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57

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Law for Innovation

A Concept for Researching Law and Innovation

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ABOUT THIS PAPER

This paper arose from ongoing discussions in research policy regarding the law of digitalisation and the legal regulation of innovation (particularly IP law). My goal is to demonstrate how closely intertwined these two fields are. Although the law of digitalisation is central to our current agenda at the Weizenbaum Institute, thoroughly addressing the innovation angle requires substantial resources. By illustrating these connections, this paper makes a clear case for the significant funding necessary to support comprehensive research in this space.

ABOUT THE WEIZENBAUM INSTITUTE

The Weizenbaum Institute is a joint project funded by the German Federal Ministry of Research, Technology and Space (BMFTR) and the State of Berlin. It conducts interdisciplinary and basic research on the digital transformation of society and provides evidence- and value-based options for action in order to shape digitalization in a sustainable, self-determined and responsible manner.

Weizenbaum Discussion Paper

Law for Innovation

A Concept for Researching Law and Innovation

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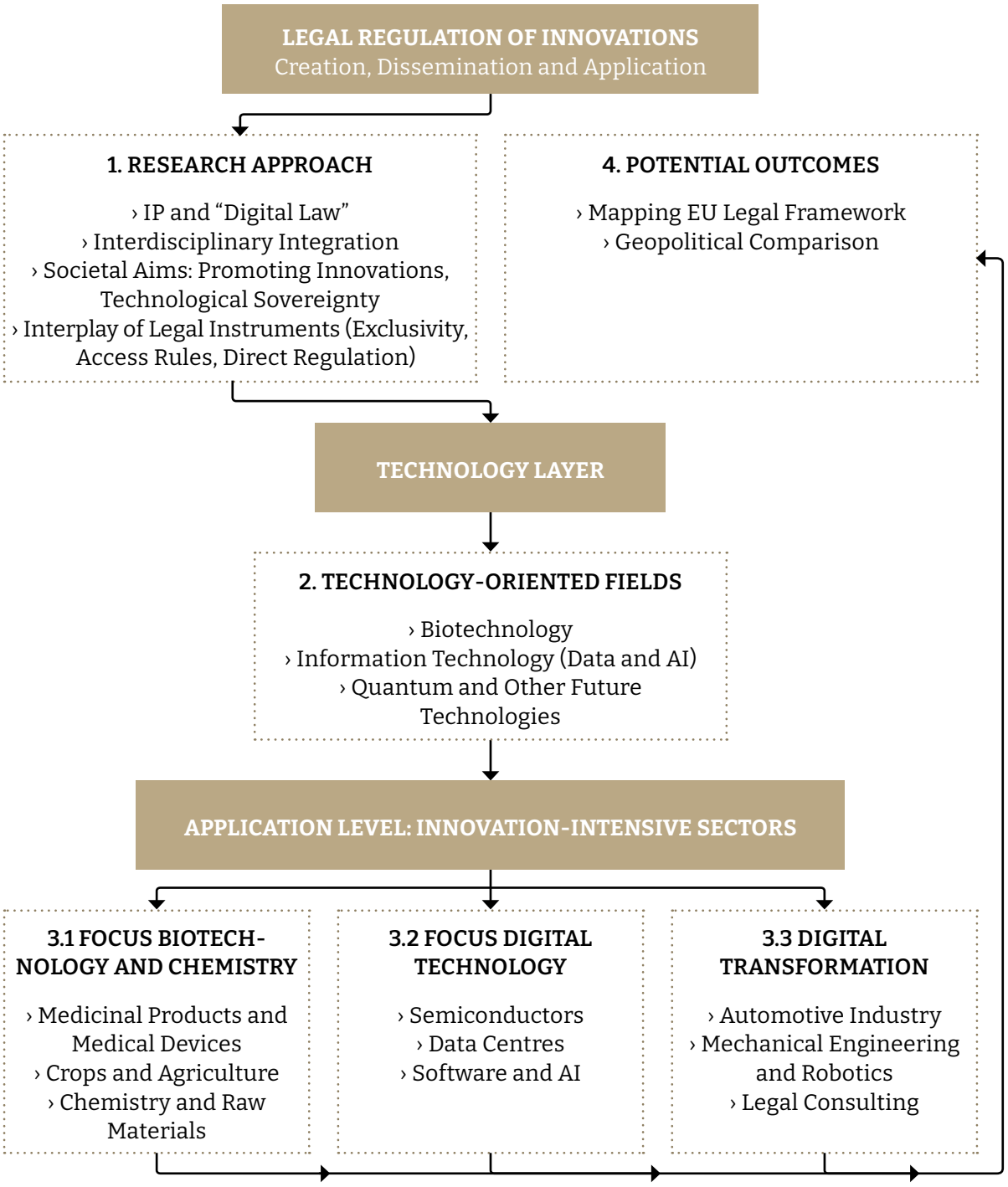
Overview



Contents

1 Research Approach

This paper proposes a concept for researching law and innovation. The concept addresses two focal points: First technology-related IP and regulation, especially in the life sciences but also in digital technologies. Second "digital law", meaning the legal framework governing digital phenomena like computer programs, internet platforms, data and artificial intelligence (AI). Based on these, research areas are identified. The two focal points are merged into one consistent research programme. IP and *Digital Law* Research is therefore understood as Research on *Law and Innovation*. Research is structured according to technologies and sectors. The document is meant as a starting point for further discussion und updates.

1.1 Object: Law and Innovation

The central research question driving this entire concept is how to better regulate innovation. Regulating innovation means influencing the creation, distribution and application of innovations using legal instruments – directly by establishing immediate rules or indirectly by creating incentives.[1] In this broad sense, regulation encompasses safety and security law (direct regulation) as well as IP law or liability law (indirect regulation).

Researching the (better) legal regulation of innovation requires an analysis of the interplay between innovations, especially technological ones (or actors concerned with them), societal objectives and the law. Arguably, there is a co-evolution between technological and legal developments.[2] However, legal regulation is not merely driven by technology but mainly by societal aims. To improve regulation, research therefore must examine how innovations influence society (and sometimes societal values), how society wishes to (or should) react and how the resulting societal aims regarding innovations can be best pursued with the law (i.e. by legal regulation).

Innovation

The term innovation is understood in a broad sense, comprising new practices, technologies or products. It can be used to signify individual innovations or the entirety of innovations in a certain field. An important subset are technological innovations which can also be called inventions. In the Schumpeterian business cycle, inventions lead to innovative products and services (innovations in a stricter sense). Therefore, innovation must be seen as a continuous process.[3]

Societal Aims

The question of how innovation should be regulated encompasses not only the choice of regulatory instruments (direct or indirect) but presupposes a decision on whether to regulate at

1 See *Zech*, Einführung in das Technikrecht, 2021, pp. 7 – 9.

2 *Eckardt*, Technischer Wandel und Rechtsrevolution, 2001, pp. 7 – 10.

3 *Fagerberg*, in: Fagerberg/Mowery/Nelson (eds.), The Oxford Handbook of Innovation, 2006, p. 5.

all. These decisions can only be taken after the societal implications of specific innovations have been considered. How innovations contribute to societal welfare determines the aims of regulation. How they are created, distributed and applied determines the instruments of regulation.

