily lives. Of these responses, 62 percent identified as experimentalists, 34 percent as computational biologists and 4 percent as administrative support personnel. The responses showed that 77 percent reported a complete shutdown of their institute.[23] Another report gained responses from 24,900 scientists globally, with more than 70 percent stating that the disruption arising from COVID-19 was an inconvenience but they could complete most of their tasks, compared with 20 percent stating they were either no longer able to perform their work function or that their role had changed completely.[24] Clearly, advances in technology have enabled us to collaborate globally while working remotely, and for scientists to continue to engage and collaborate.

The effect of COVID-19 was not limited to researchers, but also severely impacted the supply chains that support them. The response from regulatory bodies such as the National Institutes of Health was to create the Accelerating COVID-19 Therapeutic Interventions and Vaccines program to increase collaboration between actors within the life science industry. The FDA and the EMA both collaborated for the purpose of sharing clinical trial data to support the rapid approval of therapies and industry bodies. This led to interesting debates on IP surrounding the innovations and vaccine designs; indeed, many companies sought patent protection although they were primarily incentivized in the development by large contracts for the sale of vaccines. Others, such as Oxford University, developed a vaccine that they then patented and licensed to AstraZeneca on the condition that it would be broadly licensed and sold at cost during the pandemic.[25]

A different perspective on the COVID-19 pandemic is that it demonstrated that shorter timelines for bringing vaccine and drug candidates to market are possible.[26] This leads to the question of whether these shorter timelines are going to reset the life sciences industry development norms.[27]

The effects of COVID-19 upon the life sciences industry were varied. Some benefited, especially those who were able to pivot their research and activity towards development of vaccines, testing kits, medical devices and personal protective equipment (PPE). Others were severely hampered in their development of therapeutics for indications separate from COVID-19, with some attempting to repurpose existing drug candidates.[28]

In the aftermath of the pandemic, patenting trends observed by both lifes ciences patent attorneys and technology transfer professionals who participated in our survey indicate a significant impact of COVID-19. Specifically, 80 percent of life sciences patent attorneys rated the impact at 7 or higher (on a scale where 10 represents a very high impact and 1 represents no impact), while 88 percent of technology transfer professionals also rated the impact at 7 or above on the same scale.

23 Korbel, J.O. and O. Stegle (2020). Effects of the COVID-19 pandemic on life scientists. *Genome Biology*, 21(1), 113. doi:10.1186/s13059-020-02031-1.
24 Rijs, C. and F. Fenter (2020). The academic response to COVID-19. *Frontiers in Public Health*, 8. doi:10.3389/fpubh.2020.621563.
25 Gold, E.R. (2022). What the COVID-19 pandemic revealed about intellectual property. *Nature Biotechnology,* 40(10), 1428–30. doi:10.1038/s41587-022-01485-x.
26 Anderson, A.S. (2022). A lightspeed approach to pandemic drug development. *Nature Medicine*, 28(8), 1538. doi:10.1038/s41591-022-01945-6.
27 Fast-forward: will the speed of COVID-19 vaccine development reset industry norms? McKinsey; 2021. Available at: https://www.mckinsey.com/industries/life-sciences/our-insights/fast-forward-will-the-speed-of-covid-19-vaccine-development-reset-industry-norms (accessed May 24, 2025).
28 Sultana, J., S. Crisafulli, F. Gabbay, E. Lynn, S. Shakir and G. Trifirò (2020). Challenges for drug repurposing in the COVID-19 pandemic era. *Frontiers in Pharmacology,* 11. doi:10.3389/fphar.2020.588654.

1. Patenting in life sciences: general aspects

Key points

- There are three patentability criteria (novelty, inventive step or non-obviousness, and industrial applicability or usefulness) and two main supporting requirements (sufficiency of disclosure or enablement, and eligibility of subject matter).
- The patentability criteria and supporting requirements are globally accepted, but with nuanced country-specific differences.
- It is important to understand how other types of intangible assets such as trade secrets or know-how can help in the protection of life sciences innovations.
- Patent attorneys rated the inventive step or non-obviousness, illustrated with a diverse set of examples, as the most important elements for post-grant patent strength.

Assessing the particularities of patents within the field of life sciences is important as we all want to have innovations that lead to better healthcare systems and healthier lives. Nevertheless, before doing so we need to understand what a patent is. Patent law provides protection for *inventions*.

In theory, the purpose of the patent system is to encourage the disclosure of innovation for the progress of our society. An inventor discloses publicly his or her invention and, in return, is rewarded with a period of exclusivity, usually 20 years from the date of filing, during which others are excluded from performing certain specific acts with regard to the invention (as this is defined in the granted claims of the patent). Said acts include making, using, offering for sale, selling or importing the invention without authorization. In other words, it allows the owner to prevent other parties from commercially exploiting the invention. The right conferred by the patent is an *exclusionary right*; it allows the owner to exclude others from using the invention.

In practice, however, no system is perfect and there is always a debate between the advantages and disadvantages of the patent system, especially for the biomedical sector.[1] The patent does not enable or entitle the owner to practice the invention. For commercial use of most innovations in the healthcare field, regulatory approvals are required. In addition, it is ensured that the use of the invention does not infringe third-party patents. This type of conclusion is only possible in the case of a legally binding decision of non-infringement. In practice, this risk is managed by way of legally informed opinion. This typically involves a comprehensive review of all relevant third-party patents, in combination with written confirmation from a suitably qualified lawyer that any of the acts contemplated (i.e., to practice the invention) would not, if so performed, constitute patent infringement of at least one patent claim issued to one of the third-party patents. This associated legal process is often referred to as “freedom-to-operate” or “patent clearance”.[2]

To obtain a patent for an invention in any technical field, a few essential requirements must be met.

1 Gubby, H. (2020) Is the patent system a barrier to inclusive prosperity? The Biomedical Perspective. *Global Policy*, 11(1), 46–55. doi:10.1111/1758-5899.12730.
2 Gubby, H. (2020) Is the patent system a barrier to inclusive prosperity? The Biomedical Perspective. *Global Policy*, 11(1), 46–55. doi:10.1111/1758-5899.12730.

1.1 Patent-eligible subject matter

As with other fields, domains or systems around the world, the patenting system constantly evolves; what can and cannot be patented also changes. What is eligible for patenting also differs between the countries or regions in which an application is filed.

In this report we only cover the most important and relevant patent-eligibility topics for the field of life sciences within Japan, the United States of America and Europe. WIPO published a thorough report on biotechnology patentable subject matter from a global perspective, which provides a thorough analysis of country- and region-specific patent systems.[3]

Japan

The legal requirements for the patent system in Japan are described by the Japan Patent Act (Act 121 of 1959).[4] The Japan Patent Office (JPO) has also published guidelines on their website specifically for life sciences, which explain the reasoning of examiners and provide examples for the different scientific areas of life sciences.[5] The patentability requirements and the excluded subject matter are described in Articles 29 and 30 of the Patent Act.

In Japan, "a patentable invention is defined as a highly advanced creation of technical ideas utilizing a law of nature."[6] This means that mental models that do not use a law of nature are excluded from patentability. Furthermore, the discovery of an organism or a natural phenomenon is also excluded because it is not created. Additionally, methods of surgery therapy or diagnosis of humans (e.g., methods for administering medicines to humans, methods of surgery on humans, methods for introducing genes to humans using vectors, etc.) are also excluded from patentability, as they are not considered industrially applicable inventions. In contrast, patent-eligible subject matter includes medicines, including combined medicines, vectors, medical materials, medical devices, vectors, methods for manufacturing medicines or medical materials, methods for implanting medical material to mice and methods for collecting information from a human body.[7]

United States of America

The legal requirements for the patent system in the United States of America are described by title 35 of the United States Code (USC), and patent matters are dealt with by the United States Patent and Trademark Office (USPTO).[8]

The patentable subject matter is described by the 35 USC – section 101. The USPTO website contains guidance on how patent examiners should evaluate claims for patent subject matter eligibility.[9] The website also includes illustrative examples that are updated regularly and can be used as best-practice guidelines.[10] USPTO has recently published a report with regard to public views on US patent-eligible subject matter, in which stakeholders in life sciences technologies state that the current law is unclear and unpredictable.[11]

3 D. Borges Barbosa and K. Grau-Kuntz (2010). 3. Exclusions from patent-eligible subject matter and exceptions and limitations to the rights biotechnology. World Intellectual Property Organization. Available at: https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf (accessed May 24, 2025).
4 Japanese Patent Act; 1959. Available at: https://www.japaneselawtranslation.go.jp/en/laws/view/4097 (accessed May 24, 2025).
5 Examination guidelines in life sciences. Japan Patent Office; 2018. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/lifescience_kijun.html (accessed May 24, 2025).
6 Examination guidelines in life sciences. Japan Patent Office; 2018. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/lifescience_kijun.html (accessed May 24, 2025).
7 Examination guidelines in life sciences. Japan Patent Office; 2018. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/lifescience_kijun.html (accessed May 24, 2025).
8 Title 35–Patents. United States House of Representatives, United States Code (USC); 1952. Available at: http://uscode.house.gov/view.xhtml?path=/prelim@title35&edition=prelim (accessed May 24, 2025).
9 Subject matter eligibility. United States Patent and Trademark Office; 2020. Available at: https://www.uspto.gov/patents/laws/examination-policy/subject-matter-eligibility (accessed May 24, 2025).
10 Subject matter eligibility: life sciences and data processing examples. United States Patent and Trademark Office; 2019. Available at: https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_app1.pdf (accessed May 24, 2025).
11 Vidal, K.K. (2022) Patent eligible subject matter: public views on the current jurisprudence in the United States. United States Patent and Trademark Office; 2022. Available at: https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf (accessed May 24, 2025).

Typical exclusions from patent eligibility are related to "laws of nature, natural phenomena and abstract ideas", which means scientific principles, naturally occurring phenomena, mental processes and mathematical algorithms.[12] Additional considerations are also applied by examiners when deciding whether the invention is eligible, and it is also determined whether the invention is among the judicial exceptions (case law). The most important decisions for life sciences are Myriad:[13] *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* (2013) and Mayo:[14] *Mayo Collaborative Services v. Prometheus Labs Inc.* (2012). The common focus of these decisions is to prevent the granting of a patent claim that is defined in terms of a naturally occurring phenomenon, a mental act or an algorithm. Although the underlying principle is acceptable, the magnitude and speed at which the effect of these decisions was distributed through the US legal system meant that tens of thousands of already-issued US patents (mostly relating to clinical diagnostics) became unenforceable overnight.

Despite the decision, equivalent complementary DNA sequences are still considered patentable with the USPTO.

Europe

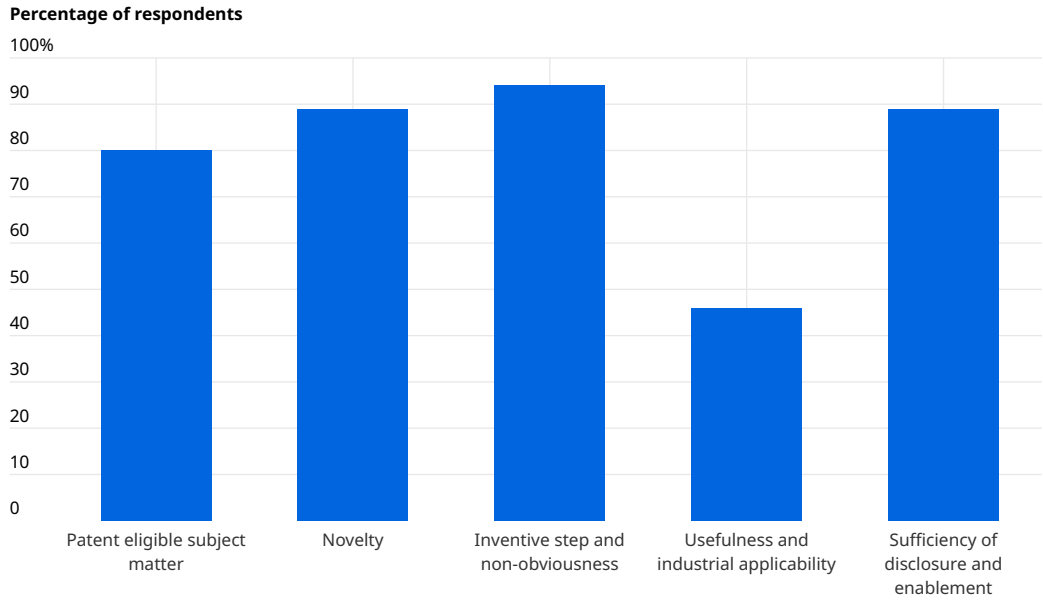
The body of law for the patent system in Europe is described by the legal texts published by EPO.[15] To better understand what comprises patentable subject matter, the texts of EPC and the guidelines for examination according to EPO are the most relevant. The patentability requirements and the excluded subject matter are described by articles 52 and 53 of EPC[16] and part G of the examination guidelines.[17]

Directive 98/44/ec of the European Parliament and the European Council (also known as the Biotechnology Directive)[18] covers aspects of the patentability requirements for the European Union. These requirements have been incorporated into part G of the examination guidelines from EPC article 52.[19]

EPO excludes inventions that are contrary to *ordre public* or morality when exploited commercially (e.g., processes for human cloning, use of human embryos for industrial or commercial purpose, etc.). Scientific discoveries are also excluded from patentability because an invention has to have a technical effect. This EPO exclusion effectively maps on to the USPTO 101 ineligibility provisions, but only to the extent implemented in pre-Myriad or pre-Mayo form. Moreover, EPO does not allow patents for treatment methods "of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body".[20] This is really a form rather than substance distinction, and does not mean that "methods of [medical treatment]" are not patentable in Europe. In this regard, the preferred EPO format is "Compound X for use in a method of [medical treatment] …."

12 35 USC § 101: Statutory Requirements and Four Categories of Invention. United States Patent and Trademark Office; 2015. Available at: https://www.uspto.gov/sites/default/files/101_step1_refresher.pdf (accessed May 24, 2025).
13 Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013). Justia U.S. Supreme Court; 2013. Available at: https://supreme.justia.com/cases/federal/us/569/576/ (accessed May 24, 2025).
14 Mayo Collaborative Services v. Prometheus Laboratories, Inc. 566 U.S. 66 (2012). Justia US Supreme Court; 2012. Available at: https://supreme.justia.com/cases/federal/us/566/66/ (accessed May 24, 2025).
15 Legal texts. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts.html (accessed May 24, 2025).
16 European Patent Convention - Patentability articles. https://www.epo.org/en/legal/epc/2020/a52.html (accessed July 29, 2025).
17 Patentability requirements. European Patent Office 2025. Available at: https://www.epo.org/en/legal/guidelines-epc/2025/g_i_1.html (accessed July 29, 2025).
18 Directive 98/44/EC of the European Parliament and of the Council. Official Journal of the European Communities; 1998. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML (accessed May 24, 2025).
19 Patentability requirements. European Patent Office; 2025. Available at: https://www.epo.org/en/legal/guidelines-epc/2025/g_i_1.html (accessed July 29, 2025).
20 European Patent Convention - Patentability articles. https://www.epo.org/en/legal/epc/2020/a52.html (accessed July 29, 2025).

Figure 1 Could you please rate the following elements based on their importance for thestrength of the patent (post-grant) in the life sciences field?



1.2 Novelty

Key points

- *Never disclose your invention publicly before filing, as grace periods are limited geographically and in time.*
- *Understand the existing prior art, as it will help you to position your novelty and claim strategy.*

The novelty aspect requires an invention to never have been previously disclosed in public in any form (verbally, digitally, written, graphically, etc.), place or language around the world. This means that describing your invention to anyone without having a non-disclosure agreement (or a confidentiality disclosure agreement) is considered a public disclosure.[21]

The doctrine of inherency or implicit disclosure (USPTO[22] or EP[23]) adds complexity to the analysis of novelty, as patent offices may raise an objection of novelty if the examiner thinks that a prior art inherently or implicitly discloses the invention. Pharmaceutical and biotechnological inventions based on new proprieties of, or new methods of using, existing compositions become difficult to patent. Different case law with regard to the doctrine of inherency is described in detail by Holman[24] and Goldman et al.[25] To avoid objections based on inherency, claim unexpected uses for an uncovered property of a known composition, and be specific in the claims by defining subgroups, subsets of diseases or dosage regimens, and/or a new technical effect.

The most common disclosures of inventions are conference posters or presentations, Master of Science (MSc) or Doctor of Philosophy (PhD) theses, or a simple chat with a friend. A discussion with a qualified patent attorney or with your technology transfer professional is bound by confidentiality and should be the first point of call when realizing an invention.

21 Krauß, J. and D. Kuttenkeuler (2021). When to file for a patent? The scientist's perspective. *Nature Biotechnology*, 60, 124–9. doi:10.1016/j.nbt.2020.10.006.
22 2112 requirements of rejection based on inherency; burden of proof. United States Patent and Trademark Office; 2024. Available at: https://www.uspto.gov/web/offices/pac/mpep/s2112.html (accessed May 24, 2025).
23 Implicit disclosure and parameters. European Patent Office; 2023. Available at: https://new.epo.org/en/legal/guidelines-epc/2023/g_vi_6.html (accessed May 24, 2025).
24 Holman, C.M. (2020) Inherency in the patenting of biotechnology and pharmaceutical innovation. *Biotechnology Law Report*, 39(2), 79–99. doi:10.1089/BLR.2020.29165.CMH
25 Goldman, M., G. Evans and A. Zappia. (2015). Inherent Anticipation in the Pharmaceutical and Biotechnology Industries. *Cold Spring Harbor Perspectives in Medicine*, 5(8), a021006. doi:10.1101/cshperspect.a021006.

There seems to be a consensus about the novelty requirement globally. Nevertheless, there are exceptions that are specific to each country or region.[26]

The JPO offers a grace period of 12 months. The USPTO grants a similar 12-month grace period for the inventor to file a patent application, even if he or she has disclosed the invention publicly in some way. The grace periods for other countries are described in more detail in a WIPO publication.[27]

The EPO offers a grace period of 6 months for only two situations, in which the publication arises from (i) a breach of contractual agreement or (ii) the disclosure of the invention at an officially recognized international exhibition.[28] An officially recognized international exhibition is defined by the terms of the 1928 Paris Convention, last updated in 1972.[29] The EPO published a list of previous exhibitions that fall within the terms of the 1928 Paris Convention.[30] Taking this into account, applicants planning to file in Europe should assume that there is no grace period.