A key challenge for innovation regulation is the limited knowledge about the effects of a given innovation at a given time.[4] Further challenges include the relationship between efficiency and fairness, as well as geopolitical dimensions of regulation. Moreover, life sciences and digital technologies exert a transformative effect on society, influencing societal values.[5]

Although the societal impact of innovations (especially technological innovations) is not always beneficial, the main objective remains *promoting innovations* to enable their potentially beneficial use. Another objective that currently is in the political focus is *technological sovereignty*.[6] Many other important aims are pursued by legal regulation of innovations, like sustainability, personal autonomy, safety and security or fairness. Sometimes, trade-offs are necessary. Research on law and innovation can, however, put an emphasis on the promoting of innovations and technological sovereignty.

Legal Regulation

IP law lies at the heart of legal rules promoting innovation. For technological innovations this role is fulfilled by patent law, supplemented by other technical IP rights. Increasingly, however, regulatory law (specifically safety law) incorporates instruments for the promotion of innovations, such as regulatory market exclusivity or "sandbox provisions". In addition, technological risks are regulated at an early stage (emerging technologies) while the innovation process is still ongoing, therefore influencing its direction. Liability law also is viewed as a tool for the indirect regulation of technological risks. This interplay between traditional legal fields (like IP law, regulatory law, liability law or contract law) needs to be researched regarding its effects on innovation.

Technology-specific regulatory law must be harmonized with IP law. For instance, regulatory market exclusivity for pharmaceuticals operates alongside patents and supplementary protection certificates. Similarly, provisions in the AI Act concerning copyright in training data and data governance must be reconciled with copyright law and trade secret protection.[7] A useful approach to understanding the interplay between IP and other areas of law is to examine technologies or economic sectors (for details, see below under 1.3).

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4 *Collingridge*, The Social Control of Technology, 1980, pp. 16-19 (discussing the dilemma of control).

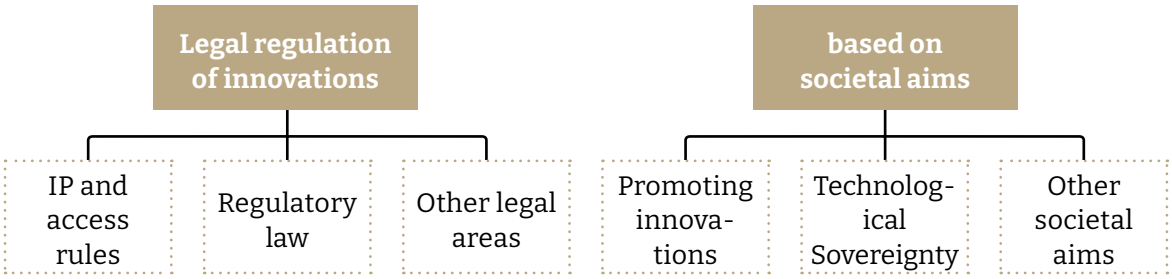
5 *Fateh-Moghadam/Zech*, in: Fateh-Moghadam/Zech (eds.), Transformative Technologien, 2021, pp. 7, 8 – 9.

6 *European Commission*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Tech Sovereignty, accompanied by an EU Open Source Strategy, COM(2026) 503 final, 3.6.2026; *Federal Ministry of Education and Research*, Technological sovereignty for Germany and Europe, Framework programme: "Research and Innovation for Technological Sovereignty 2030 (FITS2030)", January 2025.

7 For regulatory market exclusivity for pharmaceuticals, see Article 14(11) of the Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency and Article 10(1) of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. For provision concerning copyright in training data, see Article 53(1)(c) of the Artificial Intelligence Act (Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence). For data governance, see Article 10 of the Artificial Intelligence Act.

Exclusivity, as provided by IP, remains the primary mechanism for promoting innovation. In the case of regulatory market exclusivity, regulatory law functions like IP by providing exclusivity, albeit at the product marketing level rather than the technological level (as patent law does). As the example of Free and Open Software demonstrates, current innovation ecosystems require specialized rules that transcend, yet frequently still rely on, exclusivity. However, new rules transcending exclusivity for the production and distribution of immaterial goods are emerging. For example, access rules for IoT data have been implemented in the Data Act. In addition, regulatory law (and even liability law) can itself be seen as providing incentives and guardrails for innovations.[8]

Figure 1: Object of the envisioned research: legal regulation of innovations based on societal aims. The focus is on IP and its Interplay with regulatory law. Main societal aims underpinning the research comprise promoting innovation and technological sovereignty. However, other societal aims like sustainability, personal autonomy, safety and security or fairness must be considered.



1.2 Method: Integrating Different Disciplines

The research approach strives to integrate different disciplines. Although the focus is on legal research, comprising legal doctrine and legal policy, integrating methods and results of other disciplines, especially social sciences, is essential.

Legal Doctrine and Legal Policy

Researching the legal framework encompasses both legal doctrine and legal policy. Researching existing legal rules serves as more than just a starting point for legal policy considerations; given the plethora of new European legislation, particularly in digital law, accompanying the implementation of these rules on the national level has become a vital scholarly task.

EU legislation is now the primary driver of changes within a legal framework that comprises international, European and national legislation. The multi-level and multi-actor system (for instance in patent law with additional jurisprudence provided by the UPC) creates a complex situation that makes the role of legal research as an integrator increasingly important. From a legal policy perspective, the European approach to legislation with a preference for direct

8 For regulatory law as a "technology enabler" see *Kloepfer*, NuR 1997, 417, pp. 417-418; *Franzius*, VERW 2001, 487, p. 489; Zech, Einführung in das Technikrecht, 2021, pp. 64 – 66; *Duda*, in: Antoine/Radtke/Wiedemann (eds.), Innovation durch Regulierung?, 2015, 11, pp. 15 – 16.

top-down and early-on regulation warrants critical examination.[9] Even the European Commission now seeks to reduce the regulatory burden, as seen in various "omnibus" initiatives and the envisioned *European Innovation Act*.[10] In the *Communication on European Tech Sovereignty* the Commission explicitly states the aim "that businesses can spend less time on paperwork and more time on innovation".[11]

Technology and Social Sciences

Researching innovation regulation requires more than just legal expertise; it demands expertise in the relevant technologies and their scientific background, economics, social sciences (inter alia Science and Technology Studies) and history (e.g. legal history, history of technology). While this is ideally achieved by building teams, the necessary expertise (particularly regarding technologies) can also be integrated through cooperation and informal exchange with experts.

The role of social sciences deserves particular emphasis. As digital technology has spread to all areas of life, the study of society is crucial. The impact of digitalisation on society, as well as societal possibilities for setting guidelines for digitalisation, are the subject of a new discipline called Digitalisation Research.[12] Digitalisation Research is currently evolving from the interdisciplinary collaboration of all the aforementioned disciplines. It is not merely descriptive but also normative, placing strong emphasis on transferring its findings into society. Law, with its normative influence on society, holds a position of particular significance. Consequently, digital law is a cornerstone of digitalisation research.

Legal research in this setup, as already pointed out, comprises both jurisprudence and legislation. Moreover, it is not limited to a single traditional area of law. Nevertheless, there is a focus on IP and related areas of law such as regulatory exclusivity and data access rules.

Involvement of Societal Groups

Finally, societal engagement within research activities constitutes a vital component not only of Digitalisation Research but also of Innovation Studies more broadly. Collaboration with citizens, policymakers, and economic actors (not least technology transfer agencies such as Max Planck Innovation) facilitates a reciprocal exchange of information. This transdisciplinary approach ensures the practical relevance of research insights and policy proposals concerning the legal framework.

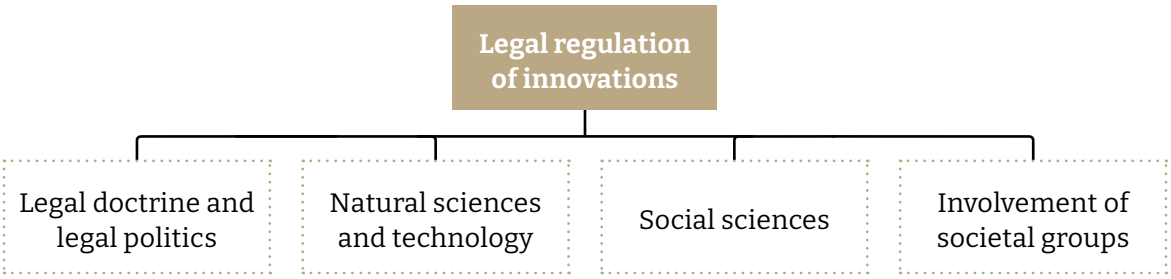
9 See *Mario Draghi*, The Future of European Competitiveness, Part A | A Competitiveness Strategy for Eu-rope, 2024, p. 30: "Regulatory barriers to scaling up are particularly onerous in the tech sector, especially for young companies". For the potential of deregulation for economic growth in Germany and in Europe, see also the collection of articles in a report by the *ifo Institute*: Overregulation in the EU? How to Boost Competitiveness with Smarter Legal Framworks, EconPol Forum 6/2024, pp. 3 – 35.

10 *European Commission*, European Innovation Act, available at: https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/shaping-eu-research-and-innovation-policy/european-innovation-act_en (last accessed on 15 May 2026).

11 *European Commission*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Tech Sovereignty, accompanied by an EU Open Source Strategy, COM(2026) 503 final, 3.6.2026, p. 7: "The Commission is pursuing a tailored technology and innovation lifecycle implementation logic and at the same time simplifying Europe's digital rules so that businesses can spend less time on paperwork and more time on innovation in the digital single market."

12 See *German Network of Institutes for Digitalisation Research* (NIfD), available at: https://www.hiig.de/en/germanetwork-institutes-digitalisation/ (last accessed on 14 February 2026).

Figure 2: Methods of the envisioned research on law and innovation. Core research (legal doctrine and legal politics) underlined.



1.3 Structure: Technologies and Economic Sectors

While legal research is often organised around traditional legal fields (such as IP or regulatory law), innovation regulation is better researched through the lens of technology-related fields and economic sectors. Such an approach has also been adopted by policymakers and legislators for political agendas and legislative acts.

When defining research areas, legal fields or individual legal acts, different and sometimes interdependent dimensions can be chosen: societal aims (from abstract to concrete), legal instruments to reach them (contracts, ownership rules, liability rules etc.) or the aspects of society to be regulated (such as technologies and economic sectors).

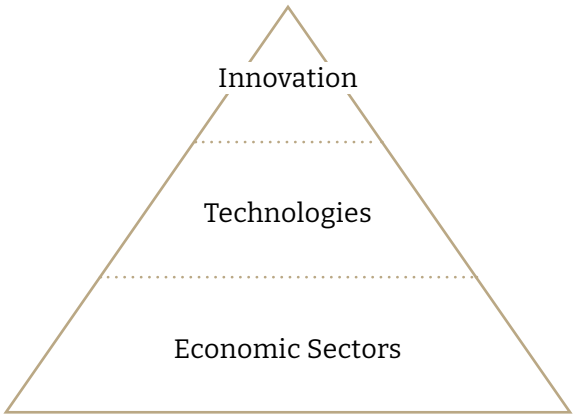
Legal regulation of innovation, with the aim of fostering the creation, diffusion and application of innovations to increase public welfare, is the common subject of all research in this concept. Societal aims, i.e. the functional aspect of regulation, act as a common denominator or overarching framework. The societal aim underlying all legal innovation research is public welfare in general which may be translated into promoting innovation but only insofar as it is conducive to public welfare.

Looking at *technologies*, such as the EU legislative approach to AI, allows for a technology-specific horizontal regulation. However, it does not account for the convergence of multiple technologies in many economic sectors (for instance, both biotechnological and digital innovations in pharmaceuticals). The *High-Tech Agenda* Germany, an initiative by the Federal Ministry of Research, Technology and Space, addresses six key technologies: AI, quantum technologies, microelectronics, biotechnology, fusion and climate-neutral energy sources, and climate-neutral mobility.[13] The focus on technologies is useful for interdisciplinary collaboration between lawyers, natural scientists and engineers. It must, however, be complemented by societal impact assessments and the research on uncertainties inherent in future technological developments. Instead of technologies per se, socio-technical phenomena should be considered. Such an approach takes the social relevance of technologies, which is essential for the law, into account and allows for collaboration with the social sciences.

13 English version available at: https://hightech-agenda-deutschland.de/fileadmin/Redaktion/Media_Kit/Infomaterial/Infomaterial_EN/BMFTR_HTAD_Broschuere_EN_digital_barrierefreie_PDF.pdf. Cf. *The High-Tech Agenda Germany at a Glance*, available at: https://hightech-agenda-deutschland.de/en/learn-more/ (sites last accessed on 17 May 2026).

Economic sectors, influenced by and reliant on innovative technologies, especially innovation-intensive sectors, with a focus on sectors important to the European and German economies, serve as practical crystallisation points for this research. The focus on economic sectors considers practical implications and allows for legal studies across different areas of law. It also respects the uncertainty surrounding future technological developments. However, uncertainties about major transformations creating new sectors remain a challenge for innovation research.

Figure 3: Levels of abstraction in the research on law and innovation. Looking at technologies remains more abstract than examining specific sectors. The peak symbolizes the even more abstract research about law and innovation in general.



In the next section (2.), research areas defined by technologies will be outlined. This is a convincing first approach for areas in which the legislator has chosen to rely on technology-specific legal acts and where, consequently, technology-specific legal fields exist. However, special attention is given to the question whether the technology-specific horizontal approach is adequate or should be complemented by a detailed look on specific sectors relying on the technologies. Further sections (under 3.) demonstrate how research can be organised around innovation-intensive economic sectors. They will be divided into three clusters, being defined by the influence of the enabling technologies: sectors with a focus on biotechnology and chemistry, sectors with a focus on digital technology and sectors who do not have a focus on digital technology but are currently undergoing digital transformation.

2 Technology-Oriented Research on Law and Innovation

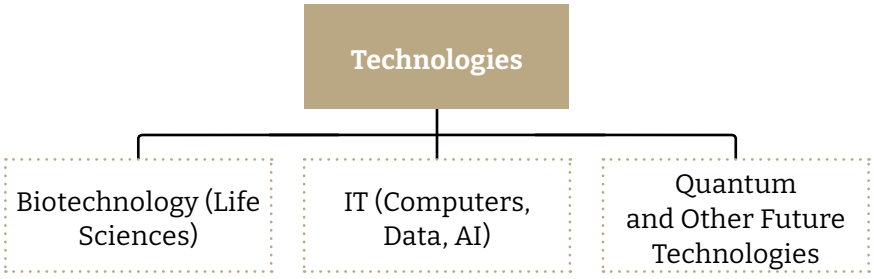
Legislation, as well as legal research, can be focused on technologies, especially emerging technologies which potentially provide huge benefits but which – at the same time – also pose huge risks or may contain risks that are difficult to assess. Examples (some of them historical) are chemistry, nuclear technology, genetic engineering, nanotechnology and artificial intelligence (AI).