The EPO recently published a report on the impact of grace periods and how they lead to more unintentional infringement because of the longer period of uncertainty (increasing from 18 to 30 months) regarding freedom to operate.[31]

1.3 Inventive step or non-obviousness

Key point

- *Highlight all unexpected results as they are more easily accepted as proof of inventive step or non-obviousness.*

Discussing inventive step (or non-obviousness) requirements is hard without first understanding the entity referred to as *person having ordinary skill in the art (PHOSITA)* or simply *person skilled in the art*, considered in the assessment of inventiveness. PHOSITA is an imaginary person that has average knowledge of a scientific field but zero creativity. For most of the topics of life sciences, a PHOSITA would be someone qualified to MSc or PhD level with an understanding of the science but without any creativity or idea of how to improve a technology or invention. Even though there are well-established methods to assess inventive step or non-obviousness in most jurisdictions to make the process as objective as possible, a certain degree of subjectivity still remains for the examiner, patent attorney and inventor(s), as no person can act 100 percent as PHOSITA.

Inventive step is one of the most important factors in the examination of a patent, and is where most of the arguments are debated between the examiner and the patent attorney. It is also one of the most difficult factors to define, as it always involves a degree of subjectivity from the examiner as well as their level of knowledge and experience.

Japan

Inventive step requirements for Japan are described in Article 29(2) of the Japanese Patent Act and in the examination guidelines published on their website.[32] The JPO define the *person skilled in the art* as a person meeting their four conditions, but also mention that a person skilled in the art could sometimes be considered as a *team of experts* from several technical fields. The JPO

26 Krauß, J. and D. Kuttenkeuler (2021). When to file for a patent? The scientist's perspective. *Nature Biotechnology*, 60, 124–9. doi:10.1016/j.nbt.2020.10.006.
27 Grace period: certain aspects of national/regional patent laws. World Intellectual Property Office; 2022. Available at: https://www.wipo.int/export/sites/www/scp/en/national_laws/grace_period.pdf (accessed May 24, 2025).
28 Gates, C. (2014). Patenting the life sciences at the European Patent Office. *Cold Spring Harbor Perspectives in Medicine*, 4(12). doi:10.1101/cshperspect.a020792.
29 Bureau International des Expositions. The 1928 Paris Convention; 1972. Available at: https://www.bie-paris.org/site/images/Documents/1928-convention-protocol-en.pdf (accessed May 24, 2025).
30 International exhibitions as referred to in Article 55 EPC. European Patent Office; 2016. Available at: https://www.epo.org/law-practice/legal-texts/official-journal/2016/etc/se4/p219.html (accessed May 26, 2025).
31 The European Patent System and the grace period - an impact analysis. European Patent Office; 2022. Available at: https://link.epo.org/web/the_european_patent_system_and_the_grace_period_study_en.pdf (accessed May 26, 2025).
32 Examination guidelines for patent and utility model. Japan Patent Office; 2024. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html (accessed May 26, 2025).

examiners begin in the same way as the European examiners with the closest prior art (referred to as the primary prior art), and determine whether the person skilled in the art would easily arrive at the claimed invention by applying the four-step analysis described in the guidelines.[33] The JPO also articulate two factors that support the inventive step: advantageous effects, an effect of different nature from that of the prior art or the same nature but significantly superior; and obstructive factor, where are other prior art documents obstruct the primary prior art document. The JPO provides several examples to aid understanding.[34]

United States of America

The non-obviousness condition in the United States of America requires an invention to be not obvious to a PHOSITA. The easiest illustration of the non-obviousness principle is by having an invention combining concepts A+B, where A and B are concepts from two distinct prior art documents. If a PHOSITA read documents A and B, would it seem obvious to combine the two? If yes, then the non-obviousness condition is not fulfilled. The non-obviousness condition is described in section 103 of 35 USC.[35] The USPTO has published examiner training material that uses real examples to illustrate in more detail the approach taken by examiners.[36]

The factual inquiries that examiners make for the non-obviousness condition include the following. What is the scope and content of the prior art? What are the differences between the prior art and the claimed invention? What is the level of ordinary skill in the pertinent art at the time the invention was made? Does any objective evidence of non-obviousness exist?[37]

Europe

Inventive step requirements for Europe are described in Article 56 of the EPC and part G, chapter VII of the guidelines for examination. As in the United States of America, an invention in Europe is considered to have an inventive step if it is not obvious to a person skilled in the art. EPO examiners use *the problem–solution approach* to assess inventive step, which presumes that inventions are solutions to different problems. European examiners analyze inventive step in three main stages: determining the closest prior art, establishing the objective technical problem, and considering if it would have been obvious to a person skilled in the art to solve the objective technical problem in the same way that the patentee now claims to be their inventive contribution to the art. When asking the latter question, EPO examiners look for evidence of an unexpected technical effect associated with the presence of the underlying structural feature(s) that achieves the inventive contribution asserted by the patentee.[38]

1.4 Sufficiency of disclosure or enablement

The sufficiency of disclosure or enablement requirement is another element of international consensus with respect to the purpose of patenting. For governments to grant the patent rights, it is necessary that the invention is described sufficiently clearly to enable a person skilled in the art (or optionally, with the benefit of common general knowledge) to reproduce the invention as claimed (across the full scope of each patent claim). Certain types of biotechnology inventions are not workable (or reproducible, to a lesser extent) without access to a particular source or form of living biological material (e.g., a new bacterial strain, or a delivery vector charged with exogenous nucleic acid). In many cases, this problem is exacerbated when the biological material in question cannot be readily and reliably replicated by a skilled person. In such scenarios, the patentee should make a parallel Biological Deposit in accordance with the governing Budapest treaty provisions.

33 Examination guidelines for patent and utility model. Japan Patent Office; 2024. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html (accessed May 26, 2025).
34 Examination guidelines for patent and utility model. Japan Patent Office; 2024. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/index.html (accessed May 26, 2025).
35 Title 35–Patents. United States House of Representatives, United States Code (USC); 1952. Available at: http://uscode.house.gov/view.xhtml?path=/prelim@title35&edition=prelim (accessed May 24, 2025).
36 Examination guidelines and training materials: obviousness. United States Patent and Trademark Office; 2010. Available at: https://www.uspto.gov/patents/laws/examination-policy/examination-guidance-and-training-materials (accessed May 26, 2025).
37 Examination guidelines for determining obviousness under 35 U.S.C. 103. United States Patent and Trademark Office; 2019. Available at: https://www.uspto.gov/web/offices/pac/mpep/s2141.html (accessed May 26, 2025).
38 Part G, Chapter VII, 5. Problem-solution approach: guidelines for examination. Available at: https://www.epo.org/en/legal/guidelines-epc/2025/g_vii_5.html

The enablement requirement in the United States of America is described in section 112 of the 35 USC, where it is deemed obligatory that an invention is described in a manner that *enables* a PHOSITA to make or use it as defined by the claims and the patent application.[39] The enablement requirement has become in recent years one of the hardest requirements for the patenting of life sciences invention in the country.

For Japan, the enablement requirement is described in Article 36(4)(i) of its Patent Act,[40] and requires the description of the patent application to be clear and sufficient for the person skilled in the art to apply it. The JPO provide several examples illustrating this requirement.[41] As for the other requirements, the USPTO provides free training materials.[42] The disclosure of invention requirements for Europe are described in Article 83 of the EPC[43] and part F, chapter III of the guidelines for examination.[44] The patent application must disclose the invention (especially its essential features) sufficiently clearly and completely for a person skilled in the art to be able to put it into practice.

WIPO recently published a study on the sufficiency of disclosure requirements, which emphasizes the specific requirements relating to the biological, chemical and artificial intelligence technical fields.[45] A comprehensive analysis relating to the disclosure requirements for genetic resources has also been published by WIPO.[46]

1.5 Usefulness or industrial applicability

As for the novelty and sufficiency of disclosure requirements, the usefulness or industrial applicability is a factor applied by most patent offices worldwide. This requirement is rarely (if at all) the main objection of examiners regarding the patentability of an invention. The JPO describes the industrial applicability criteria in Article 29(1) of its patent act,[47] and states that the word "industry" is similarly to be interpreted in a broad sense.[48] The USPTO mentions the usefulness criteria in 35 USC 101.[49] The EPO will deem an invention "susceptible of industrial application if it can be made or used in any kind of industry" in accordance with Article 57 EPC[50] and part G, chapter III of the examination guidelines. In this context, "industry" is understood to encompass the biotechnology and pharmaceutical fields.[51]

1.6 Patent law vs. know-how or trade secret

The protection of intangible assets is a crucial aspect of modern businesses, with intangible assets accounting for 90 percent of the total value of the Standard and Poor's 500 (S&P 500) index (the leading 500 companies in the United States of America) in 2020.[52] Intangible

39 2164: The enablement requirement. United States Patent and Trademark Office; 2013. Available at: https://www.uspto.gov/web/offices/pac/mpep/s2164.html (accessed May 26, 2025).
40 Japanese Patent Act; 1959. Available at: https://www.japaneselawtranslation.go.jp/en/laws/view/4097 (accessed May 24, 2025).
41 Enablement requirement. Japan Patent Office. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/document/index/02_0101_e.pdf (accessed May 26, 2025).
42 Examiner training materials. United States Patent and Trademark Office. Available at: https://www.uspto.gov/learning-and-resources/examiner-training-materials (accessed May 26, 2025).
43 Article 83: disclosure of the invention. European Patent Convention. Available at: https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ar83.html (accessed May 26, 2025).
44 Part F, Chapter III. Sufficiency of disclosure: guidelines for examination. European Patent Office. Available at: https://www.epo.org/en/legal/guidelines-epc/2025/f_iii_1.html (accessed May 26, 2025).
45 Further study on the sufficiency of disclosure (Part I). World Intellectual Property Organization; 2022. Available at: https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=582853 (accessed May 26, 2025).
46 Key questions on patent disclosure requirements for genetic resources and traditional knowledge. World Intellectual Property Organization; 2020. Available at: https://www.wipo.int/publications/en/details.jsp?id=4498 (accessed May 26, 2025).
47 Japanese Patent Act; 1959. Available at: https://www.japaneselawtranslation.go.jp/en/laws/view/4097 (accessed May 24, 2025).
48 Eligibility for patent and industrial applicability. Japan Patent Office. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/tukujitu_kijun/document/index/03_0100_e.pdf (accessed May 26, 2025).
49 Vidal, K.K. (2022) Patent eligible subject matter: public views on the current jurisprudence in the United States. United States Patent and Trademark Office; 2022. Available at: https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf (accessed May 24, 2025).
50 Article 57: industrial application. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ar57.html (accessed May 26, 2025).
51 F II, 4.9 Industrial application. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_ii_4_9.htm https://www.epo.org/en/legal/guidelines-epc/2025/g_iii_1.html (accessed July 29, 2025).
52 The soaring value of intangible assets in the S&P 500. Visual Capitalist; 2020. Available at: https://www.visualcapitalist.com/the-soaring-value-of-intangible-assets-in-the-sp-500/ (accessed May 26, 2025).

assets are considered to fall within three different categories: registered IP rights (patents, trademarks, designs), unregistered IP rights (trade secrets, customer database, know-how, etc.) and goodwill. The advantages and disadvantages of each intangible asset type need to be considered when deciding the best protection for any creation. For most pharmaceutical and biotechnological innovations, the choice of the best form of protection will be either (i) patents or (ii) know-how or trade secrets.

Know-how

Know-how is defined in many ways by different bodies, but a legal definition provided by the EPO and European Union Intellectual Property Office defines know-how as "industrial information or technique likely to assist in the manufacture or processing of goods and materials."[53] A more detailed definition of know-how from case law[54] is "factual knowledge not capable of precise, separate description. However, when used in an accumulated form, after being acquired as the result of trial and error, gives to the one acquiring it an ability to produce something which otherwise would not have known how to produce with the same accuracy or precision found necessary for commercial success."

An accepted example of know-how can be a specific supplier list for certain raw materials. Negative information (e.g., experimental conditions that produce poor results) can also be considered as know-how. As another example, assume that it is generally known that using a particular fungal strain produces protein A at a certain range of temperature and humidity. Company One can make protein A using the fungi at a much lower cost compared with its competitors, because it has found through historic trial and error that the best yield is at a very specific temperature and humidity. This knowledge is part of company One's know-how.[55]

Trade secrets

Trade secrets are defined as "confidential business information which provides an enterprise a competitive edge." To be able to state that an intangible asset is a trade secret, it needs to meet the criteria of the general standards from Article 39[56] of the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS), which are listed below.

- "It is a secret": the information must be not generally known or easily discovered.
- "It has commercial value because it is a secret": loss of the trade secret would cause a financial loss to the owner.
- "Reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret": an owner must be able to demonstrate the practical steps taken to keep the information secret.[57]

Well-known examples of trade secrets are the recipes for Coca-Cola and Colonel Sanders' Kentucky Fried Chicken. In life sciences, trade secrets can be a useful approach at the very early stages of the drug discovery process or in protecting complex information, such as the particular sequence of conditions and activities used to produce a biological product.[58]

The Unfair Competition Prevention Act (UCPA)[59] governs trade secret protection in Japan. The UCPA provides civil remedies and criminal penalties for trade secret misappropriation (UCPA, Articles 2(6) and 21).

53 IP Teaching Kit Advanced II. European Union Intellectual Property Office. Available at: https://euipo.europa.eu/knowledge/course/view.php?id=1922 (accessed May 26, 2025).
54 Mycalex Corporation v. Pemco Corporation, 64 F. Supp. 420 (D. Md. 1946). Justia U.S. Law; 1946. Available at: https://law.justia.com/cases/federal/district-courts/FSupp/64/420/1952852/ (accessed May 26, 2025).
55 IP Teaching Kit Advanced II. European Union Intellectual Property Office. Available at: https://euipo.europa.eu/knowledge/course/view.php?id=1922 (accessed May 26, 2025).
56 Part II. Standards concerning the availability, scope and use of intellectual property right. World Intellectual Property Organization. Available at: https://www.wto.org/english/docs_e/legal_e/27-trips_04d_e.htm (accessed May 26, 2025).
57 Nealey, T., R.M. Daignault and Y. Cai (2015). Trade secrets in life science and pharmaceutical companies. *Cold Spring Harbor Perspectives in Medicine,* 5(4), a020982. doi:10.1101/CSHPERSPECT.A020982.
58 Nealey, T., R.M. Daignault and Y. Cai (2015). Trade secrets in life science and pharmaceutical companies. *Cold Spring Harbor Perspectives in Medicine,* 5(4), a020982. doi:10.1101/CSHPERSPECT.A020982.
59 Unfair competition prevention act. Japanese Law Translation; 1993. Available at: https://www.japaneselawtranslation.go.jp/en/laws/view/2803/en (accessed May 26, 2025).

In the United States of America, trade secrets are protected under both federal and state laws. The Defend Trade Secrets Act (DTSA)[60] of 2016 provides a civil cause of action for trade secret misappropriation (18 USC section 1836).[61] There are examples of prosecution for life sciences trade secret theft in this country, for example, *Pacesetter Inc. v. Nervicon Co.* or the Eli Lilly scientists trying to steal information for Jiangsu Hengrui Medicine Co. Ltd.[62]

In Europe, the European Union Trade Secrets Directive (2016/943)[63] harmonizes trade secret protection across EU member states. Each member state has implemented this directive into their national laws, ensuring a consistent approach to trade secret protection.

Patents vs. know-how or trade secrets

The choice of whether to use either (i) patent protection or (ii) know-how or trade secrets depends on various factors, including the nature of the invention or innovation, the resources available to acquire and maintain protection, and the ease of enforcing the protection. Understanding the different benefits offered by these two approaches is crucial when advising innovators or making strategic decisions about the best ways to protect their intangible assets.

Patents are the most frequently used method of protection in the life sciences, as they provide commercial confidence to both investors and shareholders. Furthermore, regulatory requirements around the therapeutics field mean that simply not disclosing details of your new product or treatment may not be a viable approach to protecting your innovation. However, if circumstances allow, the use of know-how or trade secrets may have certain benefits, as outlined below.

- Duration: Patents provide a limited term of protection (20 years), but know-how or trade secrets can last indefinitely, as long as the information is kept confidential.
- Disclosure: Patents require the disclosure of the invention to the public, which can promote further innovation. However, know-how or trade secrets do not require disclosure, which may limit the dissemination of valuable knowledge.
- Cost: Patent protection can be the most expensive aspect of IP, requiring application fees, attorney fees and ongoing maintenance fees. In addition, there are opportunity costs and impacts on the ability to outsource, cooperate, license etc. Know-how or trade secrets do not incur these legal costs; instead, high investment in security measures and regular staff training to maintain confidentiality are required.
- Scope: Patent protection is conferred only by the scope of claims in view of the patent description, whereas know-how or trade secrets can cover a much broader range of information.
- Territoriality: Patent protection is territorial, requiring separate applications and fees for each jurisdiction. However, know-how or trade secrets do not have territorial limitations, although the level of protection may vary between jurisdictions.

As well as the above benefits, the use of know-how or trade secrets has the risk of a third party being able to reverse-engineer your innovation and use it.