One common aspect of these technologies is that they are often foundational technologies (also called enabling technologies). They serve as a basis for follow-on innovations (cumulative innovation) which may be used in many different sectors. This has important implications for IP law, especially regarding the question of how to best distribute profits and provide incentives along the value chain. Biotechnology and information technology (IT) are foundational technologies or, to be more precise, encompass many foundational technologies such as genome editing or AI. Consequently, Current advances in these areas are transforming many different sectors.

European legislation increasingly focuses on certain emerging technologies, such as Biotechnology, the Internet of Things, Artificial Intelligence or Quantum Technologies. This emphasis facilitates technology-focused legal research. A closer look, however, also reveals sector-specific regulation. On the national level this is mirrored by the activities of the Federal Agency for Breakthrough Innovation SPRIND, with a focus on groundbreaking technologies, or the *High-Tech Agenda Germany*, with a focus, as already mentioned, on key technologies. The concept of key technologies links the foundational character of many emerging technologies to their strategic importance (technological sovereignty).[14]

Researching law and innovation with a focus on technology should address two major areas where groundbreaking developments occur: biotechnology and information technology. In addition, potential future key technologies form a third area of interest.

Figure 4: Technology-oriented research on law and innovation



14 Cf. *Ramahandry* et al., Key enabling technologies for Europe's technological sovereignty, Study written at the request of the Panel for the Future of Science and Technology (STOA), Scientific Foresight Unit, Euro-pean Parliamentary Research Service, 2021.

2.1 Biotechnology (Life Sciences Law)

In the area of biotechnology, patent law was harmonized by the Biotechnology Directive more than 25 years ago.[15] Currently, the proposed Biotech Act I aims at regulatory law, with the "aim of creating an enabling environment to make it easier to bring biotechnology products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment".[16] It is to be followed by the Biotech Act II, to be proposed in 2026, focusing on biomanufacturing.[17]

Developments in Biotechnology

Alongside digital technology, biotechnology has become one of the fastest developing areas of technology over the last decade. This rapid development is due to new gene analysis methods such as next-generation sequencing, new tools to modify the genome, i.e. genome editing, such as CRISPR gene-editing, and new methods of predicting and understanding the structure of proteins, especially using machine learning systems, such as AlphaFold. It is worth noting that most of these breakthroughs were enabled by digital tools (bioinformatics).

Biotechnology as a Foundational Technology and its Interplay with IP

Biotechnology or, more precisely, technologies belonging to this area, such as PCR or CRISPR gene-editing, are classic examples of a foundational technologies. Compulsory licensing, therefore, plays an important role in this area (in Switzerland, there is even a special compulsory license for biotechnological research tools, Article 40b PatG-CH). In addition, naturally occurring information in the form of genetic resources contributes substantially to the development of biotechnological innovations (which led to the Nagoya Protocol on Access and Benefit Sharing in biodiversity law[18]). Due to advances in DNA sequencing, the focus has shifted from material resources to Digital Sequence Information (DSI).

Red, Green and Other Biotechnologies

The Life Sciences can be distinguished into different sectors like pharmaceutics, plant biotechnology or industrial biotechnology. Often, certain colours are attributed to different sectors. Inter alia, red biotechnology concerns the medical and pharmaceutical industries, green biotechnology refers to plants and plant protection, while white (or industrial) biotechnology applies to industrial processes. Grey (or environmental) biotechnology refers to applications for the protection of the environment (such as waste treatment and bioremediation). Life Sciences law can also be structured according to this distinction. Such a specialization can even

15 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

16 Proposal for a Regulation of the European Parliament and of the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health, and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act), 16 December 2025, COM(2025) 1022 final, p. 4.

17 *European Commission*, Commission Work Programme 2026, COM(2025) 870 final, Annex I, No. 3; see also A Strategic Framework for a Competitive and Sustainable EU Bioeconomy, 27 November 2025, COM(2025) 960 final.

18 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol on Access and Benefit Sharing). For certain plants (key crops), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) establishes a Multilateral System of Access and Benefit-sharing. For marine genetic resources, the Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (BBNJ Treaty) establishes rules for the fair and equitable sharing of benefits derived from the exploration of high-seas marine life (including digital sequence information).

be found in patent law (e.g., with special rules for plants), despite being conceived as a technology-neutral area of law. Red, green and grey biotechnology are the three major sectors.

Red biotechnology (health biotechnology) comprises pharmaceuticals manufactured using biotechnological methods (biopharmaceuticals). These include not only proteins and RNA but also more complex therapeutics such as stem cells and CAR-T cell therapy (which are closer to therapies than mere pharmaceuticals). The current Biotech Act I proposal focuses primarily on health biotechnology. Besides regulatory simplification it also aims at capital mobilization and even includes a rule on IP protection. It provides a 12-month extension of Supplementary Protection Certificates (SPC) for eligible biotechnology-derived medicinal products and advanced therapy medicinal products (ATMPs).[19] Eligibility depends not only on chemical and therapeutic novelty but also on European clinical research and domestic manufacturing. This aims at keeping or rather bringing back the entire biotechnology value chain to the EU. The Biotech Act proposal also addresses the increasing importance of digital technology in biotechnology. It facilitates the use of personal data (in line with the EHDS Regulation) and introduces regulatory sandboxes for AI (in line with the AI Act). Red biotechnology, alongside green biotechnology, was at the heart of the Biotechnology Directive which also addressed ethical issues in patent law – issues that, arguably, should have been resolved by regulatory law.[20]

Green biotechnology comprises classical breeding as well as plant-related genetic engineering and genome editing. Genetic engineering law will undergo major changes due to the politically agreed *Regulation on plants produced by certain new genomic techniques and their food and feed* (NGT Regulation) which also affects patent law.[21] In patent law, the Biotechnology Directive addresses all areas of biotechnology. However, green biotechnology was further developed by a fierce legal policy debate concerning new breeding methods such as marker-assisted breeding. The NGT Regulation will also affect patent law, albeit only with minor amendments such as transparency obligations.

Industrial biotechnology, as already mentioned, will be addressed by the Biotech Act II proposal. In patent law, most questions relevant to industrial biotechnology are answered by the Biotechnology Directive. Environmental biotechnology is closely connected with industrial biotechnology and often relies on industrial processes which are applied to environmental tasks.

19 Article 27(1) of the Proposal for a European Biotech Act, COM(2025) 1022 final.

20 See also *Bartels*, Ethik und Patentrecht, 2020.

21 Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, COM(2023) 411 final, 5 July 2023. The agreement on new EU rules for plants obtained by using new genomic techniques (NGTs) was reached on 3 December 2025 by the Council and the European Parliament. See Council of the European Union, LIMITE doc. 16660/25, 11 December 2025.