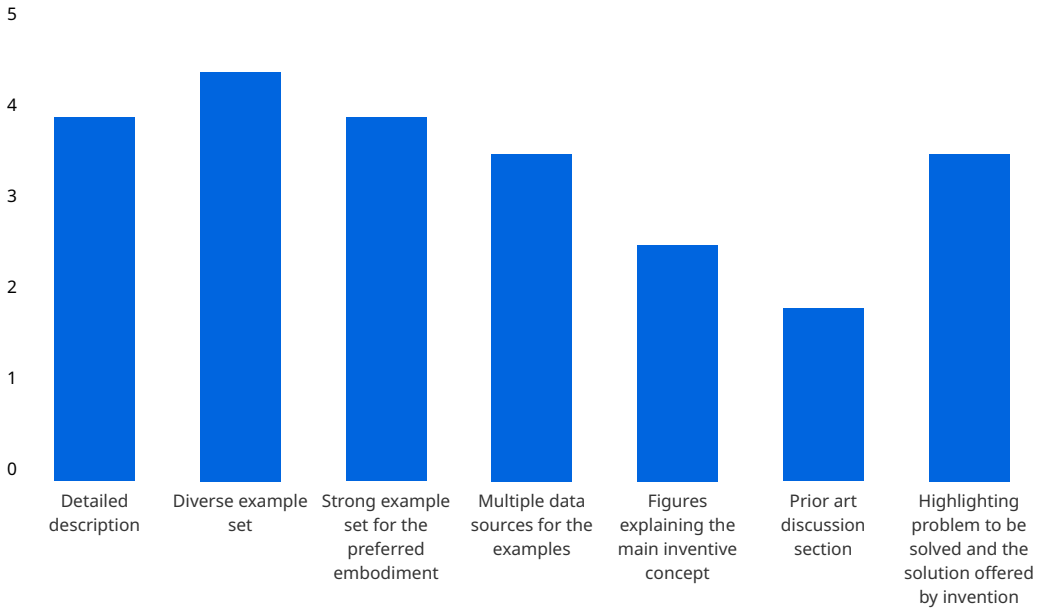
If trade secrets are the chosen method of protection, knowledge of prior use rights is important. If an entity files a patent on your trade secret innovation, you cannot challenge it as a result of its secrecy but you may defend yourself against patent infringement through prior use rights. Prior use rights are limited territorially and require the acts to have been performed in good faith. The USPTO published a report that details the particularities of prior use rights in Japan, the United States of America and Europe (including Denmark, France, Germany and the United Kingdom).[64]

60 Defend Trade Secrets Act of 2016. United States Congress; 2016. Available at: https://www.congress.gov/bill/114th-congress/senate-bill/1890 (accessed May 26, 2025).
61 18 U.S. Code § 1836 - Civil proceedings. Cornell Law School, United States Code. Available at: https://www.law.cornell.edu/uscode/text/18/1836 (accessed May 26, 2025).
62 Nealey, T., R.M. Daignault and Y. Cai (2015). Trade secrets in life science and pharmaceutical companies. *Cold Spring Harbor Perspectives in Medicine,* 5(4), a020982. doi:10.1101/CSHPERSPECT.A020982.
63 EUR-Lex - 32016L0943. European Union; 2016. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016L0943 (Accessed May 26, 2025).
64 Report on prior user rights. United States Patent and Trademark Office. Available at: https://www.uspto.gov/sites/default/files/ip/global/prior_user_rights.pdf (accessed May26, 2025).

1.7 Impact of key patenting requirements on patent strength

Understanding the relative importance of these different factors for patentability, and the way in which they can impact upon strengths of any patent granted, can be useful when considering how to prioritize a patent budget or assess shortcomings in potential filings. As shown in Figure 2, experienced patent attorneys responding to our poll considered inventive step as having the greatest impact on sustainability of a granted patent. The issue of novelty based on prior art, and data-based issue of sufficiency of disclosure or enablement, were viewed as joint second, while patentable subject matter and industrial applicability came third and fourth, respectively. Bearing these relative weightings in mind may be useful when assessing the strengths or weaknesses of patents in your portfolio, or when deciding whether a particular innovation is ready for filing.

Figure 2. Could you please rate the importance of the following elements for the strength/ defensibility of a patent application in the life sciences sector?



Source: WIPO analysis based on questionnaires completed by patent attorneys and technology transfer professionals.

1.8 The role and sources of experimental data

Key points

- *There is always a compromise between the amount of data gathered to support the claims across their whole breadth, and the incentive of the first-to-file system.*
- *WIPO Standard 26 (ST.26) of reporting biological sequences allows for consistent reporting across the different bodies.*

1.8.1 Main data sources

In ideal circumstances, the same guidelines that are used for the publication of life sciences research should be used for life sciences patenting. Nature Publishing Group outlines a non-exhaustive list of the elements to be reported for life sciences research to improve the transparency and reproducibility of published results. The list includes experimental design reporting (sample size, randomization, blinding, etc.), statistics reporting (*t*-tests, *P*-values, mean, median, standard errors, etc.), description of reagents (cell lines, antibodies, catalogue numbers, primary citations, etc.), description of methods or protocols, and data deposition policies. The same document has links to guidelines regarding the reporting for biomarker studies, molecular structure determination, chemical compound characterization and

microscopy.[65] The Proceedings of the National Academy of Sciences journal also published the MDAR (materials, design, analysis and reporting) framework for transparent reporting in the life sciences.[66] The MDAR author checklist provides guidance regarding all the details to be reported for a transparent and solid data set in life sciences. Because of the pressures of the first-to-file system, in practice the data required for a patent filing can be more preliminary than the level required for a peer-reviewed article. Some jurisdictions allow for post-filing data to be used during prosecution to support more limited data present in the application (e.g., recent decision of the EPO Enlarged Board of Appeal).[67] Usually, post-filing data for the sufficiency of disclosure or enablement requirement are more easily accepted by examiners than new data in support of the inventive step. New data in support of the inventive step are accepted only in very specific circumstances (e.g., comparing the invention with the closest prior art to show unexpected advantageous results).[68]

Given the broad range of inventions encompassed within life sciences, it is very hard to outline all the potential data sources that can be used as exemplification for patent applications. Nevertheless, the data can be categorized into a few types of classes: *in vitro*, *in vivo* and *ex vivo*. There are other types of inventions in the life sciences field that are not a drug but are a system, device or method; data to support the scope of such claims have to be linked to what is considered relevant for that specific subfield.

Most of the inventions in the life sciences field are relevant to a part of the drug development process pathway, and the experimental data that are required to meet certain criteria along the pathway will also be used when patenting. Additional data might sometimes be required for patent applications to fully support the desired scope of claims. Since this report is focused on the disclosure and filing of new patent applications, more emphasis is given to data required in the earlier stages of drug discovery. A high-level overview of the drug development process is provided on the FDA website,[69] with a more detailed overview presented by Hughes et al.[70] in the British Journal of Pharmacology.

Some of the most used data sources in life sciences patents are sequences of nucleotides and amino acids. The sequences are reported according to the global sequence listing standard managed by WIPO. Sequence listings are required for patent application that mention DNA or RNA sequences of 10 or more nucleotides, or peptide sequences of four or more amino acids (irrespective of whether such sequences are mentioned in the claims). To address the drawbacks of WIPO Standard 25 (ST.25), which did not comply with the International Nucleotide Sequence Database Collaboration (INSDC) requirements, did not account for nucleotide analogues or D amino acids or branched sequences, and allowed for an inconsistent enforcement across patent offices, the sequences reporting standard was updated to ST.26 in July 2022. In comparison to the sequence listing being submitted in text format, ST.26 requires the sequence listing in an XML electronic format.[71]

A further feature of the sufficiency of disclosure or enablement requirement is that the data source used to support a patent application must show "possession" of the invention at the time of filing. This means that if the invention involves biological data this must be deposited or, if certain properties of compounds are important for the claims, they have to be measured across the entire scope of the claims (e.g., melting point). The possession condition is applied depending on the nature of the invention and state of knowledge.[72]

65 Reporting life sciences research. Nature; 2015. Available at: https://www.nature.com/documents/nr-reporting-life-sciences-research.pdf (accessed May 26, 2025).
66 Macleod, M., A.M. Collings, C. Graf, V. Kiermer, D. Mellor, S. Swaminathan, et al. (2021). The MDAR (materials design analysis reporting) framework for transparent reporting in the life sciences. *Proceedings of the National Academy of Sciences, USA*, 118(17), e2103238118. doi:10.1073/pnas.2103238118.
67 Communications from the Board of Appeal. European Patent Office. Available at: https://www.epo.org/law-practice/case-law-appeals/communications/2023/20230323.html (accessed May 26, 2025).
68 Altman, D., C. Sweeney and T. Yasui (2014). Preparing effective experimental data for pharmaceutical patent applications from US and Japanese perspectives. *Pharmaceutical Patent Analyst*, 3(5), 469–73. doi:10.4155/ppa.14.38.
69 The Drug Development Process. United States Food and Drug Administration; 2018. Available at: https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process (accessed May 26, 2025).
70 Hughes, J.P., S.S. Rees, S.B. Kalindjian and K.L. Philpott (2011). Principles of early drug discovery. *British Journal of Pharmacology*, 162(6), 1239–49. doi:10.1111/j.1476-5381.2010.01127.x.
71 WIPO Standard ST.26 goes live! World Intellectual Property Organization; 2022. Available at: https://www.wipo.int/pct/en/news/2022/news_0039.html (accessed May 26, 2024).
72 Liberto, M. and P.J. Cuomo (2021). Don't be caught without possession (of your invention): what you need to know about the written description requirement. *IP Litigator*, 27(2). Available at: https://www.mintz.com/sites/default/files/media/documents/2021-05-12/Liberto%20Cuomo%20Print.pdf (accessed May 26, 2025).

In vitro

In vitro refers to experiments performed outside of a living organism in a controlled environment such as a petri dish, centrifuge tubes, cell culture flasks, etc. *In vitro* assays are used significantly in the early drug discovery and preclinical research stages to establish profiles of both (i) drug metabolism and pharmacokinetics and (ii) absorption, distribution, metabolism and excretion. A non-exhaustive list of *in vitro* experimental data sources includes cell line assays, patient isolates assays and analysis, receptor binding tests, solubility tests, hERG binding assay, HepG2 cytotoxicity assay, P450s assays, microsomal assays to understand metabolic stabilities, drug metabolism assays, immunological assays (immunogenicity, immunophenotyping, cellular immune response) and genomics assays.

In vivo

In vivo refers to experiments performed in a living organism. Although important during the preclinical stage onward, *in vivo* studies are more costly and time-consuming compared with *in vitro* and *ex vivo* experiments, and are therefore used less often during the earlier drug discovery stages. *In vivo* experimental data sources often utilize animal models as primary disease models to obtain data demonstrating the effectiveness of the therapy at the preclinical stage, and to establish pharmacokinetic and pharmacodynamic profiles. The animal model of choice will vary for each of these applications. Once suitable data have been gathered to indicate effectiveness and safety, the drug candidate will progress to clinical phases where *in vivo* studies are conducted in humans.[73]

Ex vivo

Ex vivo refers to experiments performed on a tissue taken from a living organism. This type of model is considered to be a compromise between *in vitro* and *in vivo* models. *Ex vivo* assays have been developed for a wide range of applications; Xu et al.[74] describe the different types of *ex vivo* assays used for studying the transport of drugs across intestinal barriers, and Meijer et al.[75] describe different *ex vivo* models for use in the development of cancer therapies. *Ex vivo* models can also be presented for other types of innovations such as medical devices or training devices or systems (e.g., *ex vivo* testing of flexor tendon model to improve surgical training).[76]

1.8.2 Support of claims and patentability

Understanding the strength of a patent and its claims requires an understanding of the usual structure of a patent. The typical parts of a patent application are the description, which is split into different sections (title of the invention, technical field, background art, summary of the invention, brief description of the drawings and detailed description), claims, drawings and an abstract. These parts are described in detail in WIPO's patent drafting manual.[77]

The claims define the legal protection provided by the patent, and are interpreted by reference to the description supported by examples. The latter provide specific embodiments of the invention, and collectively provide a data support package illustrating the key technical effects of the invention. The description should envision as many of the potential variations of the invention as possible in order to provide the necessary written basis required to support amendment of claims, should this be required during the prosecution of the patent (some jurisdictions do not allow amendments that are not covered in the detailed description). As an absolute minimum, a patent application must include enough technical details (typically working examples and experimental data) to support any technical effect that is later cited.

73 Romero, L. and J.M. Vela (2014). Alternative models in drug discovery and development part II: in vivo nonmammalian and exploratory/experimental human models. In: *In Vivo Models for Drug Discovery*. Wiley, 59–90. doi:10.1002/9783527679348.ch03.
74 Xu, Y., N. Shrestha, V. Préat and A. Beloqui (2021). An overview of in vitro, ex vivo and in vivo models for studying the transport of drugs across intestinal barriers. *Advanced Drug Delivery Rev*iews, 175, 113795. doi:10.1016/j.addr.2021.05.005.
75 Meijer, T.G., K.A. Naipal, A. Jager and D.C. van Gent (2017). Ex vivo tumor culture systems for functional drug testing and therapy response prediction. *Future Science OA,* 3(2). doi:10.4155/fsoa-2017-0003.
76 Papavasiliou, T., R. Nicholas, L. Cooper, J.C.Y. Chan, J. Ibanez, C.J. Bain, et al. (2022). Utilisation of a 3D printed ex vivo flexor tendon model to improve surgical training. *Journal of Plastic, Reconstructive and Aesthetic Surgery,* 75(3), 1255–60. doi:10.1016/j.bjps.2021.11.027.
77 WIPO patent drafting manual, second edition. World Intellectual Property Organization; 2023. Available at: https://tind.wipo.int/record/44657?v=pdf (accessed May 26, 2025).

The examples section typically begins with a materials and methods section, after which the different examples of embodiments of the invention are provided. Data are usually presented from the proof of the concept or underlying mechanism to *ex vivo* data, *in vivo* (animal model) data and clinical trial data (if available). When presenting the data, each significant result should be given its dedicated example, that is: Example 1, proof of concept; Example 2, *in vitro* data for certain subpopulation; Example 3, *in vitro* data for another subpopulation; Example 4, animal model experiments etc. Presenting the data in a story-like manner may help the examiner comprehend their relevance and the way in which they support the claimed invention. Making use of tables, graphs and figures is another strategy to highlight and summarize the key results in an easily understandable manner. The figures and graphs are usually presented separately from the text, normally at the end of the patent specification. A summary of the figures is usually presented in a "Brief description of the figures" section, and their relevance discussed in more detail in the Examples. When preparing the figures for the patent application, contrasting colors and different markers and legends should be used, as they will need to be presented in greyscale to satisfy the requirements of most patent offices.

When filing the patent application, the preferred embodiments should be covered in the examples section and at different levels of generalization to demonstrate that the invention works across the full area defined by the claims. To enhance visualization of the concept, the claims could be considered as a tool to describe a map of the patent landscape. For example, consider a patent application claiming Switzerland as a space in the patent landscape of planet Earth. If the patent application shows examples across the whole area of Switzerland, it would be difficult for the examiner to constrain the land to something else; however, if the examples covered only the Geneva and Lausanne area, then the examiner may decide to constrain the land to the French-speaking area only. On other words, the examples should demonstrate operability of the invention across the entire scope of claims (as eventually granted). As another example, if a claim cites an essential technical feature in terms of a range of 1–100 units, a sweet spot of preferred examples within the subrange of 40–60 units may be observed. However, to justify the broader range, additional exemplification (of the technical effect relied upon) within the 1–10 and 90–100 subranges would be required. The nature of the invention is also a factor of influence on the examiner's restrictiveness, with pioneering inventions being allowed a broader scope.

In some cases, prophetic examples can be used to describe experiments that have not been performed but are planned. Such examples can describe predicted or simulated results, but examiners in the life sciences do usually not assign much importance to these types of examples (unless they are substantiated by experimental data). To have a strong position for the inventive step or non-obviousness requirement, any unexpected or surprising result or effect compared with the prior art or the knowledge in the field should be highlighted within the examples section.

Understanding the relevant prior art for an invention is crucial for a well-drafted patent application and claims. The claims are usually drafted to protect the invention, and to prevent any envisaged potential workarounds by competitors. The independent claims start from the essential elements of the invention with dependent claims adding other elements that, during prosecution, form alternative claims in case the examiner does not accept the independent claims as filed (onion-layer strategy). In exchange for a fee, several jurisdictions offer the possibility of conducting a search for prior art and a written opinion on the patent application. Many patent attorneys use this search and/or written opinion to refine the claims prior to the international application.

There is always a fine balance between how early to file a patent application and how much exemplification data to gather. Ideally, an application is filed as soon as the inventive concept is proven and exemplified. However, in very competitive fields, an application should be filed as soon as the inventive concept is clear, with filing updates used to incorporate more data as acquired.

How data are used within a patent application is an important consideration to how life science patent attorneys who participated in our survey rank different elements of drafting and data use for the patent defensibility. A diverse set of examples is considered to be the

most important element, followed by a detailed description of and a strong example set for the preferred embodiments. Utilizing multiple data sources in examples and highlighting the problem that the invention solves is also seen as important. Less significance is given to the figures, and even less to the prior art discussion section. The prior art discussion section is avoided by some patent attorneys, as it may be used by the examiner in the arguments against the application during prosecution.

Some jurisdictions (most notably the United States of America) impose a duty on patent applicants, inventors and/or representing patent attorneys to disclose all known prior art information that "a reasonable examiner would be substantially likely to consider important in deciding whether to allow an application to issue as a patent."[78] This duty of disclosure is met by filing a list of references through an information disclosure statement (IDS). The IDS is usually filed at the same time as filing the patent application, or within 3 months of the filing the application for no fee. Additional fees are only applicable if filing more than one IDS, which is usually done for prior art documents identified in other jurisdictions. Failure to comply with this duty may lead to the unenforceability of the patent for "inequitable conduct." The EPO does not impose this duty but, in some circumstances, it might ask for prior art cited by other offices. The JPO also applies a duty of disclosure, but the failure to comply does not affect the validity of the patent.

78 Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380. Cornell University Law School; 1998. Available at: https://www.law.cornell.edu/patent/comments/97_1438.htm (accessed May 26, 2025).

2. Patent application filing and prosecution

Key points

- The PCT system underpins the most employed patent strategy by both patent attorneys and technology transfer professionals: filing of a priority application, followed by an international application (PCT) and national phase entry 30–31 months later.
- Patent budgets define the constraints of an IP strategy and can be optimized by clearer communication with patent attorneys and decreasing the official filing fees where possible.
- It is important to understand the different factors of patent prosecution (acceleration or delay, better communication with the examiner, etc.) in designing a commercially relevant patenting strategy.
- A substantial proportion of life sciences innovations require the deposit of a biological material at an international depositing authority (Budapest Treaty) to be able to fulfill the disclosure requirements.
- Claims of the composition of matter, product or system type (e.g., active ingredients, device) are believed to offer the strongest post-grant protection, assuming proper support within the specification.