2.2 Information Technology: Data and AI

Information technology is, arguably, the perfect example of a foundational technology. From computers and computer programs (software) to digital networks, data analysis and artificial intelligence (AI), digital technologies enable innovations across all sectors. IT law has been following this development. While computers and computer programs are still relevant (e.g., under the Computer Programs Directive in copyright law), the internet and its platforms present some of the major current regulatory challenges (which are addressed by the Digital Services Act, the Digital Markets Act, the Directive on Copyright in the Digital Single Market and other European legal instruments). Furthermore, the importance of data analysis inspired the Data Act which introduced inter alia data access rules for the Internet of Things.

Key innovations are currently found in AI (such as agentic AI, including multi-agent orchestration, physical AI, new model architectures and, not least, domain-specific models and systems). AI law and data law (concerning training data for AI) are therefore the main legal fields in IT where innovation regulation is debated. The AI life cycle comprises several steps, starting with the definition of a problem and proceeding to data acquisition and preparation, model development and training, evaluation and refinement, eventually resulting in the deployment (and even decommissioning) of an AI solution. Thus, the value chain spans from training data to new models and systems, and ultimately to AI-generated output.[22]

Data Access: Data Act and Trade Secrets Directive

The first step is gaining access to training data. The Data Act aims to unlock the value of industrial data by regulating access to and portability of data.[23] For the Internet of Things (IoT) and cloud computing, this development represents a fundamental change in data sovereignty. A key question for the functioning of the data access mechanism will be its interplay with trade secrets protection. However, the application of the Trade Secrets Directive to raw data remains to be clarified.

Starting with data privacy law, data law has now evolved into a fully-fledged area of legal research, where data protection (data privacy) is complemented by an economic data law (comprising data access).[24] Additional legal acts include, among others, the Data Governance Act and the Open Data Directive (concerning public sector information). Data-driven innovation is increasing in many areas – e.g., in the mobility and especially the automotive sector, in pharmaceuticals or in mechanical engineering, but most prominently in AI-driven innovation and in the form of training data.

22 For an overview of the underlying IP law questions see *Drexl/Hilty/Desaunettes-Barbero/Globocnik/Otero/Hoffmann/Kim/Kulhari/Richter/Scheuerer/Slowinski/Wiedemann*, Artificial Intelligence and Intellectual Property Law, Position Statement of the Max Planck Institute for Innovation and Competition of 9 April 2021 on the Current Debate, 2021.

23 See Articles 3-12 of the Data Act (governing business-to-consumer and business-to-business data sharing, and obligations for data holders required to make data available pursuant to Union law), and Articles 23-32 of the Data Act (governing switching between data processing services).

24 See *Hennemann*, Datenrecht, 2025; Müller, Recht der Datenwirtschaft, 2024.

Currently, sector-specific data laws are evolving. Most prominently, the *Common European Data Spaces* include 14 sectors (domains) which comprise agriculture, cultural heritage, energy, finance, the European Green Deal, health, manufacturing (industry), language, media, mobility, public administrations, research and innovation (which loops back to the overall topic), skills, and tourism.[25] The European Health Data Space (EHDS)[26] has already been adopted, facilitating the access to electronic health data for both primary and secondary uses. As data law develops separately in different sectors, important research questions should – at the outset – be addressed according to the respective sector.

Training data: IP and Regulation

The current debate concerning AI and IP focuses on training data protected by copyright and on the Text and Data Mining (TDM) exceptions (Article 3 and 4 of the DSM Directive). The EU DSM Directive permits in Article 3 commercial TDM unless rights holders explicitly "opt-out". If applicable to AI training (which currently is the prevailing view), these exceptions allow AI developers to train models on copyrighted works without permission, provided the content is lawfully accessed. Rights holders can reserve their rights (opt-out) to prevent TDM of their content, though this does not apply to non-commercial scientific research according to Article 4 DSM Directive. The underlying public policy questions are how this contributes to the development of new AI models (fostering innovation) and whether this leads to a fair distribution of the value generated by developing AI models based on existing copyright-protected works. However, these aspects are only part of the overall innovation-framework concerning AI. Other questions include whether AI models and systems themselves are or should be protected and whether results generated with the help of AI are or should be protected. Patent law may also play a role if training data is deemed a product obtained directly by a process which is the subject matter of a patent (under Article 25 lit. c UPCA, § 9 No. 3 PatG).

Besides IP law, under Article 10 of the AI Act (data governance requirement for high-risk AI systems), training data are also regulated concerning their implications for the safety of the trained models. The potential liability of data suppliers for faulty data has remained untested so far. The AI Act also influences copyright protection for training data, as Article 53(1)(c) AI Act obligates providers of general-purpose AI models to comply with copyright law (and especially the reservation of rights under the TDM exception).

AI Models and Systems

Looking at AI models and systems, the question of their potential copyright protection and patentability arises. Whereas patentability will be decided similarly to computer programs or mathematical methods, copyright protection will often not apply due to the lack of a human author's own intellectual creation (and hence, of a "work").

25 See Article 30(h) and Recital 2 of the Data Governance Act.

26 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

The potential lack of copyright protection for AI models plays an important role for Free and Open-Source licenses concerning AI. Without copyright protection, existing licensing regimes (e.g. regarding copyleft licensing) might not be applicable. However, it might suffice that only parts of a model in different training stages are protected.

As with training data, regulatory law (especially the AI Act) influences IP questions regarding AI models and systems. Transparency requirements may conflict with trade secrets protection (which currently is the main protection mechanism). Standardisation (cf. Article 40 AI Act) may lead to standard essential IP rights (if applicable).

The AI Act marks one of the world's first comprehensive attempts to regulate the development and deployment of AI systems, including the regulation of general-purpose AI models. It covers the AI value chain from AI models to AI systems and puts the providers of high-risk AI systems in the centre of the regulation. Sector-specific regulation, such as the Machinery Regulation[27] (for robots and other machines) and the Medical Devices Regulation[28] (for medical devices), remains in place and interacts with the AI Act (especially through Article 6(1)(b) AI Act).[29] The relevant sector-specific regulatory acts have also been adapted to digitalisation, e.g., when the Machinery Directive was replaced by the Machinery Regulation or the Medical Devices Directive by the Medical Devices Regulation. Whether the horizontal approach to AI regulation taken by the AI Act is adequate, remains an open research question.[30] Arguably, the AI Act can also be seen as a mixed approach, as it is also based on existing sector-specific product regulation.

The AI Act also addresses innovation. Explicitly mentioned as "measures in support of innovation" (Chapter VI), the AI Act provides AI regulatory sandboxes (Articles 57-59 AI Act) and the testing of high-risk AI systems in real-world conditions outside of these sandboxes (Articles 60, 61), as well as support for SMEs, including start-ups (Article 62) and derogations for microenterprises (Article 63). The efficacy of these provisions remains to be seen.

Liability for AI, as the final piece of the regulatory puzzle, will not only be governed by general tort law but also by product liability law which after its revision also encompasses software and AI, regardless of its physical manifestation.[31]

27 Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC.

28 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

29 See at 3.1.1 and at 3.3.2.

30 See *Ossmann-Magiera*, Regulating AI: A technology law perspective on regulatory strategies for emerging technologies, 2025.

31 Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC; see also the definitions of "product" in Article 4(1) and "component" in Article 4(4).

AI-Generated Output

AI-generated output represents the last stage in the AI value chain. Copyright and patent law arguably differ regarding the requirement of human creation. Whereas copyright requires a human creation as a substantive protection requirement, patent law only requires an inventor to determine ownership of a patent. This difference must be seen from an innovation policy perspective. Arguably, there is no immediate need for legislative intervention. This might change, not because of a need for incentives, but because AI is able to produce content which can be mistaken for human-generated content. This is not only a challenge for human creativity but also for IP rights tailored to it.

Current Large Language Models generate primarily language-based output. This technology influences the perspective on human thinking and creation which is also, to a great extent, based on language. The technology is also very accessible for everyday use, being the reason for its societal impact and its public attention. Similarly, other generative models, creating images or sounds, enjoy public attention. However, AI can also be used in areas like scientific research and technological development. An example for this is protein modelling which was already mentioned under 2.1. Another example is weather forecasting. This will be improved by AI models relying on even larger amounts of training data than large language models. They serve as an example of AI-driven innovation beyond language models, raising the question of how to secure sources for training data which are not readily available on the internet (and not works of art which are potentially protected by copyright). The generation of weather data in the necessary granularity and in real time is investment intensive (although alternative approaches like citizen science weather stations exist). Moreover, the necessary computing power is even larger than that for large language models. Therefore, the involvement of public funding will most likely remain necessary.

2.3 Quantum Technology and Other Future Technologies

Quantum technologies, such as quantum communication, quantum sensors and quantum computing, hold great promise for the future. However, these technologies are still under development – and in the case of quantum computing, as far as can be said from public sources, they are still far from practical application. Nevertheless, they are already addressed by the European and German legislators (i.a., in the *High-Tech Agenda Germany*).

European Legislative Initiative on Quantum Technologies (EU Quantum Act)

The *EU Quantum Act* (expected in 2026)[32] is a comprehensive legislative framework aimed at boosting research, strengthening industrial capacity for quantum computing/sensing, and secure critical supply chains. The act seeks to foster a sovereign ecosystem, reducing dependence on foreign technology. As with the Biotech Act, the European Commission rightly aims to establish functioning innovation ecosystems.

32 *European Commission*, Commission Work Programme 2026, COM(2025) 870 final, Annex I, No. 3.

Although quantum technology or technologies (especially quantum computing) are an obvious candidate for future technology regulation,[33] the question remains whether a regulatory effort in 2026 is premature (making it a perfect example of the Collingridge Dilemma[34]). However, technology-based sectors are already emerging, especially telecommunication based on quantum cryptography. This can be discussed in further detail once the legislative proposal for the EU Quantum Act has been published. Quantum technology differs from current digital technology as it requires novel materials (superconductors, optical materials, topological insulators), making it highly dependent on innovation coming from materials science. From a patent law perspective, quantum technologies, like biotechnologies and digital technologies, act as foundational technologies, carrying significant implications for follow-on innovations.

Other Potential Future Technologies

Besides quantum technology, other future technologies are a subject of public debate: Virtual reality could be an example of a technology constantly evolving into a widespread societal adaption (similar to AI). Arguably, however, it will not call for a detailed regulation comparable to the AI Act. Among the foundational technologies, optical computing may succeed electronic computing (it might also be a possibility for realising quantum computing). Current computing and mobile telecommunication will be improved (2nm-technology and 6G respectively). Superconductivity will be improved to achieve higher temperatures. Whether and when practical fusion energy will be realistic is still an open question.

Quantum and other future technologies like fusion energy are still in their infancy where it is unclear in what direction and how far they will evolve. It is difficult to promote specific technologies before they fully exist. Therefore, regulatory intervention is less promising than technology-neutral open incentive mechanisms like patent law. These are also areas in which regulatory intervention might be less important than the creation of functioning innovation ecosystems with close ties between industry and academia. Such an ecosystem approach is already part of the Biotech Acts[35] and of the Communication on European Tech Sovereignty[36].

The importance of academic training, academic research, and their connections to industries, creating functioning ecosystems for innovation, is also addressed by the European Research Area Act likely to be proposed in 2026.[37]

33 For a first overview of the regulatory problems see Aboy/Corrales Compagnucci/Minssen (eds.), Quantum Technology Governance I, Law and Regulation, 2026.

34 *Collingridge*, The Social Control of Technology, 1980, pp. 16-19.

35 Proposal for a European Biotech Act I, 2025/0406 (COD), p. 5: "In a second stage, following this health-focused initiative, the Commission will address in 2026 the wider biotech ecosystem beyond health to ensure a competitive internal market for all areas of biotechnology." The proposal speaks of the "EU bio-tech ecosystem" several times throughout the text.

36 *European Commission*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Tech Sovereignty, accompanied by an EU Open Source Strategy, COM(2026) 503 final, 3.6.2026, Section 3.

37 *European Commission*, Commission Work Programme 2026, COM(2025) 870 final, Annex I, No. 3.

3 Sector-Oriented Research on Law and Innovation

This part examines sector-specific research questions. It starts with biotechnology- and chemistry-related sectors (1.) and proceeds to digital technology sectors (2.) and sectors undergoing digital transformation (3.). The selection aims to capture particularly innovative and economically relevant sectors. These are the sectors relying on or being transformed by the key technologies discussed under 2. Concentrating on economic sectors, however, allows to address the economic implications of legal interventions more clearly than concentrating merely on technologies. This is especially important for sectors undergoing rapid development or transformation.

3.1 Sectors with a Focus on Biotechnology and Chemistry

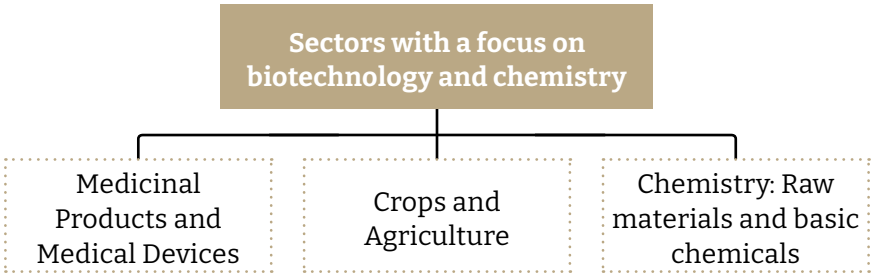
The following sectors are primarily based on natural sciences and related technologies. Innovations in these sectors are rooted in biotechnology, chemistry and other natural sciences. However, digital technology also plays an increasingly important role in these areas.

European legislation reflects both a technology- and a sector-oriented approach. Some technology-centred regulation is horizontal (such as the AI Act), while some is sector specific (such as the NGT Regulation aimed at the crops sector). As will be seen, some sectors, such as the pharmaceutical industry, are subject to sector-specific regulation as well as sector-specific IP law (at least special rules within patent law).

Research questions concerning different economic sectors include: What are the special features of a certain sector concerning innovation and innovation cycles (foundational innovations, follow-on innovations), the diffusion of innovations and their societal impact? How is, in a certain sector, innovation currently regulated within a specific sector? What should be implemented?

Three particularly interesting sectors should be examined: Medicinal products (1.1) and crops (1.2) are two major areas of the life sciences industry. The chemical industry (1.3) forms a basis not only for the life sciences industry but for the whole economy.