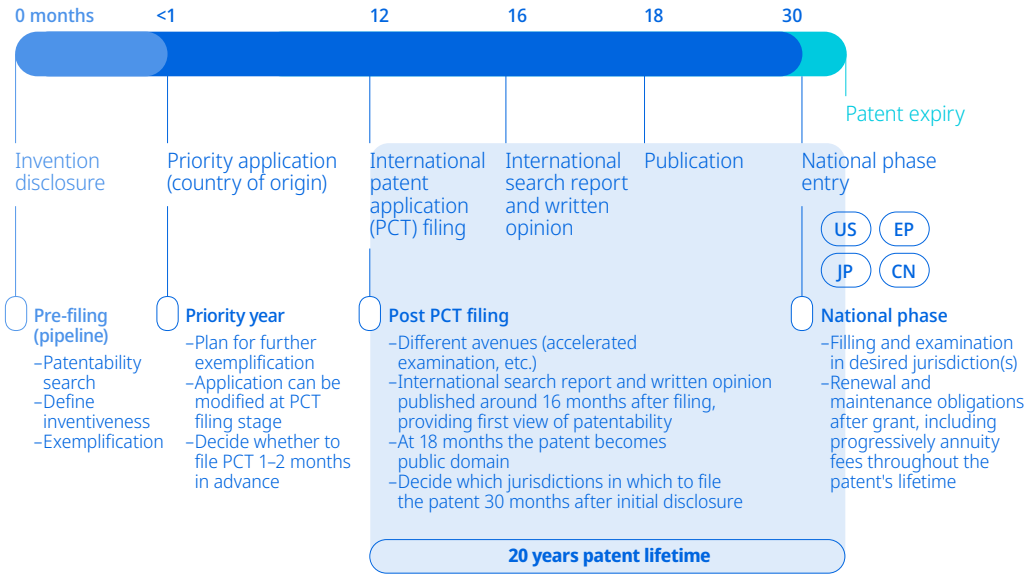
2.1 Common procedural elements

Innovations are influenced by different factors, and patent application filing strategy is best discussed with a patent professional or attorney for the best advice on how and when to file to best protect your invention with respect to your business strategy.

Life sciences patent attorneys and technology transfer professionals who participated in our survey indicated that the main patenting strategy they employ in the pharmaceutical and biotechnology sectors is filing a priority application in the country of origin (or a provisional application), followed by a PCT application 12 months later, and a subsequent national phase entry in selected countries at 30–31 months. This approach was reported far more frequently than directly filing a PCT application followed by national phase entry. Strategies based on filing full patent applications directly in selected countries were used less often.

The most common strategy, which was also favored by the attorneys participating in our survey, is: filing a priority application, followed by a PCT application 12 months later and a national phase entry 30–31 months after the priority filing. The second-most favored strategy is beginning by filing a PCT application followed immediately by national phase entry. The key milestones of the most common patent filing strategy are presented in Figure 3.

Figure 3 The key milestones of the most common patent filing strategy



Note: PCT =Patent Cooperation Treaty.

2.1.1 Application filing: what you need to know

Patent systems are now globally aligned and operate on a first-to-file principle. This means that if two different inventors make the same invention in different parts of the world, the protection is going to be granted to the inventor who files first, even if the other inventor can prove that they made the invention first. Historically, the USPTO used a first-to-invent principle until 2011 when the America Invents Act was passed; the transition from first-to-invent to first-to-file occurred for applications filed after March 16, 2013.[1] The first-to-invent system was associated with multiple disputes about who developed an invention first. The most notable dispute was over who demonstrated the invention of CRISPR-Cas9 first.[2]

The Paris Convention priority year should form an essential part of all informed patent filing strategies. From our experience of working with business start-ups and spinouts in life sciences, this priority year may lead to a better understanding of your invention and the science behind it. Information gleaned during this period will often shape the course of downstream prosecution. During this 12-month period, inventors and research teams frequently continue experimental work and technical validation related to the invention. Additional data generated in this phase may clarify the mechanisms underlying the invention, confirm its practical feasibility, or reveal alternative embodiments and improvements. Such developments can inform subsequent patent filings that claim priority from the initial application, allowing applicants to refine claim scope, strengthen the technical disclosure, and anticipate potential examination issues.

For short-term research projects this period is often the most active in terms of experimental support data, which then feeds directly into the patent specification of the Paris Convention or PCT filing that is claiming the earlier priority date. These data may also provide important defensive value, for example in post-grant revocation proceedings.

Accordingly, the priority year should not be viewed solely as a procedural interval between filings, but also as a strategic opportunity to consolidate the scientific foundation of the invention and ensure that later patent applications more accurately reflect its technical potential and commercial relevance.

Another possibility that has associated risks is, if the data produced in the first 12 months are not sufficient or satisfactory, the initial application can be retracted (without anyone knowing

1 How the first-to-file rule legally affects patent applications. U.S. Justia; 2024. Available at: https://www.justia.com/intellectual-property/patents/first-to-file-rule/ (accessed May 26, 2025).
2 Ledford, H. (2022). Major CRISPR patent decision won't end tangled dispute. *Nature*, 603, 7901. Available at: https://www.nature.com/articles/d41586-022-00629-y (accessed May 26, 2025).

about it *if abandoned formally*) and a new application filed to gain another 12 months of experimentation. The risk of this strategy is that you lose your protection for the initial priority date, and the protection starts from the new application date. This means that if anyone filed a similar invention before the new application date, they would be awarded the protection. As patent applications are only published 18 months after their filing date, there is no way of mitigating this except by closely monitoring your competitors and the patent landscape you are working within.

A very important aspect of patent filings is the cost, especially for companies or entities with small patent budgets. In this regard, the most effective way of minimizing costs is ensuring a well-prepared invention disclosure record is available (together with any helpful annotated notes) to your trusted patent counsel, who will then prepare and file the corresponding patent specification. A well-prepared invention disclosure record contains all the relevant data for your invention from the beginning, highlighting any unexpected results, and mentions the closest prior art documents you have found.

Another method of lowering costs is to decrease your official filing fees. Different jurisdictions have varied fees for different types of entities and, in most jurisdictions, filing fees are dependent on the number of claims in the application.

At the JPO there is no excess claim fee, but the request for examination fee[3] is structured as a fixed fee and a variable fee dependent on the number of claims in the patent application. The USPTO offers a 50 percent discount off their official filing fees[4] for small entities (main criteria of less than 500 employees; details in 37 CFR 1.27)[5] and a 75 percent discount off their official filing fees for micro-entities (details in 37 CFR 1.29).[6] The USPTO also have additional fees[7] for more than three independent claims and more than 20 claims in total. The EPO does not implement different fees for different entities, but has additional fees for each claim for 15–50 claims and even higher fees for each claim for more than 51 claims.[8] WIPO further describes other factors that influence the cost of the patent application in their *Twelve ways to manage global patent costs* article.[9]

2.1.2 Prosecution: what you need to know

In terms of prosecution, the first thing to understand is that examiners may be considering different cases in potentially quite different scientific areas simultaneously. They won't have a doctorate-level understanding of each subfield of their scientific background. Patent examiners also enjoy stories, in the sense that the patent application needs to be presented in a coherent way (e.g., this is the present gap in the industry or technical area, the invention fills that gap with results that would have been unexpected). Examiners may also misunderstand some features of the claim, as we all personally experience when juggling different projects in parallel; it is therefore the responsibility of the patent attorney to be as clear as possible. Back-and-forth written arguments might not always be the best way of communicating, and a telephone conversation or online meeting may be better in some cases. Additional communication will usually lead to higher costs; however, if required to resolve a misunderstanding, keep these extra costs to a minimum by ensuring any additional communication takes place early in the examination process.

There are certain situations where an applicant may wish to accelerate their patent application(s) (e.g., getting a patent granted before raising an investment round). There are

3 Schedule of fees. Japan Patent Office; 2022. Available at: https://www.jpo.go.jp/e/system/process/tesuryo/hyou.html (accessed May 26, 2025).
4 USPTO fee schedule. United States Patent and Trademark Office; 2025. Available at: https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule (accessed May 26, 2025).
5 37 CFR 1.27 - Definition of small entities and establishing status as a small entity to permit payment of small entity fees. United States Government Publishing Office. Available at: https://www.govinfo.gov/app/details/CFR-2011-title37-vol1/CFR-2011-title37-vol1-sec1-27/summary (accessed May 26, 2025).
6 37 CFR 1.29 - Micro entity status. United States Government Publishing Office. Available at: https://www.govinfo.gov/app/details/CFR-2013-title37-vol1/CFR-2013-title37-vol1-sec1-29 (accessed May 26, 2025).
7 USPTO fee schedule. United States Patent and Trademark Office; 2025. Available at: https://www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule (accessed May 26, 2025).
8 Fees. European Patent Office; 2025. Available at: https://my.epoline.org/epoline-portal/classic/epoline.Scheduleoffees?page=0 (accessed May 26, 2025).
9 Twelve ways to manage global patent costs. WIPO Magazine; 2017. Available at: https://www.wipo.int/wipo_magazine/en/2017/04/article_0007.html (accessed May 26, 2025).

acceleration routes specific to each jurisdiction, such as the Accelerated/Super Accelerated[10] examinations at the JPO, Track One applications[11] at the USPTO or the Programme for Accelerated Prosecution of European (PACE)[12] patent applications. Each of these acceleration routes has its own conditions, fees and procedure. The patent prosecution highway (PPH),[13] an alternative acceleration route, is a bilateral agreement between two patent offices that allows one office to accelerate examination at the applicant's request if a corresponding application has been found allowable or patentable by the counterpart office. This began as a JPO–USPTO agreement, and now includes more than 50 intellectual property offices around the world.

As discussed in Chapter 1 of this report, there are differences in the bespoke practice of each patent office and in how examiners implement this practice when assessing patent applications. If a patent application is filed in several jurisdictions around the world, it needs to be adapted for each specific jurisdiction to maximize the chances of allowance. Although patent attorneys are usually only qualified to act for one or two patent offices, they partner with firms in other jurisdictions for filings outside their own region.

Examiners will typically raise a wide range of case-specific objections during prosecution, which usually fall within a defined category as illustrated in Figure 4.

Figure 4 Different objections that the life sciences patent attorneys who participated in our survey reported receiving either frequently or very frequently

Source: WIPO analysis based on questionnaires completed by patent attorneys and technology transfer professionals.

2.2 Life sciences and the international patent system

2.2.1 PCT

The PCT is an agreement between 157 countries[14] that was established by WIPO in 1970. The PCT enables innovators to seek international protection for their inventions by filing a single international application and then deciding in which member country(ies) of the PCT they wish to obtain protection. This treaty provides a streamlined process and delays the examination of the patent application until the national phase entry at 30–31 months from the initial priority filing. The delay of examination is very useful, especially for early-stage technologies and life sciences innovations that can experience many barriers before being clearly understood.[15]

2.2.2 TRIPS

The TRIPS agreement[16] is a legal contract that was established by the World Trade Organization (WTO). The agreement sets the minimum standards of regulations relating to the different forms of IP to be applied by the governments of all WTO member nations.

10 Examination (patents). Japan Patent Office. Available at: https://www.jpo.go.jp/e/system/patent/shinsa/index.html (accessed May 26, 2025).
11 USPTO's prioritized patent examination program. United States Patent and Trademark Office; 2021. Available at: https://www.uspto.gov/patents/initiatives/usptos-prioritized-patent-examination-program (accessed May 26, 2025).
12 4. Accelerated prosecution of European patent applications. European Patent Office. Available at: https://www.epo.org/en/legal/guidelines-epc/2025/e_viii_4.html (accessed July 30, 2025).
13 PPH Portal. Japan Patent Office. Available at: https://www.jpo.go.jp/e/toppage/pph-portal/index.html (accessed May 26, 2025).
14 The PCT now has 157 contracting states. World Intellectual Property Organization. Available at: https://www.wipo.int/pct/en/pct_contracting_states.html (accessed May 26, 2025).
15 PCT FAQs: protecting your inventions abroad: frequently asked questions about the Patent Corporation Treaty (PCT). World Intellectual Property Organization. Available at: https://www.wipo.int/pct/en/faqs/faqs.html (accessed May 26, 2025).
16 Overview: the TRIPS agreement. World Trade Organization. Available at: https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (accessed May 26, 2025).

In this report, we highlight the specific articles and effects of the TRIPS agreement relevant to the field of life sciences.[17]

In terms of life sciences patents, the TRIPS agreement mainly repeats what is covered in Chapter 1. An important highlight of the TRIPS agreement is that it requires members to grant a patent if it has an *adequate* disclosure of the invention. The main purpose of the patent system, a key part of the "social contract", is to incentivize innovation and disclosure. It is only disclosure that enables other people to use the invention and for new developments to happen. In the field of life sciences, many patent applications have parallel scientific publications that describe the invention in greater detail.

In considering public health, there are some exclusions from patentability that WTO members are allowed to make[18] (detailed in Section 1.1 Key patenting requirements):

- diagnostics, therapeutic and surgical methods for the treatment of humans or animals
- certain plant and animal inventions, and essentially biological processes for their production
- inventions for which commercial exploitation must be prevented to protect *ordre public* or morality, including to protect animal or plant life or health.

These exclusions act more as guidelines for the WTO member nations, as there is flexibility in terms of implementation as can be seen in the global divergence of patent-eligible subject matter.

2.2.3 Budapest Treaty

As discussed in Chapter 1, sufficient disclosure of the invention is required; however, there exist situations in which the invention is linked to biological material that cannot be described in writing in the patent application in a way that can be reproduced by the person skilled in the art. In such cases, the disclosure provision can be fulfilled by depositing a sample of the biological material at one of the international depositary authorities.

The international depositary authorities are scientific institutions that comply with the Budapest Treaty. The Budapest Treaty, adopted in 1977 (implemented from 1980) and administered by WIPO, is an agreement regarding international recognition of the deposit of microorganisms or biological material for the patenting process. As for the PCT, the treaty makes it easier for the inventors to file internationally by eliminating the need to deposit the sample of biological material in all the countries in which patent protection is desired. All states that are part of the treaty undertook to recognize deposited microorganisms or biological material as part of their patenting process, regardless of which of the member states is the depository authority. As of January 26, 2023, there are 49 international depositary authorities; Japan has two, the United State of America has three and Europe has more than 20.[19]

2.2.4 Biotechnology Directive

The European Biotechnology Directive (Directive 98/44 EC)[20] governs the patenting of biotechnological inventions in EU member states. However, the examination and granting of a European patent for a biotechnological invention are governed by the EPC. The key points of the Biotechnology Directive, incorporated into the EPC in 1999, are listed below.

- Biological processes for the production of plants or animals (breeding) are essentially excluded from patentability (even a process consisting of entirely natural phenomena such as crossing or selection): Directive Article 2(2) (EPC Rule 26(5)).

17 TRIPS and pharmaceutical patents: fact sheet. World Trade Organization. Available at: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm (accessed May 26, 2025).
18 TRIPS and pharmaceutical patents: fact sheet. World Trade Organization. Available at: https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm (accessed May 26, 2025).
19 Summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977). World Intellectual Property Organization. Available at: https://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html (accessed May 26, 2025).
20 Directive 98/44/EC of the European Parliament and of the Council. Official Journal of the European Communities; 1998. Available at: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML (accessed May 26, 2025).

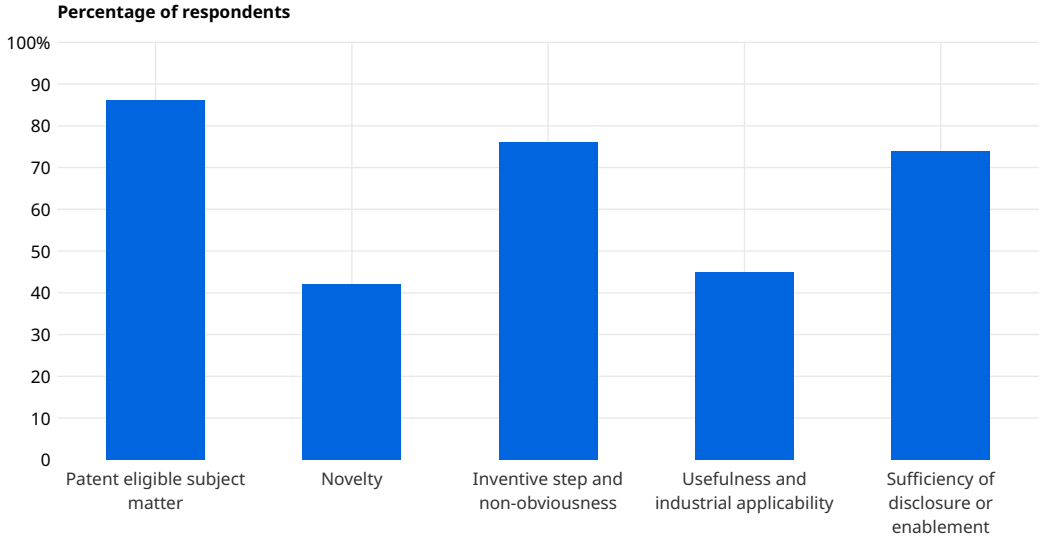
- This was a subject of divergence between the EPO and the European Commission. The latest EPO Enlarged Board of Appeal decision (G3/19) on this matter in May 2020 reversed its previous contradictory decisions (G2/12 and G2/13) to clarify that plants or animals produced by an essentially biological process are not patentable. This decision only applies for patents or patent applications filed after July 1, 2017, and brings more certainty to innovators in the field of technology in agriculture.[21]
- The uses of human embryos for industrial or commercial purposes are excluded from patentability (Directive Article 6(2)(c), EPC Rule 28(c)).
- The industrial application of gene sequences must be disclosed (Directive Article 5(3), EPC Rule 29(3)).

A more in-depth analysis of the exclusions relating to human embryos is described by Choudhary et al.,[22] and the EPO has a useful webpage[23] relating to biotechnology inventions. Wested et al.[24] discuss the overlap between the Biotechnology Directive and both the TRIPS agreement and EPC regulation.

2.2.5 Aspects of regional and national patent law divergences in life sciences

Divergences between patent offices in terms of main patentability criteria are discussed in the Section 1.1. Our survey of life science patent attorneys identified the most important factor for those working in this field as the difference in approach to patent-eligible subject matter, followed by differences regarding inventive step and sufficiency of disclosure (results presented in Figure 5). As expected, and described in Sections 1.1.2 and 1.1.3, there is more consensus globally regarding the novelty and industrial applicability factors.