Figure 5: Research on sectors with a focus on biotechnology and chemistry



3.1.1 Medicinal Products (Pharmaceuticals) and Medical Devices

The pharmaceutical sector (together with plant protection) arguably has the longest tradition of innovation-fostering rules in regulatory law. Patent law also entails many special rules concerning the pharmaceutical sector. The legislative framework will undergo changes due to the recently agreed on *Pharma Package*.[38] Pharmaceuticals (i.e. medicinal products) comprise drugs and vaccines. A closely related sector concerns medical devices. From research to marketing, the whole business cycle for medicinal products (from research to market to bedside) is densely regulated. Research is increasingly influenced by data law whereas marketing is shaped not only by regulations on safety, efficacy and quality but also on pricing and reimbursement. There is a trend towards more complex molecules (biopharmaceuticals) and, at times, a blurring of the line between medicinal products and medical therapies (e.g., in Advanced Therapy Medicinal Products, ATMPs).

Pharmaceutical Substances (Small Molecules and Biologics): Research and Marketing Authorization

Pharmaceutical substances comprise *small molecules* (which are chemically synthesised), biologics (biopharmaceuticals which are produced biotechnologically) and *vaccines*. Research is conducted on substances, production methods and indications, leading to different kinds of innovation.

In patent law, the protection of pharmaceutical substances and novel indications as compounds is a major area of legal doctrine.[39] In addition, the Bolar exemption (facilitating the necessary studies and trials for obtaining marketing authorization)[40] plays an important role in facilitating generics and will be extended as part of the politically agreed Pharma Package. Supplementary Protection Certificates (SPCs) are an intellectual property right that serve as an extension to a patent right specifically for pharmaceutical and plant protection products (creating an exception to the "one size fits all" approach to the duration of protection followed by patent law). This, in turn, can be extended by six months for medicines developed for children with completed paediatric investigation plans (PIPs). Similarly, the European Biotechnology Act proposal envisions a 12-month extension for eligible biotechnology-derived medicinal products and advanced therapy medicinal products (ATMPs).[42] This shows how very specific regulatory law directly influences IP law in the pharmaceutical sector.

38 Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, 26 April 2023, COM(2023) 193 final. Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, 26 April 2023, COM(2023) 192 final. The agreement to amend the EU's pharmaceutical legislation was reached on 11 December 2025 by the Council and the European Parliament.

39 Article 54(4) and (5) EPC, §§ 3(3) and (4) PatG.

40 Article 10(6) of the Directive 2001/83/EC, Article 27(d) of the UPC Agreement, § 11 Nr. 2b PatG.

41 Article 85 of the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, COM(2023) 192 final.

42 Article 27(1) of the Proposal for a European Biotech Act, COM(2025) 1022 final.

In addition, European pharmaceutical law contains rules that function similarly to intellectual property rights and grant exclusivity for a certain period of time. Orphan drugs (treatment for rare diseases) are incentivised by a 10-year market exclusivity.[43] The Pharma Package will modify this by reducing the baseline exclusivity to nine years while creating a special 11-year exclusivity for "breakthrough" orphan drugs (Article 71 of the Pharma Package Regulation). For all medicinal products, regulatory data protection and market exclusivity are provided. Originators are protected by an eight-year regulatory data protection period (preventing preclinical and clinical trial data from being used by competitors) and a 10-year marketing protection period (during which generics cannot enter the market) which may be extended by one additional year for a significant new indication (so-called "8+2+1" formula). This also is currently undergoing changes as part of the Pharma Package (Articles 80, 81 of the Directive, Article 29 of the Regulation): While the eight-year period of regulatory data protection (which the Commission initially wanted to reduce to six years) will be maintained, the additional two years of market protection for generics will be reduced to one year. However, this can be extended through various targeted incentives up to a maximum of 11 years in total (yielding an 8+1[+1+1] formula). The targeted incentives comprise extensions for: unmet medical need, new active substance and trials, or a significant new indication (1 year each, with a cumulative maximum of 2). Whether this increased flexibility will foster useful innovations through more targeted incentives or decrease them due to greater legal uncertainty remains to be seen.

Whereas regulatory data protection may be seen as an incentive for developmental activities in the form of clinical studies, other areas of law also influence these activities. Data protection (data privacy) under the GDPR plays a major role (under the Digital Omnibus initiative, however, this might be influenced by a more precise definition of the term "personal data"). In Germany, the Medizinforschungsgesetz (MFG) seeks to increase Germany's attractiveness as a location for innovative medical research, inter alia by simplifying bureaucratic processes. The Pharma Package Directive provides for regulatory sandboxes.

As an additional piece of the legal framework concerning medicinal products, liability law must be mentioned. Under European law product liability is concerned, whereas in Germany an additional strict liability rule for medicinal products exists.

Biopharmaceuticals: Complex Molecules, Natural Substances, and AI

Biopharmaceuticals, produced using living organisms, are not only more complex and costly to develop than small molecules but also more difficult to copy, giving the originators stronger factual exclusivity. Any product derived from independently cultivated production strains can only be similar but not identical to the original product, therefore called a biosimilar (biosimilar medicinal products). Consequently, applications concerning biosimilar medicinal products cannot rely entirely on clinical data from the original product (contrary to generic medicinal products, Article 9 of the Pharma Package Directive) but must provide supplementary data (Article 11 of the Pharma Package Directive).

43 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products.

As already mentioned in the section about biotechnology (2.1), the proposed Biotech Act I seeks to foster health biotechnology in Europe. One of the proposed measures is the introduction of a 12-month extension of the Supplementary Protection Certificate (SPC) for eligible biotechnology-derived medicinal products and advanced therapy medicinal products (ATMPs).

Clearly Defined Social Needs: Orphan Drugs, Pediatric Use, Unmet Medical Need, and Critical Medicines

An interesting aspect of pharmaceutical regulation is that the legislator has identified several clearly defined social needs. Orphan drugs (with the special category of breakthrough orphan drugs) and pediatric use have already been mentioned. The Pharma Package also introduced, as discussed, an additional regulatory market protection for a medicinal product that addresses an unmet medical need (Articles 81(2)(a), 83 of the Pharma Package Directive).

In addition, legislative measures have been implemented to prevent supply shortages, most notably the *Critical Medicines Act* (CMA). In Germany, a similar goal is pursued by the Arzneimittel-Lieferengpassbekämpfungs- und Versorgungsverbesserungsgesetz (ALBVVG). Article 5a of the Pharma Package Regulation connects regulatory market exclusivity with an obligation to supply.

Social needs and preferences are also researched by medical sociology. Social acceptance of certain medicines influences their effect on public health. A prominent example is the acceptance of vaccines which was highlighted during the COVID-19 pandemic. These sociological questions contribute to the interdisciplinary research on law and innovation in the pharmaceutical sector.

Being Prepared: Antibiotics

Particularly interesting is a new legal instrument to promote the development of new antibiotics (Articles 40-43 of the Pharma Package Regulation). The Transferable Exclusivity Voucher (TEV)[44] grants the developer of a "priority antimicrobial" one additional year of regulatory data protection which can be applied to another centrally authorised product in the developer's portfolio (transferability). This measure addresses the problem of incentivising the development of pharmaceuticals which should be used as sparingly as possible (reserve innovations). Whether linking the innovation of an antibiotic to the price of a seemingly unrelated medicine is the right approach is an interesting research question. The mechanism is subject to complex safeguards, for instance ensuring the capacity to supply,[45] a sales cap (blockbuster clause),[46] restrictions on further transfer[47] and a cap on the total number of vouchers available[48].