Figure 5 Ranking of patentability factors in view of jurisdiction divergences according to life sciences patent attorneys who participated in our survey



Source: WIPO analysis based on questionnaires completed by patent attorneys and technology transfer professionals.

One of the most important divergences between patent offices in the field of life sciences is in their approaches to the patentability of many different types of gene sequencing inventions. Nicol et al.[25] reviewed the divergences in international patent law relating to genes since the 1980s in five main jurisdictions (Australia, Canada, China, the United States of America and Europe; see Table 1[26]), and concluded that divergence has never been greater than at present.

21 G 0003/19 (Pepper (follow-up to Tomatoes II and Broccoli II)) of 14.5.2020. European Patent Office; 2020. Available at: https://www.epo.org/law-practice/case-law-appeals/recent/g190003ex1.html (accessed May 26, 2025).
22 Choudhary, L. and A. Kumar (2022). Stem cell patenting: moral and legal dilemma. *Journal of Intellectual Property Rights*, 27, 42–51. Available at: http://nopr.niscpr.res.in/handle/123456789/59278 (accessed May 26, 2025).
23 Biotech patents. European Patent Office; 2024. Available at: https://www.epo.org/news-events/in-focus/biotechnology-patents.html (accessed May 26, 2025).
24 Wested, J. and T. Minssen (2017). TRIPS and the life sciences: perspectives on limitations to patentability. *SSRN Electronic Journal*. doi:10.2139/SSRN.2986751.
25 Nicol, D., R.C. Dreyfuss, E.R. Gold, W. Li, J. Liddicoat and G. Van Overwalle (2019). International divergence in gene patenting. *Annual Review of Genomics and Human Genetics*, 20, 519–41. doi:10.1146/annurev-genom-083118-015112.
26 Sterner, R.C. and R.M. Sterner (2021). CAR-T cell therapy: current limitations and potential strategies. Blood Cancer Journal, 11(4), 69. doi:10.1038/s41408-021-00459-7),.

Table 1 Gene patenting divergence

Jurisdiction	Isolated naturally occurring nucleotide sequences	Equivalent complementary DNA (cDNA)	Methods of genetic diagnostics
Australia	x	x	✓
Canada	✓?	✓?	✓?
China	✓?	✓?	x
United States of America	x	✓	x
Europe	✓	✓	✓

2.3 Typical claim structures

Since claims are the most important part of a patent, it is important to understand the different types of claims and how these claims are used by companies to protect their commercial products.

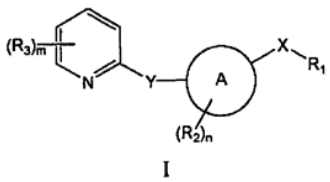
2.3.1 Products

Selection inventions (Markush claims)

The Patent Information Initiative for Medicines (Pat-INFORMED) database[27] provides a straightforward method of identifying the patent portfolios of small-molecule drugs. This database was set up with the purpose of helping procurement services worldwide, by linking the drug's international non-proprietary names with the relevant patent portfolios. The small-molecule drug (active pharmaceutical ingredient or API) market is valued at more than USD 50 billion per year as reported by the European Fine Chemicals Group.[28] In most instances the chemical structure of an API is completely new, meaning that a composition-of-matter patent is the best way to protect it. This is usually done with Markush structures,[29] which symbolize chemical structures that represent a group of related compounds using common structures and certain variable groups or substituents.

As an example, searching for Vismodegib (a basal cell carcinoma drug developed by Roche, called Erivedge(R)) on Pat-INFORMED shows us the 91 associated patents. Looking at claim 1 of EP1789390B1[30] we see the following:

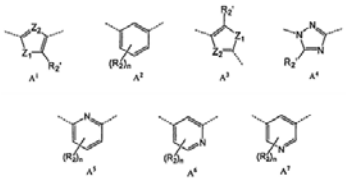
"1.A compound of formula I



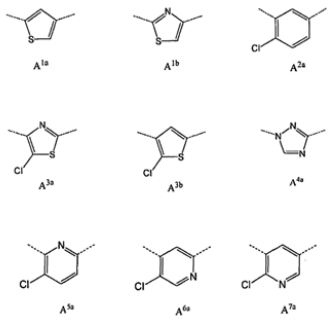
I

"wherein A is a ring selected from the group consisting of A^1 – A^7,

27 Pat-INFORMED: the gateway to medicine patent information. Available at: https://www.wipo.int/pat-informed/en (accessed May 26, 2025).
28 API market. European Fine Chemicals Group; 2024. Available at: https://efcg.cefic.org/the-industry/ (accessed May 26, 2025).
29 Markush search now available in PATENTSCOPE. World Intellectual Property Organization; 2021. Available at: https://www.wipo.int/patentscope/en/news/pctdb/2021/news_0006.html (Accessed May 26, 2025).
30 EP1789390B1 Pyridyl inhibitors of hedgehog signalling. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/035517336/publication/EP1789390B1?q=EP1789390B1 (accessed May 26, 2025).



"each with their own variable structure, wherein Z1 is O, S, NR5, wherein NR5 is H or alkyl, Z2 is CH, CR2 or N, and R2 is Cl, and n is 1 or A is a ring selected from A1a, A1b, A2a, A3a, A3b , A4a, A5a, A6a, A7a.



"X is alktylene, NR 4 C(O), NR 4 C(S), N(C(O)R 1)C(O), NR 4 SO, NR 4 SO 2 , NR 4 C(O)NH, NR 4 C(S) NH, C(O)NR 4, C(S)NR 4, NR 4 PO or NR 4 PO(OH); Y is absent, CHR 4 , O, S, SO, SO 2 or NR 4; R1 is selected from the group consisting of alkyl, a carbocycle or a heterocycle each of which is optionally substituted with hydroxyl, halogen, amino, carboxyl, amidino, guanidino, carbonyl, nitro, cyano, acyl, alkyl, haloalkyl, sulfonyl, sulfinyl, alkoxy, akylthio, carbamoyl, acylamino, sulfamoyl, sulfonamide, a carbocycle or a heterocycle; wherein said amino, amidino, alkyl, acyl, sulfonyl, sulfinyl, alkoxy, alkylthio, carbamoyl, acylamino, sulfamoyl, sulfonamide, carbocycle and heterocycle substituent is optionally substituted with, halogen, haloakyl, hydroxyl, carboxyl, carbonyl, or an amino, alkyl, alkoxy, acyl, sulfonyl, sulfinyl, phosphinate, carbocycle or heterocycle that is optionally substituted with hydroxyl, carboxyl, carbonyl, amino, halogen, haloalkyl, alkyl, alkoxy, alkylthio, sulfonyl, sulfnyl, acyl, a carbocycle or a heterocycle; R3 is halogen, hydroxyl, carboxyl, alkyl, acyl, alkoxy, alkoxycarbonyl, carbamoyl, alkylsulfide, sulfinyl, sulfonyl, a carbocycle or a heterocycle wherein each alkyl, acyl, alkoxy, alkoxycarbonyl, carbamoyl, alkylsulfide, sulfinyl, sulfonyl, carbocycle and heterocycle is optionally substituted with hydroxyl, halogen, amino, nitro, alkyl, acyl, sulfonyl or alkoxy; R4 is H or alkyl; m is 0-3; and salts and solvates thereof."

The claim as it is granted protects many possibilities and variations of the basic chemical structure, and even the salts and solvates derived from it. This broad claim has the support of 319 exemplification structures, which show the different embodiments of the Markush structures.

If the chemical structure of the API is already known in the prior art, then claims to the compound itself will not be patent-eligible. In this case, the next best protection would be a salt or hydrate form, or a crystal or co-crystal form, of the API. Other protection strategies include different formulations of the API, dosage regimes, methods of manufacture, etc. Large pharmaceutical companies use all these strategies to create a patent thicket around their most important products, and to try to extend the patent lifetime of their portfolio. Markush claims can also be used in a written form by using the expression of "consisting of" and then the list of substituents to be protected.[31]

Device claims

Companies will often use several types of claims in a patent application as a strategy to protect the invention from as many aspects as possible. An example of this approach is seen in granted claim EP2801823B1 that, although primarily directed at an antibody, also includes protection for a device, a kit for detection and a method of detection, all of which make use of the antibody in

31 WIPO patent drafting manual, second edition. World Intellectual Property Organization; 2023. Available at: https://tind.wipo.int/record/44657?v=pdf (accessed May 26, 2025).

its claim set. This is possible when all types of claims are linked to the same inventive concept, as illustrated by claim number 7 of patent EP2801823B1.[32]

"7. A device for detecting the presence or absence of whipworm antigens from a sample, the device comprising a solid support, wherein the solid support has immobilized thereon at least one antibody of any one of Claims 1 to 6."

Monoclonal antibody (mAb): example from Nivolumab drug

Claims to protect monoclonal antibodies are normally based upon the sequence of the antibody. Within this, the sequences of the complementarity-determining regions (CDRs) and variable regions will frequently be part of the claim because of the importance of their contribution to the binding properties of the antibody. Opdivo® (Nivolumab) is one of the best-selling antibody drugs in recent years. The main granted claim (EP2161336B2) for Nivolumab drug is:

"An isolated human monoclonal antibody, comprising:

a. a heavy chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 4; and
b. a light chain variable region comprising amino acids having the sequence set forth in SEQ ID NO: 11; wherein the antibody specifically binds human Programmed Death 1 (PD-1) protein."[33]

CGTs

Cellular therapies are one of the leading life sciences trends, and several cell therapy treatments have already been approved by the FDA. One of these therapies is ciltacabtagene autoleucel (CARVYKTI®) for the treatment of adult patients with relapsed or refractory multiple myeloma.[34]

Claim 1 of the granted ciltacabtagene autoleucel patent (US11535677B2) is:

"An isolated nucleic acid comprising a nucleic acid sequence encoding a multivalent chimeric antigen receptor (CAR) comprising a polypeptide comprising: (a) an extracellular antigen binding domain comprising a first anti-BCMA binding moiety and a second BCMA binding moiety, wherein each of the first and the second anti-BCMA binding moieties is a VHH domain; (b) a transmembrane domain; and (c) an intracellular signalling domain, wherein the first BCMA binding moiety comprises a CDR1 comprising the amino acid sequence of SEQ ID NO:15; a CDR2 comprising the amino acid sequence of SEQ ID NO:53; and a CDR3 comprising the amino acid sequence of SEQ ID NO:91, and the second BCMA binding moiety comprises a CDR1 comprising the amino acid sequence of SEQ ID NO:18; a CDR2 comprising the amino acid sequence of SEQ ID NO:56; and a CDR3 comprising the amino acid sequence of SEQ ID NO:94."

In this case, while the product itself is a cell therapy, these claims are directed to nucleic acids encoding the CARs that provide the cells with their therapeutic utility.[35]

2.3.2 Methods of treatment

Methods of treatment are excluded from patentability in many jurisdictions to allow medical practitioners to provide the best treatment to a patient without worrying about infringing a patent. However, most patent offices will allow alternative routes by which corresponding protection may be obtained. In EPO practice this involves medical use claims, which take the form of purpose-limited product claims such as: "1. A composition for use in treating

32 EP2801823B1 Methods, devices, kits and compositions for detecting whipworms. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/041316526/publication/EP2801823B1?q=EP2801823B1 (accessed May 26, 2025).
33 EP2161336B2 Human monoclonal antibodies to programmed death 1(PD-1) and methods for treating cancer using anti-PD-1 antibodies alone or in European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/037396674/publication/EP2161336B2?q=EP2161336B2 (accessed May 26, 2025).
34 CARVYKTI. United States Food and Drug Administration; 2024. Available at: https://www.fda.gov/vaccines-blood-biologics/carvykti (accessed May 26, 2025).
35 US11535677B2 Chimeric antigen receptors targeting BCMA and methods of use thereof. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/055417644/publication/US11535677B2?q=US%2011535677%20B2 (accessed May 26, 2025).

fatty liver disease in a patient in need thereof, wherein the composition comprises an anti-ActRIIB antibody."[36]

A similar approach is used at the JPO, where granted claim 1 of the patent protecting the same product is formulated: "1. A composition for treating fatty liver disease in a patient in need of treatment for fatty liver disease, said composition comprising an amino acid sequence which is at least 90% identical to the sequence of amino acids 29 to 109 of SEQ ID NO: 2."[37]

The same patent family does not have a granted claim in the United States of America, but since methods of treatments are accepted at the USPTO, the applicant was able to pursue the claim: "A method for treating fatty liver disease in a patient in need thereof, the method comprising administering to the patient an anti-ActRIIB antibody."[38]

2.3.3 Claims including ranges

Further use of different types of claims in the same patent is shown in EP3319640B1,[39] which includes claims for both a composition and a method; both claims use ranges to protect their antifungal invention.

"1. A composition comprising nanoparticles formed of a polymer and terbinafine, wherein the nanoparticles comprise particles in at least two distinct particle sizes groups comprising: a) a first species in the range of 0.5 to 5 nm; and b) a second species in the range of 150 to 250 nm.

...

"13. A method of producing a composition for the treatment of a fungal infection comprising mixing a polymer capable of forming nanoparticles with terbinafine under conditions suitable to allow the formation of nanoparticles, wherein: a) the nanoparticles are formed under conditions to enable production of nanoparticles in the range of 0.5 to 5 nm and in the range of 150 to 250 nm; or b) the mixture is further processed so as to only select those nanoparticles in the range of 0.5 to 5 nm and in the range of 150 to 250 nm, and wherein the nanoparticles are formed or processed into at least two distinct particle sizes groups comprising: i) a first species in the range of 0.5 to 5 nm; and ii) a second species in the range of 50 to 250 nm."

The same patent application has been filed in Japan, the United States of America and Europe. To illustrate the differences, in the United States of America, the first claim offers narrower protection as the claim mentions "said nanoparticles consisting of two particle size species," although in Europe the claim mentions "at least two distinct", which means there can be more. The first claim of the Japanese granted patent is similar to the European patent in terms of "comprising particles of at least two different particle size groups", but it is more restricted as it mentions concentration ranges for terbinafine ("0.06–0.6 mg/mL") and for the polyhexamethylene biguanide ("0.2–0.4 mg/mL").[40]

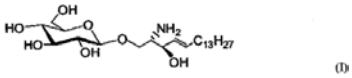
2.3.4 Diagnostics claims

In practice, the impact of the different approaches to patenting diagnostics (Section 3.2) in Japan, the United States of America and Europe can be seen in the different claims granted for Centogene's patent, "Method to monitor Gaucher's Disease."[41]

36 EP3260130B1 Methods for treating fatty liver disease. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/043970317/publication/EP3260130B1?q=EP3260130B1 (accessed May 26, 2025).
37 EP3260130B1 Methods for treating fatty liver disease. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/043970317/publication/EP3260130B1?q=EP3260130B1 (accessed May 26, 2025).
38 EP3260130B1 Methods for treating fatty liver disease. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/043970317/publication/EP3260130B1?q=EP3260130B1 (accessed May 26, 2025).
39 EP3319640B1 Composition and methods of treatment. Accessed February 24, 2023. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/054013539/publication/EP3319640B1?q=EP3319640B1 (accessed May 26, 2025).
40 EP3319640B1 Composition and methods of treatment. Accessed February 24, 2023. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/054013539/publication/EP3319640B1?q=EP3319640B1 (accessed May 26, 2025).
41 EP3318881B1 Method to monitor Gaucher's Disease. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/044652046/publication/EP3318881B1?q=EP3318881B1 (accessed May 26, 2025).

In Japan the obtained granted claim is: "1. A method for identifying a subject having Gaucher disease to be subject to a therapy for use in treating Gaucher disease, wherein the treatment comprises treating a sample of the subject having Gaucher disease, is free lyso-Gb1 testing for the presence of a biomarker, wherein the subject having Gaucher disease is subject to the therapy if the sample tests positive for the biomarker wherein said sample is selected from the group consisting of a blood sample, a serum sample, a plasma sample, a whole blood sample, and a sample derived from whole blood collected on a dry blood filter card."[42]

In the United States of America, the obtained granted claim is formulated as: "1. A method for generating quantitative data for a subject consisting of determining a level of a biomarker in a blood sample from the subject, wherein the biomarker is free lyso-Gb1, and wherein the subject is suffering from Gaucher's disease or suspected of suffering from Gaucher's disease, and wherein the level of free lyso-Gb1 is determined by means of mass spectrometric analysis."



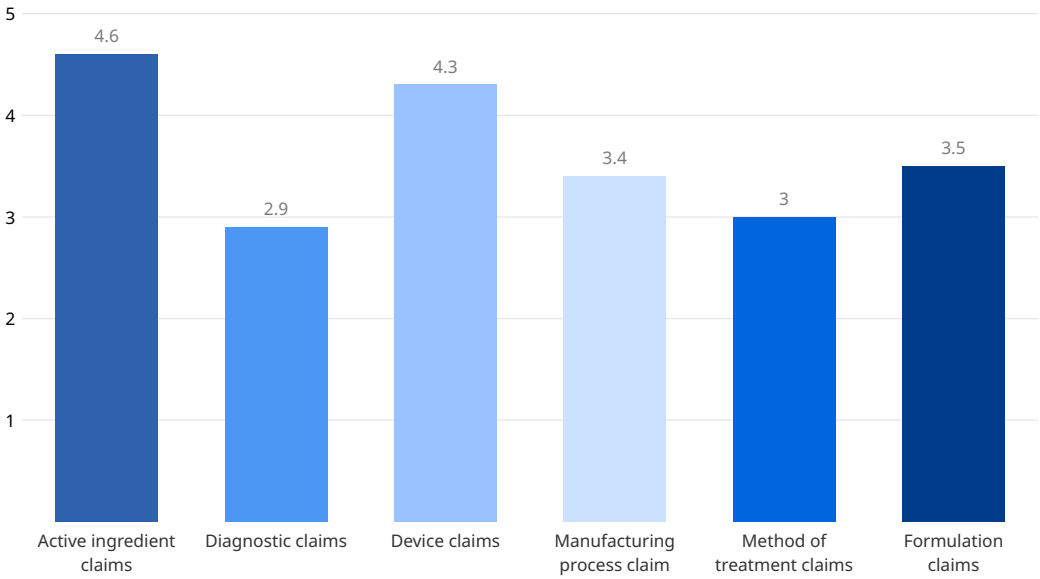
(I)

The granted claim in Europe is similar to the Japanese granted claim: "1. A method for determining the course of Gaucher's disease in a subject comprising the step of determining at several points in time a level of a biomarker present in a sample from the subject, wherein the sample is selected from the group consisting of a blood sample, a serum sample, a plasma sample, a whole blood sample and a sample from whole blood collected on a dry blood filter card, wherein the biomarker is free lyso-Gb1 of formula (I) and wherein the level of the biomarker is indicative of the severity of the disease in the subject."[43]

2.3.5 Defensibility strength of claim types

It is important to understand the different types of claims and how they can protect different aspects of invention. We therefore asked patent attorneys how they rank the defensibility in their experience, from weak 1 to strong 5, of each type of claim, considering sufficient support within the patent application; our survey results are presented in Figure 6.

Figure 6 Defensibility strength of claim types as viewed by the life sciences patent attorneys who participated in our survey



Source: WIPO analysis based on questionnaires completed by patent attorneys and technology transfer professionals.

42 EP3318881B1 Method to monitor Gaucher's Disease. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/044652046/publication/EP3318881B1?q=EP3318881B1 (accessed May 26, 2025).
43 EP3318881B1 Method to monitor Gaucher's Disease. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/044652046/publication/EP3318881B1?q=EP3318881B1 (accessed May 26, 2025).

3. Main application fields

Key points

- The importance of the sufficiency of disclosure or enablement and written description for life sciences patenting is highlighted by recent case law decisions (i.e., Juno v. Kite, Amgen v. Sanofi). The claims need to be supported across the whole breadth by the examples provided.
- Patenting diagnostics in the United States of America have been greatly impacted by the Mayo v. Prometheus decision of the Supreme Court. Nevertheless, different strategies to protect diagnostics within the country have been developed.
- There is more than one IP strategy that can lead to success (e.g., acceleration or delaying of prosecution, broader vs. narrower initial claims, etc.), and each company or technology transfer office should consider their strategy in view of their unique circumstances.

3.1 Vaccines

The patenting of vaccines has been well discussed recently as a result of the COVID-19 pandemic. The use of previously patented technologies in the face of this challenge has allowed vaccine development and production to be much faster than might otherwise have been expected, although the implementation of a patent waiver on the COVID-19 vaccines was also proposed.[1,2,3] The *Moderna v. Pfizer* patent race[4] and dispute[5] was also very highly publicized as a result of the pandemic. A very thorough analysis of the patent landscape on COVID-19 was published by WIPO in 2022.[6] WIPO also published a more general vaccine patent landscape report in 2012[7] and a vaccine innovation and access report in 2017.[8]

3.1.1 Patentable elements: case study

Vaccines are compositions designed to stimulate and prepare the immune system against certain infections or diseases. As well as active ingredients (antigens), vaccines have many other components such as adjuvants that help to boost the immune response, preservatives, stabilizers and also trace components from the manufacturing process. Vaccines can be classified either from the pathogens they target (viruses, bacteria, etc.), their ability to replicate in the host (live vs.

1 10 Arguments against a waiver of intellectual property rights. University of Oxford Law Blogs. Available at: https://blogs.law.ox.ac.uk/business-law-blog/blog/2021/06/10-arguments-against-waiver-intellectual-property-rights (accessed May 26, 2025).
2 Vaccines and patents: how self-interest and artificial scarcity weaken human solidarity. British Politics and Policy at London School of Economics; 2021. Available at: https://blogs.lse.ac.uk/politicsandpolicy/vaccines-and-patents/ (accessed May 26, 2025).
3 A patent waiver on COVID vaccines is right and fair. *Nature*, 2021, 593(7860), 478. doi:10.1038/D41586-021-01242-1.
4 Storz, U. (2022). The COVID-19 vaccine patent race. *Nature Biotechnology*, 40(7), 1001–4. doi:10.1038/s41587-022-01376-1.
5 The mRNA vaccine patent fight expands. Science; 2022. Available at: https://www.science.org/content/blog-post/mrna-vaccine-patent-fight-expands (accessed May 26, 2025).
6 COVID-19-related vaccines and therapeutics: preliminary insights on related patenting activity during the pandemic. World Intellectual Property Organization; 2022. Available at: https://tind.wipo.int/record/45030?ln=en&v=pdf (accessed May 26, 2025).
7 Patent landscape report on vaccines for selected infectious diseases. World Intellectual Property Organization; 2012. Available at: https://tind.wipo.int/record/28195?ln=en&v=pdf (accessed May 26, 2025).
8 Vaccines: accelerating innovation and access. World Intellectual Property Organization; 2017. Available at: https://tind.wipo.int/record/29017?ln=en&v=pdf (accessed May 26, 2025).

dead active ingredient) or by the vaccine technology (DNA or RNA, virus-like particles, synthetic peptides, polysaccharide conjugates, whole inactivated or live attenuated).[9]

The wide range of possible vaccine technologies coupled with the different types of claims and patenting strategies have led to a colossal number of possible patent-eligible elements and protection avenues. Examples of potential protection avenues for vaccines are presented by Sterne and Longsworth,[10] who discuss different patent claims and their associated viral target. In this report, we focus on synthetic peptide vaccines as they have smaller and simpler structures compared with other technologies. Malonis et al.[11] and Hamley[12] review the development of peptide vaccines for various diseases from the influenza virus to different types of cancer.

As a case study, we consider BiondVax Pharmaceutical's patents on the polypeptide vaccine for the influenza virus. The patent families that BiondVax have filed can be seen in the Global Dossier[13] (an online service providing access to all related patent family data and communication with patent offices). BiondVax filed its first patent application as a priority application on August 2, 2007, with the application being continued as an international (PCT) application on August 3, 2008 (it is possible to file a PCT after the 12-month period has expired under PCT Rule 26 bis3[14]) and then nationalized in many jurisdictions (Australia, China, Japan, the Republic of Korea, the United States of America and Europe, etc.). Their original filed claim was broad: "1. A synthetic or recombinant influenza multi-epitope polypeptide comprising multiple copies of a plurality of influenza virus peptide epitopes arranged in a configuration selected from an alternating sequential polymeric structure $(X1X2X3...X_m)_n$ and a block copolymer structure $(X1)_n(X2)_n(X3)_n...(X_m)_n$." Subsequent claims mentioned the ranges for *m* and *n*, and further defined the peptide epitopes and number of amino acid residues.

The international search report (ISR) and the international preliminary report on patentability (IPRP) cited only two documents relevant to the novelty and inventive step requirements, and considered claims 9–17, 21 and 22 as being patent-eligible.[15] Their claims are supported by a materials and methods section, followed by 12 examples. Examples 1–3 present three different multimeric polypeptide structures, with the DNA sequences encoding the peptide epitopes and the corresponding amino acid sequences being presented as figures. Examples 4–9 and 11 present mouse *in vivo* studies relating to immune response, efficacy and toxicology, and example 10 is a prophetic example relating to Phase I/IIa clinical trials. The last example reports the synthesis of the peptides.[16]

The patent was granted in most of the chosen jurisdictions (between July 2013[17] and November 2019[18]) after various amendments to the original claims that better describe the structure of the peptides – both in terms of the sequential polymeric structure but also in terms of their amino acid sequences – consistent with the presented examples and description of their invention. The company has further strengthened its patent portfolio with a further patent family in peptide vaccines for the influenza virus.[19]

9 Ghattas, M., G. Dwivedi, M. Lavertu and M.G. Alameh (2021). Vaccine technologies and platforms for infectious diseases: current progress, challenges, and opportunities. *Vaccines*, 9(12), 1490. doi:10.3390/vaccines9121490.
10 Patents, professional perspective - patenting compounds, compositions, and methods for viral infections. Bloomberg Law; 2020. Available at: https://www.bloomberglaw.com/external/document/X92S2AHS000000/patents-professional-perspective-patenting-compounds-composition (accessed May 26, 2025).
11 Malonis, R.J., J.R. Lai and O. Vergnolle (2019). Peptide-based vaccines: current progress and future challenges. *Chemical Reviews Journal*, 120(6), 3210–29. doi:10.1021/acs.chemrev.9b00472.
12 Hamley, I.W. (2022). Peptides for vaccine development. *ACS Applied Bio Materials*, 5(3), 905–44. doi:10.1021/acsabm.1c01238.
13 Global dossier-public access dossier. World Intellectual Property Organization. Available at: https://inspire.wipo.int/global-dossier-public-access-dossier (accessed May 26, 2025).
14 Regulations under the PCT: rule 26bis. World Intellectual Property Organization. Available at: https://www.wipo.int/pct/en/texts/rules/r26bis.html (accessed May 26, 2025).
15 WO2009016639 Multimeric multiepitope influenza vaccines. World Intellectual Property Organization. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2009016639&_fid=WO2009016639 (accessed May 26, 2025).
16 WO2009016639 Multimeric multiepitope influenza vaccines. World Intellectual Property Organization. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2009016639&_fid=WO2009016639 (accessed May 26, 2025).
17 CN101795709B Multimeric multiepitope influenza vaccines. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/040305020/publication/CN101795709B?q=pn%3DCN101795709B (accessed May 26, 2025).
18 BRPI0815008B1 Vacinas multiméricas com múltiplos epítopos contra influenza. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/040305020/publication/BRPI0815008B1?q=pn%3DBRPI0815008B1 (accessed May 26, 2025).
19 WO2015151103A1 Compositions of multimeric-multiepitope influenza polypeptides and their production. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/054239499/publication/WO2015151103A1?q=pn%3DWO2015151103A1 (accessed May 26, 2025).

3.2 Diagnostics

Patenting diagnostic methods require different approaches in different jurisdictions around the world, and patent applications are usually adapted to each jurisdiction by patent attorneys practicing in the jurisdiction at the national phase entry stage. Careful consideration is required when drafting the application, as certain regions are very stringent about how the claims can be amended during prosecution in view of the detailed description. Obtaining a diagnostic granted patent at the USPTO is more complex than at the JPO or EPO. The International Association for the Protection of Intellectual Property (AIPPI) has recently published a report[20] on the patentability of diagnostics methods internationally. The AIPPI report explores the current law and practice as well as proposals for improvements and harmonization of current law, and is based on a survey run by the association.

3.2.1 Japan

The JPO provides a handbook and guidelines document for life sciences inventions.[21] Methods of treatment of the human body by surgery or therapy, and diagnostic methods practiced on the human body, are outside the scope of industrially applicable inventions because they are regarded as medical activity and are considered unpatent-eligible. In Japan, compositions, devices or kits for use in diagnosis that are practiced on the human body are considered industrially applicable and are therefore patent-eligible subject matter. Examples of patent-eligible subject matter as presented in the JPO guidelines include: methods for collecting information from a human body (e.g., X-ray, computed tomography scan, etc.), methods of operation of a medical device, medical devices, and a combination of physical and biochemical means (e.g., "A cancer treatment system comprising: a micro capsule X which contains an anti-cancer agent and releases the agent when disintegrated by a convergence supersonic wave, and an apparatus having means to obtain image data showing the position of the tumor, means to focus the convergence supersonic wave on the position of the tumor based on the image data, and means to irradiate the convergence supersonic wave onto the micro capsule X").

3.2.2 United States of America

The diagnostics patent field in the United States of America was shaken in 2012 when the Supreme Court (*Mayo Collaborative Servs. v. Prometheus Labs., Inc. - 566 U.S. 66, 132 S. Ct. 1289*)[22] decided that the diagnostic method claim of Prometheus was not patent-eligible subject matter, as the claim was considered as being a law of nature (specifically, the correlation between the metabolites in the blood and the thioguanine drug dosage) and that the steps in the claim were "routine, well-understood and conventional activity previously engaged in by scientists in the field." Many articles have been written about this decision, but it is important to understand the resulting considerations for patenting diagnostics in this country.[23] For the purposes of this document, we are only highlighting how this decision impacts current patent drafting. Most of the diagnostics methods are based on discovering a biological correlation rather than a new test method. In view of the *Mayo v. Prometheus* decision, a biological correlation is a law of nature, and it is not patent-eligible. Unfortunately, too often new diagnostics are designed on the understanding of a biological relationship (i.e., the correlation between a marker and a drug or disease state or metabolite) rather than on new test methods, which means that the relationship without anything further is a natural law and not patent-eligible. A few ways of addressing a rejection under Section §101 of Title 35 of the United States Code (U.S.C,) which governs patent-eligible subject matter under the U.S Patent Act, are: avoid basing the construction of the claim on the biological correlation; avoid using a general determining type step; outline anything unexpected or out of the ordinary; and try to distance the biological relationship from a law of nature.[24]

20 Verschuur, A.M., A. Laakkonen, R. Nack, G. Henry, L. Lecomte and L. Shen. Patentability of diagnostic methods: summary report. International Association for the Protection of Intellectual Property; 2023. Available at: https://aippi.org/content/uploads/2022/02/Study-Guidelines-Q280.pdf (accessed May 26, 2025).
21 Examination guidelines in life sciences. Japan Patent Office; 2018. Available at: https://www.jpo.go.jp/e/system/laws/rule/guideline/patent/lifescience_kijun.html (accessed May 24, 2025).
22 Mayo Collaborative Services v. Prometheus Laboratories, Inc. 566 U.S. 66 (2012). Justia US Supreme Court; 2012. Available at: https://supreme.justia.com/cases/federal/us/566/66/ (accessed May 24, 2025).
23 Moving Past Mayo: US Diagnostic Methods Patents in 2022. JMB Davis Ben-David Knowledgebase. Available at: https://jmbdavis.com/knowledgebase/moving-past-mayo-us-diagnostic-methods-patents-in-2022/?utm_source=mondaq&utm_medium=syndication&utm_term=Intellectual-Property&utm_content=articleoriginal&utm_campaign=article (accessed May 26, 2025).
24 Dorn, B.R. (2013). *Mayo v. Prometheus*: a year later. *ACS Medicinal Chemistry Letters,* 4(7), 572–3. doi:10.1021/ml400230u.

Other strategies for patenting diagnostics include measuring new biomarker(s) without a diagnostic step; new ways of measuring new biomarker(s) (e.g., an improved method measuring or isolating a new biomarker from bodily fluid); or methods of treatment linked to the diagnostic test (e.g., a method of treating a certain disease with a drug, where one of the steps is the measurement of the biomarker).[25] An example of a diagnostic claim that was found patent-eligible by the US Supreme Court is "A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of: determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day, wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day" from the *Vanda v. West-Ward*[26] case in 2018.[27]

Ten years from the *Mayo v. Prometheus* decision, a bill titled the "Patent eligibility restoration act of 2025" was introduced by senator Thom Tillis. It aims to clarify the patent-eligibility matters of the different biotechnology debates from the past decade, especially for the diagnostics field. At the time of writing, the bill is many months/years? from a final vote in US Congress.[28] The bill was introduced at the same time as a Nature Biotechnology article[29] calling for a reform of the US patent system, with a focus on improving patients' lives by attracting more investment in the space incentivized by the protection offered by patents. It has also been reported that the Supreme Court decision in 2012 led to a drop of USD 9.3 billion in the total investment for diagnostic technologies in the 4 years that followed.[30]

3.2.3 Europe

Diagnostic methods can be patented in Europe as long as the method is not practiced on a human or animal body, established by determining whether there is an interaction with the human or animal body. If the method requires the presence of the live body, even without direct physical contact, then the practiced criterion is still fulfilled.[31]

For diagnostic methods practiced on the human or animal body, there is a guideline[32] to determine whether a claim is excluded from patentability in Europe. To be excluded from patentability, the claim must include *all* of the following steps:

a. examination: data collection
b. comparison: collected data vs. standard values
c. finding significant deviation during the comparison
d. decision: attribution of the deviation to a particular clinical picture.

Considering the above, methods practiced on the body that are just obtaining information (data) from a living human or animal body (e.g., X-ray investigations, magnetic resonance

25 Strategies for securing patents related to diagnostic methods in light of continuing confusion from the courts. Quarles Law Firm, Attorneys, Lawyers; 2020. Available at: https://www.quarles.com/newsroom/publications/strategies-for-securing-patents-related-to-diagnostic-methods-in-light-of-continuing-confusion-from-the-courts (accessed May 26, 2025).
26 Vanda Pharm. Inc. v. W.-Ward Pharm. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018). Accessed June 2, 2023. https://law.justia.com/cases/federal/appellate-courts/cafc/16-2707/16-2707-2018-04-13.html
27 Holman, B.C.M. (2021). The federal circuit continues to grapple with the questio*n of patent eligibility for diagnostic methods. Biotechnology Law* Report, 40(3), 151–73. doi:10.1089/blr.2021.29233.cmh.
28 Tillis introduces landmark legislation to restore American innovation. Thom Tillis; 2022. Available at: https://www.tillis.senate.gov/2022/8/tillis-introduces-landmark-legislation-to-restore-american-innovation (accessed May 26, 2025).
29 Coruzzi, L.A. (2022). Patents benefit patients and patent reform would spur diagnostic and therapeutic development. *Nature Biotechnology*, 40(8), 1178–80. doi:10.1038/s41587-022-01405-z.
30 Hoyt, A. (2022). The impact of uncertainty regarding patent eligible subject matter for investment in U.S. medical diagnostic technologies. *Washington and Lee Law Rev*iew, 79(1). Available at: https://scholarlycommons.law.wlu.edu/wlulr/vol79/iss1/8 (accessed May 26, 2025).
31 G II, 4.2.1.3 Diagnostic methods. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2_1_3.htm (accessed May 26, 2025).
32 G II, 4.2.1.3 Diagnostic methods. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_4_2_1_3.htm (accessed May 26, 2025).

imaging studies, etc.) are not excluded from patentability. Diagnostic methods that are using isolated samples are considered patent-eligible because they do not fall under the exception to patentability of Article 53(c).[33]

For exemplification purposes, the following claim is an exception under Article 53(c) because it includes all the four steps described above and is performed on a living subject: "A method of diagnosing Alzheimer's disease in a living subject, which comprises: establishing a baseline pupil diameter for the pupil of the subject; using automated apparatus to repetitively and episodically image the subject's pupil and measure pupil diameter, which measurements are made after the administration to the eye of the subject of a neural transmitter mediator in an amount insufficient to cause a significant pupil constriction or dilation if the subject is not afflicted with Alzheimer's disease and during a time when said neural transmitter would have an observable effect on pupil diameter in a subject afflicted with Alzheimer's disease; and processing said measurements in said automated apparatus to provide a comparison of pupil diameter changes after said administration against said baseline or against Alzheimer's characteristic pupil diameter rates of change."[34]

As a second example, the following claim is patent-eligible as the collected data are not compared with standard values, and it does not find a significant deviation to attribute a particular clinical picture: "A method of detecting regional variations in oxygen uptake from the lungs of an air-breathing animal subject, said method comprising administering into the lungs of said subject a diagnostically effective amount of a gaseous hyperpolarized magnetic resonance imaging agent, detecting the magnetic resonance signal from said agent in said lungs, and characterized in that by determining the temporal variation in relaxation rate for said signal for at least one region of interest within said lungs, a qualitative or quantitative value or image indicative of the oxygen concentration in said at least one region of interest is generated from said variation, and if desired the time dependency of such concentration."[35]

Strategies for drafting diagnostic patents in Europe include drafting a method that has a step of measuring a certain marker in an isolated sample, e.g. "A method of diagnosing non-alcoholic steatohepatitis (NASH) and/or the hepatic fibrosis status of a subject, wherein the method comprises: (I) measuring, in a sample obtained from a subject, levels of at least three biomarkers being a pro-inflammatory cytokine, a chemokine and a glycosaminoglycan contributing to cell-adhesion and tissue modeling; (II) combining the levels of said at least three biomarkers measured in step (I) in a mathematical model; and (III) determining whether the subject is afflicted with NASH and/or determining its hepatic fibrosis status, said at least three biomarkers comprising IL-8, CXCL10 and Hyaluronic acid (HA)"),[36] a method of predicting the response to a certain drug by measuring a specific marker from a sample (e.g., "A method of predicting responsiveness of an individual suspected of having, or having been diagnosed as having, a cancer to a DNA-damage therapeutic agent, the method comprising: a. measuring expression levels of one or more biomarkers in a test sample obtained from the individual, wherein one or more of the biomarkers are selected from the group consisting of CXCL10, MX1, IDO1, IFI44L, CD2, GBP5, ITGAL and APOL3; b. deriving a test score that captures the expression levels; c. providing a threshold score comprising information correlating the test score and responsiveness; d. and comparing the test score to the threshold score; wherein responsiveness is predicted when the test score exceeds the threshold score due to the cancer being associated with a DNA damage response deficiency (DDRD)"),[37] and an improved method of measuring or isolating a specific marker from a sample, or a kit or device for the specific diagnostic (e.g., "Use of a kit in a method for diagnosing NASH and/or the hepatic fibrosis status of a subject of any one of claims 1-10, said kit comprising: (i) reagents for measuring, in a sample obtained from

33 Article 53: exceptions to patentability. European Patent Convention, Convention on the Grant of European Patents; Part II: substantive patent law, Chapter I: patentability. European Patent Office. Available at: https://www.epo.org/en/legal/epc/2020/acii_i.html (accessed May 26, 2025).
34 Use of a hyperpolarized gas for MRI detection of regional variations in oxygen uptake from lungs. WIPO. Available at: https://patentscope.wipo.int/search/en/WO1999053332 (accessed July 6, 2025)
35 Use of a hyperpolarized gas for MRI detection of regional variations in oxygen uptake from lungs. WIPO. Available at: https://patentscope.wipo.int/search/en/WO1999053332 (accessed July 6, 2025)
36 EP3655780B1 Biomarker combinations to evaluate non-alcoholic steatohepatitis and/or hepatic fibrosis status. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/059631684/publication/EP3655780B1?q=EP3655780B1 (accessed May 26, 2025).
37 EP2619574B1 molecular test for predicting responsiveness to DNA-damage therapeutic agents in individuals having cancer. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/045832248/publication/EP2619574B1?q=EP2619574B1 (accessed May 26, 2025).

a subject, levels of at least three biomarkers being a pro-inflammatory cytokine, a chemokine and a glycosaminoglycan contributing to cell-adhesion and tissue modeling, said at least three biomarkers comprising IL-8, CXCL10 and HA; and (ii) instructions for (a) combining the biomarker levels in a mathematical model; (b) obtaining a score from the mathematical model; and (c) making the diagnosis; or (d) comparing the biomarker levels to threshold levels of said biomarkers; and (e) making the diagnosis of NASH on the basis of the comparison made in step (d)").[38],[39]

3.2.4 Patentable elements: case study

Interest in the diagnostics field intensified as a result of the increased requirement for diagnostic kits during the COVID-19 pandemic. Rapid advancements in proteomics technologies, including the development of liquid biopsies, companion and at-home diagnostics, are some of the key trends that have the potential to make a high impact on healthcare.[40] The vast potential for new technologies and the differences in assessing diagnostics patents between the different jurisdictions means that there is no fixed method for obtaining protection. Nevertheless, solid experimental data demonstrating the invention is key, and patent attorneys will always find new techniques for protecting your diagnostic (whether it is a piece of equipment, device or laboratory technique), such as switching the perspective to the particular chemical agent or entities that are used.[41]

As a case study we can use a patent family from Mobidiag, a Finish diagnostics company. Mobidiag has filed more than 10 patent families in the diagnostics field since 2003. Their patent family on the "Methods for determining the presence of diarrhoea causing pathogens" was filed as a priority application in both Finland and the United States of America on June 27, 2012, followed by a PCT application 12 months later on June 27, 2013. The application was nationalized and granted in Australia, Canada, China, Denmark, Germany, Japan, Poland, Spain and the United States of America.[42] The originally filed claim was "1. Method for determining the presence of diarrhoea causing pathogens in a biological sample comprising the steps of: i) contacting the sample or nucleic acid isolated therefrom with primer pairs in a multiplex PCR assay comprising two or more separate PCR reactions, wherein the primers of said primer pairs amplify each of the ETEC amplicons as defined by SEQ ID NOS:61-63 at least partly; ii) performing a polymerase chain reaction with reaction mixes obtained from step i) so that the target sequences of diarrhoea causing pathogens are specifically amplified, if said sequences are present in the sample; and iii) detecting the presence of amplified target sequences in the reaction mix, wherein the presence of any of the target sequences is indicative of the presence of diarrhoea causing pathogens in the sample."

The ISR and the IPRP cited two documents relevant for the novelty and inventive step requirements for claims 20 and 23–27, and a further two documents for claims 22–26. For claims 1–19, 21, 28 and 29, the documents cited were only to demonstrate the general state of the prior art , as these claims were considered patent-eligible. The IPRP also raised the issue of the application having 12 separate inventions as, in the examiner's view, it lacked a single general inventive concept.[43] The supporting experimental data for this patent family were not presented as different examples, but as an example in the style of a scientific paper with sections for materials and methods, results and discussion, presenting a clinical study of the invented method on human stool samples.[44]

38 EP3655780B1 Biomarker combinations to evaluate non-alcoholic steatohepatitis and/or hepatic fibrosis status. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/059631684/publication/EP3655780B1?q=EP3655780B1 (accessed May 26, 2025).

39 A (very) brief guide to patenting diagnostic inventions. AOMB Intellectual Property; 2022. Available at: https://www.nweurope.eu/media/17351/aomb_codex4sme-_diagnostics_rene-raggers.pdf (accessed May 26, 2025).

40 Lill, J.R., W.R. Mathews, C.M. Rose and M. Schirle (2021). Proteomics in the pharmaceutical and biotechnology industry: a look to the next decade. *Expert Review of Proteomics*, 18(7), 503–26. doi:10.1080/14789450.2021.1962300

41 3 Successful strategies for patenting diagnostic technologies. Med Device Online; 2021. Available at: https://www.meddeviceonline.com/doc/successful-strategies-for-patenting-diagnostic-technologies-0001 (accessed May 26, 2025).

42 WO2014001648 Method for determining the presence of diarrhoea causing pathogens. World Intellectual Property Organization; 2014. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014001648&_fid=EP133272163 (accessed May 26, 2025).

43 WO2014001648 Method for determining the presence of diarrhoea causing pathogens. World Intellectual Property Organization; 2014. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2014001648&_fid=EP133272163 (accessed May 26, 2025).

44 WO2014001648A1 Method for determining the presence of diarrhoea causing pathogens. European Patent Office; 2014. Available at: https://worldwide.espacenet.com/patent/search/family/049782335/publication/WO2014001648A1?q=pn%3DWO2014001648A1 (accessed May 26, 2025).

The first claims granted in Europe only had the small modification: "...SEQ ID NOS:61-63, wherein at least 20 nucleotides long sequence of each of the target amplicons are amplified; ii) performing a polymerase...". In contrast, the first claims granted in Japan[45] and in the United States of America[46] were significantly modified from the original claim with specificity around each nucleic acid sequence from the claim. This is in accordance with the high divergency between jurisdictions when patenting diagnostics.

The innovation and strong IP position of Mobidiag were key factors in its acquisition in 2021 by Hologic for more than USD 700 million.[47]

3.3 Therapeutics

The area of therapeutics is immense, and a lengthy report could be written on this topic alone. For this report, we focus solely on the major types of therapeutics (CGT, mAb and small-molecule therapeutics) that cover most of the current global therapeutics market.

3.3.1 Biologics

CGTs

The CGT field can be split into many subfields; however, the most significant activity within this field is focused on chimeric antigen receptor (CAR) cell therapies, which form the major category of approved advanced therapeutics. As evidenced in the survey responses we received from patent attorneys and technology transfer professionals (cell and gene therapies are one of the key innovation trends in life sciences. Several patent landscapes have been published on CAR-T cell therapies: the EPO published an extensive report in 2019,[48] and two reports on the evolution of patenting activity[49] and a global systematic analysis[50] were published in Nature Biotechnology in 2019 and 2020, respectively.

CAR cell therapies are personalized treatments for cancers; autologous treatments involve the harvesting of a sample of lymphocytes from a patient (T cells, natural killer [NK] cells, etc.) and reprogramming them to express the CARs on the surface of each cell. These cells are inserted back into the patient's body and will attack the cancer cells. Compared with small-molecule drugs, which are just an active compound, it is more difficult to patent CAR cell therapies as they are specific to each patient.[51] This is one justification for the push to develop allogeneic therapies (i.e., that do not have to be donor matched).

Most jurisdictions have limitations regarding the patentability of methods of medical treatment; are CAR cell therapies therefore patent-eligible? The answer depends on the way the therapies are characterized. If they are characterized as a method of treatment, then indeed it will be very hard to obtain protection.[52]

45 JP6498115B2. European Patent Office. Method for determining the presence of diarrhoea causing pathogenshttps://worldwide.espacenet.com/patent/search/family/049782335/publication/JP6498115B2?q=pn%3DJP6498115B2 (accessed May 26, 2025)

46 US10724106B2 Method for determining the presence of diarrhoea causing pathogens. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/049782335/publication/US10724106B2?q=pn%3DUS10724106B2 (Accessed May 26, 2025).

47 Hologic to acquire Mobidiag, innovator in near-patient, acute care diagnostic testing, for approximately $795 million. Hologic, Inc.; 2021. Available at: https://investors.hologic.com/press-releases/press-release-details/2021/Hologic-to-Acquire-Mobidiag-Innovator-in-Near-Patient-Acute-Care-Diagnostic-Testing-for-Approximately-795-Million/default.aspx (accessed May 26, 2025).

48 Clarke, N. and B. Jürgens. Landscape study on patent filing - chimeric antigen receptor T-cell immunotherapy. European Patent Office; 2019. Available at: https://link.epo.org/web/patent_insight_report-chimeric_antigen_receptor_t-cell_immunotherapy_en.pdf (accessed May 26, 2025).

49 Jürgens, B. and N.S. Clarke (2019). Evolution of CAR T-cell immunotherapy in terms of patenting activity. *Nature Biotechnology*, 37(4), 370–5. doi:10.1038/s41587-019-0083-5.

50 Lyu, L., Y. Feng, X. Chen and Y. Hu (2020). The global chimeric antigen receptor T (CAR-T) cell therapy patent landscape. *Nature Biotechnology*, 38(12), 1387–94. doi:10.1038/s41587-020-00749-8.

51 Picanco-Castro, V., C. Gonçalves Pereira, K. Swiech, K.C. Ribeiro Malmegrim, D. Tadeu Covas and G. Silveira Porto (2020). Emerging CAR T cell therapies: clinical landscape and patent technological routes. *Human Vaccines and Immunotherapies*, 16(6), 1424–33. doi:10.1080/21645515.2019.1689744.

52 Abinader, L. and J. Contreras (2019). The patentability of genetic therapies: CAR-T and medical treatment exclusions around the world. *American University International Law Review*, 34(4). Available at: https://digitalcommons.wcl.american.edu/auilr/vol34/iss4/2 (accessed May 26, 2025).

The strategies for protecting CAR cell therapies focus on protecting the components of the CAR cell, the CAR cells themselves and the methods of producing the CAR cells. Composition of matter claims (the CAR cells themselves) are usually the preferred method of protection, because these would protect the cells irrespective of how they are made. The downside of composition of matter CAR cells claims is that it is much harder to prove infringement compared with small-molecule claims because of the patient dependency. Methods of manufacturing the CAR cells is another option of protection, but competitors only infringe if they use an identical method in the production of the CAR cell therapy.[53]

At the JPO, CAR cell therapies are protected by product or composition of matter claims and methods of production. The JPO guidelines for life sciences[54] emphasize the importance of clarity in the claims and the enablement requirement for inventions related to genetic engineering.

In the United States of America, in view of *Juno Therapeutics v. Kite Pharma Inc.* No. 20-1758 (Fed. Cir.2021),[55] the most important element when patenting cell therapies is having a good written description and exemplification for the desired broadness of the claim. This is challenging as there are numerous possible variations, but the written description and provision of examples to fulfil the enablement requirement require careful consideration.[56]

At the EPO, similarly to the JPO, methods of treatment of the human body are excluded from patentability under Article 53(c). Claims are therefore focused on the CAR cells themselves, the nucleic acids encoding the CAR construct, their components or their methods of manufacture.[57]

mAbs

Therapeutic mAbs account for five of the top 10 drugs in terms of projected sales for 2025.[58] The mAb field is relatively well established, meaning that obtaining patent protection for a broad claim has become increasingly difficult as there are already many prior art documents.[59]

In the United States of America, the decision of the Federal Circuit in *Amgen v. Sanofi* No. 20-1074 (Fed. Cir. 2021)[60] that invalidated Amgen's patent demonstrated the importance of the enablement requirement for biologics (similarly to the cell therapy field). This decision also made it more difficult to use epitope claims for antibody protection in the future. The argument of the Federal Circuit was that the skilled person would have to screen millions of antibody candidates to determine which antibodies fell under the functional definition of the claim. On November 4, 2022 the Supreme court granted *certiorari* (an order by which a higher court reviews a case tried in a lower court) to Amgen's petition, and its decision should make it clearer to patentees what is expected of them for the support required.[61] On May 18, 2023, the Supreme Court unanimously affirmed that Amgen failed to provide enough detail to recreate the full scope of its claimed invention.[62] A contrasting example of issues currently discussed in relation to the United States of America patent system concerns observations that large patent portfolios held by certain pharmaceutical companies may contribute to delays in the market entry of biosimilars (generics of biologic drugs) compared with other jurisdictions.[63]

53 Haley, J.F., K. Mangasarian and B.M. Gummow. Patent issues in CAR-T technology. Intellectual Asset Managament; 2020. Available at: https://www.iam-media.com/global-guide/global-life-sciences/2020/article/patent-issues-in-car-t-technology (Accessed May 26, 2025).
54 2112 requirements of rejection based on inherency; burden of proof. United States Patent and Trademark Office; 2024. Available at: https://www.uspto.gov/web/offices/pac/mpep/s2112.html (accessed May 24, 2025).
55 *Juno Therapeutics v. Kite Pharma.* United States Court of Appeals for the Federal Circuit; 2021. Available at: https://cafc.uscourts.gov/opinions-orders/20-1758.opinion.8-26-2021_1825257.pdf (accessed May 26, 2025).
56 Holman, C.M. (2021). In *Juno v. Kite* the Federal Circuit strikes down patent directed towards pioneering innovation in CAR T-cell therapy. *Biotechnology Law Report*, 40(6), 372–88. doi:10.1089/blr.2021.29252.cmh.
57 Abinader, L. and J. Contreras (2019). The patentability of genetic therapies: CAR-T and medical treatment exclusions around the world. *American University International Law Review*, 34(4). Available at: https://digitalcommons.wcl.american.edu/auilr/vol34/iss4/2 (accessed May 26, 2025).
58 Leading drugs worldwide based on projected 2025 sales. Statista; 2025. Available at: https://www.statista.com/statistics/973523/top-drugs-by-year-on-year-sales-increase/ (accessed May 26, 2025).
59 Lahrtz, F. (2015). How to successfully patent therapeutic antibodies. *Journal of Biomolecular Screening*, 20(4), 484–91. doi:10.1177/1087057114567457.
60 United States Court of Appeals for the Federal Circuit. Accessed February 28, 2023. https://law.justia.com/cases/federal/appellate-courts/cafc/20-1074/20-1074-2021-06-21.html
61 Full scope enablement in functional limitation claims. Norton Rose Fulbright; 2022. Available at: https://www.nortonrosefulbright.com/en-jp/knowledge/publications/ea0e1523/full-scope-enablement-in-functional-limitation-claims (accessed May 26, 2025).
62 *Amgen v Sanofi.* Supreme Court decision; 2023. Available at: https://www.supremecourt.gov/opinions/22pdf/21-757_k5g1.pdf (accessed May 26, 2025).
63 Goode, R. and B. Chao (2022). Biological patent thickets and delayed access to biosimilars, an American problem. *Journal of Law and the Biosciences*, 9(2). doi:10.1093/jlb/lsac022.

The same *Amgen v. Sanofi* dispute in Japan had a different initial outcome in 2019, with the IP High Court of Japan ruling in favor of Amgen and maintaining that the patent satisfies the enablement and support requirements.[64] Nevertheless, the same IP High Court of Japan decided in favor of Regeneron (Sanofi's co-development partner) in January 2023.[65]

The EPO have published guidelines on the approaches used to assess antibody-specific patentability.[66] Similarly to cell therapies patenting, for most antibody patents the claims should be quite focused and narrow. Broader claims could potentially be achieved when a new target for an antibody is identified, or when a target has been associated with a novel medical use. These guidelines discuss the different methods of defining the antibody (structure, nucleic acid sequence encoding the antibody, target antigen, production process, epitope, etc.). New antibodies that can bind to an established antigen need to be defined by their amino acid sequence. The EPO requires an antibody to be defined by the six CDRs of the variable domains of the light and heavy chains. As opposed to small-molecule therapeutics, the unique structure of an antibody to a known target is not considered an inventive step by the EPO. The EPO requires a new antibody to a known target to show "an unexpected effect" compared with already known antibodies to the same target. The EPO will often take the view that the generation of a new antibody against a known target falls under the category of routine experimentation, unless an unexpected property of the new antibody can be demonstrated in view of the closest prior art. The guidelines for examination need to be combined with the EPO Board of Appeal decisions when deciding the specific patent filing strategy.[67]

3.3.2 Small molecules

Patenting small molecules is more straightforward than biologics, as the chemical structures can be described more precisely and are easier to produce. A detailed comparison of small molecules and biologics, and their influence on the cost and patient access, is presented in an article by Makurvet.[68]

As for biologics, the balance between the broadness of the claims and the support provided in the written description is very important, especially for Markush-type claims that allow for a huge number of combinations (example of a Markush claim is presented in Section 2.3.1).

Pharmaceutical companies form patent thickets (overlapping clusters of patents) around their key APIs by first protecting the key class of molecules with Markush claims and then extending the protection by patenting crystal and salt forms of the API, co-crystals, formulations with the API, delivery systems, methods of manufacturing and use of their API. This strategy allows companies to obstruct competitors from designing around their patents, and to extend the duration of protection and delay entry to the market for generics.[69] Another strategy employed by companies is to repurpose their inventions (APIs) for new therapeutics uses, especially cancer-related new uses.[70]

3.3.3 Patentable elements: case study

As described in the Introduction, the field of therapeutics is immense; the immunotherapy field in particular is generating wonderful innovations that are already treating diseases previously thought of as incurable. As a case study, we describe a patent family from Noile-Immune Biotech, a Japanese company focused on cancer immunotherapy. One of their first patent

64 Biologics patent dispute between Amgen and Sanofi in Japan. Clarivate Intellectual Property; 2019. Available at: https://clarivate.com/intellectual-property/blog/amgen-vs-sanofi/ (accessed May 26, 2025).
65 *Amgen v. Sanofi* and Regeneron: Japan IP High Court overrules its own decision on validity of Amgen patent. Kluwer Patent Blog; 2023. Available at: https://patentblog.kluweriplaw.com/2023/05/15/amgen-v-sanofi-and-regeneron-japan-ip-high-court-overrules-its-own-decision-on-validity-of-amgen-patent/ (accessed May 26, 2025).
66 G II, 5.6 Antibodies. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_6.htm (accessed May 26, 2025).
67 G II, 5.6 Antibodies. European Patent Office. Available at: https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_6.htm (accessed May 26, 2025).
68 Makurvet, F.D. (2021). Biologics vs. small molecules: drug costs and patient access. *Medicine in Drug Discovery*, 9, 100075. doi:10.1016/j.medidd.2020.100075.
69 Gurgula, O. (2020). Strategic patenting by pharmaceutical companies: should competition law intervene? *International Review of Intellectual Property and Competition Law; International Review of Industrial Property and Copyright Law*, 51(9), 1062–85. doi:10.1007/S40319-020-00985-0.
70 Mucke, H.A.M. (2021). What patents tell us about drug repurposing for cancer: A landscape analysis. *Seminars in Cancer Biology*, 68, 3–7. doi:10.1016/j.semcancer.2019.09.010.

families called "Proliferation-inducing and migration-enhancing (PRIME)" is focused on CAR-T cell technology, and improves local trafficking of CAR-T cells and other immune cells into solid tumors.[71] Noile-Immune filed their priority application on October 9, 2014, and then continued with a PCT application on October 6, 2015. At the 30–31-month (March–April 2017) stage the application was nationalized in a wide range of jurisdictions, not only within the usual Japan, the United States of America and Europe, but also Israel, the Russian Federation, Asia and Latin America.[72] Since nationalization, the patent was granted in all jurisdictions except for Thailand. The main claim filed at the PCT stage is: "A CAR expression vector comprising a nucleic acid encoding a chimeric antigen receptor (CAR) and a nucleic acid encoding a T cell immune function-enhancing factor, wherein the nucleic acid encoding an immune function-enhancing factor is a nucleic acid encoding interleukin-7 and a nucleic acid encoding CCL19, a nucleic acid encoding a dominant negative mutant of SHP-1, or a nucleic acid encoding a dominant negative mutant of SHP-2."

The ISR cited 10 documents relevant for inventive step; however, the IPRP mentioned that it considered claims 1 and 3–9 patent-eligible because none of the cited documents describe an expression vector that encodes the T-cell immune function promoters IL-7 and CCL19, especially one that exhibits a therapeutic effect against tumors.[73] The Japanese patent was granted very soon (June 23, 2017) after the national phase with the first claim as filed. This granted Japanese patent was used as part of a strategy to accelerate the prosecution of the patent in other countries through the PPH (see Section 2.1.2), filed in both the United States of America[74] and in Europe.[75] The claims in Europe were accepted as filed under the PPH, but in the United States of America a few written arguments and an interview with the examiner were required for an allowance of the claims with a minor modification to the first claim: "1. A CAR expression vector comprising a nucleic acid encoding a chimeric antigen receptor (CAR) and a nucleic acid encoding a T cell immune function-enhancing factor, wherein the nucleic acid encoding the T cell immune function-enhancing factor consists of a nucleic acid encoding interleukin-7 and a nucleic acid encoding CCL19."

The supporting data for the patent was presented in 13 examples that included data for the preparation of the T cells expressing the IL-7 and CCL19, different *in vitro* experiments (CAR expression assay through flow cytometry, measurement of the secreted IL-7 and CCL19, cell numbers and survival rate of the CAR expressing T cells, T cell migration experiments, the proliferative potential of T cells, etc.) and different *in vivo* experiments (the therapeutic effect in mouse tumor models, *in vivo* survival of CAR expressing T cells, the effect of infiltrating into the tumor tissue, etc.). All the experiments described the different aspects of the invention, supporting the full scope of their claim.

Another observation about Noile-Immune's patenting strategy is that, for the patent family described above, they still have live patent applications in Japan[76] and the United States of America[77] even though they already have granted patents in these jurisdictions. Maintaining live patent applications in the jurisdictions of your biggest markets is a risk mitigation strategy, as it potentially allows a company to obtain some protection in the case that one of the granted patents becomes invalidated for some reason.

71 PRIME CAR-T. Noile-Immune Biotech. Available at: https://www.noile-immune.com/en/Our_Science/prime_car-t.html (accessed May 26, 2025).
72 WO2016056228 CAR expression vector and CAR-expressing T cells. World Intellectual Property Organization; 2014. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016056228&_cid=P12-LFQVLV-10525-1 (accessed May 26, 2025).
73 WO2016056228 CAR expression vector and CAR-expressing T cells. World Intellectual Property Organization; 2014. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2016056228&_cid=P12-LFQVLV-10525-1 (accessed May 26, 2025).
74 US20170291953 Car expression vector and car-expressing T cells. World Intellectual Property Organization; 2015. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=US205085294&_fid=WO2016056228 (accessed May 26, 2025).
75 EP3205720 CAR expression vector and CAR-expressing T cells. World Intellectual Property Organization; 2015. Available at: https://patentscope.wipo.int/search/en/detail.jsf?docId=EP202597293&_fid=WO2016056228 (accessed May 26, 2025).
76 JP2022048153A CAR expression vector and CAR expression T cells. Japan Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/055652864/publication/JP2022048153A?q=pn%3DJP2022048153A (accessed May 26, 2025).
77 US2021253726A1 CAR expression vector and CAR-expressing T cells. European Patent Office. Available at: https://worldwide.espacenet.com/patent/search/family/055652864/publication/US2021253726A1?q=pn%3DUS2021253726A1 (accessed May 26, 2025).

4. Patent strategy

Key points

- Patent strategy can be viewed from different perspectives: filing strategy, that is, how to obtain maximum legal protection for your invention; and commercial strategy, that is, how the patent portfolio advances the commercial strategy of the business.
- Businesses, technology transfer offices (TTOs) and inventors need to work with patent attorneys to align the two perspectives to arrive at the optimal strategy for their business success.
- Aligning filing and commercial strategies requires effective two-way communication.

4.1 Filing strategy

The main limiting factors determining the filing strategy are cost, time requirements and existing prior art. All three factors need to be taken into consideration in conjunction with the commercial strategy of the company.

As mentioned in Section 2.1.1, the main cost drivers are the official filing fees and an inefficient communication process with the patent attorney. The volume of the patent application and the number of individual claims can also increase costs by increasing the filing and translation fees (where applicable). Key strategies for managing the costs include making use of reduced fees (e.g., if classified as a small entity in the United States of America), effective communication with patent attorneys, a good understanding of the existing prior art and a well-crafted patent application. If costs were non-limiting, then every company would file patents in every country with a patent system in place. That is never the case, because even huge companies such as Apple or Google would experience diminishing returns on the cost to file when enough of the jurisdictions with large markets for their products are covered.

Time constraints and pressures may arise for many reasons, such as an urgent need to file an application because of an imminent disclosure or a different competitor working the same field, investor requirements or for prestige purposes.

Because of the need for inventions to be novel and non-obvious compared with what has been brought to the market previously, prior art acts as a constraint on the scope of protection available. This pressure can be particularly acute in technical fields that have high levels of patenting activity.

4.2 Commercial strategy

The factors described regarding filing strategy in Section 4.1 above are relevant for commercial strategy, but from a different perspective. Whether to file a patent is decided according to anticipated return on investment. Consideration of all aspects is important, such as which markets offer the most financial returns from the sale of the product or service protected by the

patent(s), which countries or jurisdictions would be involved in the supply chain for the product or service, and how competitors can be prevented from copying the innovation.

As a hypothetical example, if a company had enough budget to file in four jurisdictions, but there are five big market jurisdictions and another two jurisdictions that are main suppliers of the raw materials for the product, then at least one of the jurisdictions of interest should be related to the raw materials.

From a commercial perspective, other types of IP rights are considered for the same invention. For some process patents where it would be difficult to demonstrate that a competitor might infringe, it could be considered that maintaining the IP as a trade secret (Section 1.6) is the best commercial decision.

The commercial strategy is also heavily dependent on the state of research and development in the particular field, the innovation process of a company and how they prioritize the different projects.

For patent attorneys to be able to offer the best advice regarding the optimal strategy, they need to understand both the filing constraints (budget, time, prior art) and the commercial aims of the business.

4.3 Improved communication approaches

The communication between businesses, TTOs or inventors and patent attorneys can be improved (as with any communication) with greater empathy and by trying to understand what each party is trying to achieve.

In academia, researchers and inventors who are pushing the boundaries of science and innovation are usually motivated by the rapid sharing of their work with other colleagues or innovators around the world. Researchers and innovators are not necessarily motivated by money, and believe that patenting a technology may not be the best method of making an impact.

Patent attorneys strive to offer the best patent protection to their clients by drafting strong patent applications, influenced by the different requirements described earlier in this chapter. Their success is measured by writing patents that define commercially relevant protection, are robust against opposition or invalidation proceedings, and do not allow competitor companies to work around the claims.

There are a few points of friction that are commonly present between researchers or inventors and their patent attorneys and patenting requirements.

a. Private-practice patent attorneys work with different companies, different technologies and usually prioritize projects according to deadlines, while an in-house patent attorney can specialize in a specific field and can dedicate more time to the most important projects.
b. Examiners try to analyze the patent application from the PHOSITA perspective but, in reality, there is still a degree of subjectivity that relates to the examiner's background and experience. It is very difficult for an examiner to determine whether something is or is not obvious in hindsight. For this reason, most patent offices have a well-defined process for assessing the inventive step.
c. Researchers or inventors often need to publish details of their research for career advancement. However, if such publications take place before a patent application is filed, they will constitute highly relevant prior art in most jurisdictions, rendering patent protection difficult or impossible to achieve. There can therefore be pressure to prepare a patent application rapidly, so that it can be filed before the invention is published in a journal or presented at a conference.
d. The expertise of researchers and academics in their field can hinder them in identifying the inventions in their work; however, a patent attorney could potentially find inventive concepts in the work that could seem trivial to the researcher.
e. There is a requirement to have only one invention per patent, and patent attorneys often wish to persuade patent office examiners of patentability by telling a coherent story across

the patent application. Attempts to add new information at the last minute can lead to significant rewriting, and may mean that the entire application needs to be reviewed for consistency and to ensure a single inventive concept.

All these issues can be addressed with greater insight into the needs of both inventors and patent attorneys. Based on our experience and the results of our survey, we recommend the strategies in the following subsections.

4.3.1 Researchers and inventors

When discussing their work or invention with a patent attorney, researchers or inventors should consider the following.

a. Describe the work or invention in its entirety without omitting anything, even though it might seem trivial. Emphasize any result that is surprising or unexpected in line with your knowledge of the field. When describing this, it is helpful to also explain the different methods or paths by which you could achieve the same results. Also, consider how a competitor researcher would try to achieve the same result.
b. Mention all previous disclosures of the work or similar work (e.g., MSc thesis with poor results, poster at a small conference, etc.)
c. Perform a search of prior art documents (prior patents or scientific papers) and identify any similar technology or inventions. Alternatively, provide the most relevant keywords to a technology transfer or patent search professional.

4.3.2 Patent attorneys

Based on the experience of the patent attorneys and technology transferprofessionals who participated in our survey, the following recommendationsemerge for obtaining a high-quality disclosure when discussing a client's workor invention:

a. Explain the key requirements for patenting and how they link to the scientific data.
b. Explain the suitable patent timeline and the key milestones.
c. Explain the compromise between the claim breadth and its defensibility during examination and after grant.
d. Explain the risks of prior disclosure and wrong inventorship.

Conclusion

The foundation of the patent system is based on inventors disclosing their invention fully to the public in exchange for the exclusive rights to the claimed invention, irrespective of the technical field.

As with all patent applications, life sciences inventions need to be supported by experimental data and other technical information. However, the first-to-file patent system, the need to meet inventor requirements regarding publication of results, and the cost and complexity of clinical trials frequently means that the difference between the technology to be patented (e.g., a new cell therapy for a particular disease) and the data that can be produced in support (e.g., illustrating efficacy in a suitable in vitro disease model) is often greater than in other fields. It is therefore important to ensure that patent attorneys and their clients are aware of the challenges and co-operate effectively to overcome these.

We conclude this report by emphasizing the key points that are relevant for all life sciences inventions.

- The scope of the claimed invention must be supported by the description and the examples presented in the application. If the scope is too broad, then the prosecution is lengthier and more costly and can lead to a rejection; if the scope is too narrow, then competitors may find strategies to work around it.
- The reporting of the scientific data must be in accordance with both current knowledge and practices in the art, and with required standards (e.g., ST.26 sequence listings)[1] and treaties (e.g., Budapest Treaty,[2] TRIPS agreement,[3] Biotechnology Directive,[4] etc.).
- Knowledge of prior art documents is essential when preparing the patent application, as it can be used to show how the invention is better than the current state of the art and to avoid overlap in scope.
- Understanding the specific requirements of different jurisdictions of interest, and how these may impact upon protection, is important.
- Clear, complete and timely communication between patent attorneys and researchers or inventors is essential.

1 Romero, L. and J.M. Vela (2014). Alternative models in drug discovery and development part II: in vivo nonmammalian and exploratory/experimental human models. In: *In Vivo Models for Drug Discovery*. Wiley, 59–90. doi:10.1002/9783527679348.ch03.
2 G 0003/19 (Pepper (follow-up to Tomatoes II and Broccoli II)) of 14.5.2020. European Patent Office; 2020. Available at: https://www.epo.org/law-practice/case-law-appeals/recent/g190003ex1.html (accessed May 26, 2025).
3 Summary of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977). World Intellectual Property Organization. Available at: https://www.wipo.int/treaties/en/registration/budapest/summary_budapest.html (accessed May 26, 2025).
4 Choudhary, L. and A. Kumar (2022). Stem cell patenting: moral and legal dilemma. *Journal of Intellectual Property Rights*, 27, 42–51. Available at: http://nopr.niscpr.res.in/handle/123456789/59278 (accessed May 26, 2025).

List of acronyms

3D	three dimensional
AI	artificial intelligence
AIPPI	International Association for the Protection of Intellectual Property
API	active pharmaceutical ingredient
ATMP	advanced therapy medicinal product
CAR-T	chimeric antigen receptor T
CDR	complementarity-determining region
CGT	cell and gene therapy
COVID-19	coronavirus disease
CRISPR	clustered regularly interspaced short palindromic repeats
DNDD	de novo drug design
EMA	European Medicines Agency
EMR	electronic medical record
EPC	European Patent Convention
EPO	European Patent Office
FDA	United States Food and Drug Administration
IDS	information disclosure statement
IP	intellectual property
IPRP	international preliminary report on patentability
ISR	international search report
JPO	Japan Patent Office

3D	three dimensional
mAb	monoclonal antibody
MDAR	materials, design, analysis and reporting
ML	machine learning
NASH	non-alcoholic steatohepatitis
NK	natural killer
PCT	Patent Cooperation Treaty
PHOSITA	person having ordinary skill in the art
PPE	personal protective equipment
PPH	patent prosecution highway
S&P 500	Standard and Poor 500
UCPA	Unfair Competition Prevention Act
UK	United Kingdom
UKIPO	UK Intellectual Property Office
US	United States
USC	United States Code
USD	United States dollar
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Patenting Healthcare-related Inventions provides a reference document for essential stakeholders involved in patenting innovation within the life sciences sector, particularly within the technical fields of biotechnology and pharmaceuticals.

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