44 Articles 40-43 of the Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, COM(2023) 193 final. Cf. *Valtere*, Challenges and Prospects in the EU's Proposal to Foster Antimicrobial R&D and Ensure Access, 2025, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5680842 (last acessed 04.07.2026).

45 The applicant must demonstrate the capacity to supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market (Article 40(4)(a) of the Pharma Package Regulation).

46 The voucher cannot be used for any product that has had annual gross sales exceeding €490 million in the Union in the preceding four years (Article 41 (1) of the Pharma Package Regulation).

47 Article 41(3) of the Pharma Package Regulation: "A voucher may be transferred to another marketing authorisation holder and shall not be transferred further."

48 The total number of vouchers available is capped at five (reduced from the ten in the initial proposal) (Article 43 of the Pharma Package Regulation).

Between Pharmaceutics and Therapy: Advanced Therapy Medicinal Products (ATMP)

Personalised medicine blurs the line between pharmaceuticals or devices on one hand and therapy on the other.[49] CAR-T cell (chimeric antigen receptor T-cell) therapy, as an important example, uses engineered T cells from the patient to treat cancer. A special regulation governs Advanced Therapy Medicinal Products (ATMPs) like CAR-T cells.[50] The Biotech Act also specifically addresses ATMPs. The Pharma Package provides special regulatory rules for ATMPs, such as the hospital exemption and, potentially, an "adapted framework" for less complex ATMPs (Articles 2 and 28, Recital 18 of the Pharma Package Directive).

Medical Devices and Digital Health

Medical devices are increasingly characterized by digital technology. The Medical Device Regulation (MDR)[51], replacing the old Medical Device Directive, is a product regulation which very early adapted the regulation of physical products to include digital products (software as a medical device, cf. Article 2(1) MDR). Consequently, product liability was extended to apply to software too.[52]

The Medical Device Regulation now also relates to AI regulation. The AI Act may apply if AI-based medical devices are concerned. AI systems could be classified as high-risk according to Article 6(1) AI Act if they are intended to be used as a safety component for the medical device (Article 6(1) lit. a AI Act), and if a third-party conformity assessment is necessary according to the MDR (Article 6(1) lit. b, Annex I number 11 AI Act). The resulting double compliance is intended by the lawmaker (see recital 64 AI Act). However, an agreement was reached at the political level to reduce the regulatory burden.[53]

Data as the Basis for Pharmaceutical Research

Not only clinical data (which come into play when applying for marketing authorization) but also real-world data are increasingly important for the development of new pharmaceuticals. Whereas the General Data Protection Regulation (GDPR)[54] has already been playing an important role, the introduction of the European Health Data Space Regulation (EHDS)[55] will significantly enhance the ability to access relevant data.

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49 *Fausch*, Personalised medicine as a challenge for patent law, 2020.

50 Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.

51 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

52 See fn. 31.

53 See *Council of the European Union*, Press Release, Artificial Intelligence: Council and Parliament Agree to Simplify and Streamline Rules, 7 May 2026, available at: https://www.consilium.europa.eu/en/press/press-releases/2026/05/07/artificial-intelligence-council-and-parliament-agree-to-simplify-and-streamline-rules/ (last accessed on 15 May 2026): "As for the AI act's rules for industrial AI and their interplay with sectoral legislation in sectors such as medical devices, toys, lifts, machinery and watercraft, a compromise was found between the co-legislators on a mechanism that allows to resolve situations in which sectoral law has similar AI-specific requirements to the AI act, by limiting the latter's application in those specific cases through implementing acts." See also *Council of the European Union*, Interinstitutional File: 2025/0359 (COD), Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence - Letter sent to the Eu-ropean Parliament, 13 May 2026.

54 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

55 Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

3.1.2 Crops and Agriculture

The green sector experiences an increasing rate of innovation. The technological developments range from conventional breeding to (classical) genetic engineering and on to genome editing. Technologies such as breeding-by-editing (using intra-species genome editing) significantly speed up the breeding process. Further, external drivers like increased constraints due to climate change act as an accelerator. Alongside the development of new plants, plant protection plays a major role.

Conventional Breeding and Genetic Engineering

Plant innovations are subject to special legal protection under plant variety rights.[56] Therefore, patent law contains rules concerning the delineation between patents and plant variety rights (Article 53(b) EPC). Broadly speaking, this rule excludes classical breeding from patent protection but includes genetic engineering. The advent of marker-assisted breeding sparked a succession of case law and legislative changes, resulting in methods and results being treated alike (Rule 28(2) EPC).[57] Marker-assisted breeding and resulting plants were ultimately decided to be excluded from patentability.

Regulatory law intervenes through seed marketing legislation. Interestingly, German seed law explicitly evaluates the societal value of new plant varieties by requiring the demonstration of a cultural value ("landeskultureller Wert") for many new plant varieties. § 34 SaatG (German Seed Marketing Law) stipulates that a variety possesses cultural value if it promises a significant improvement for crop production, the utilisation of the harvested crop, or the utilisation of products derived from the harvested crop, compared to other approved varieties. The EU plans to replace multiple existing Directives concerning plant reproductive material (PRM) with a single Regulation.[58] A key aspect of this regulation will be the introduction of a mandatory Value for Sustainable Cultivation (VSC) test, focusing on climate resilience.

Regarding genetically engineered plants, genetic engineering law is concerned.[59] However, within the EU – due to the legal and the political climate – genetic engineering in the plant sector has historically remained unsuccessful.

56 Regulation (EC) No. 2100/94 on Community plant variety rights.

57 For an overview see *Metzger/Zech*, A Comprehensive Approach to Plant Variety Rights and Patents in the Field of Innovative Plants, in: Godt/Lamping (eds.): A Critical Mind, Hanns Ullrich's Footprint in Internal Market Law, Antitrust and Intellectual Property, 2023, pp. 619 – 654.

58 Proposal for a Regulation of the European Parliament and of the Council on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC (Regulation on plant reproductive material), COM(2023) 414 final. Trilogue negotiations concerning the Plant Reproductive Material (PRM) Regulation began in February 2026. A provisional agreement was reached on 15 June 2026 (https://www.consilium.europa.eu/en/press/press-releases/2026/06/15/council-and-parliament-reach-provisional-deal-on-new-rules-for-plant-reproductive-material/, last accessed on July 2026).

59 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

New Genomic Techniques

Genome editing has led to a renewed debate over the regulation of genetic engineering. One of the central legal disputes in 2025 concerned the regulation of plants produced by using New Genomic Techniques (NGT) such as CRISPR/Cas. After the European Court of Justice decided in 2018 that NGT plants generally fall under the restrictive GMO Directive 2001/18/EC,[60] the EU Commission initiated a reform process that resulted in a provisional agreement between the Council and Parliament in December 2025.[61] The legal framework distinguishes between two categories to account for scientific progress while maintaining the precautionary principle: Category 1 (NGT1) includes plants considered equivalent to conventionally bred plants. They are designed to have genetic modifications that could have also occurred naturally or through conventional breeding, containing no "foreign" (transgenic) DNA. For these plants, the complex risk assessment and labelling requirements for end products are waived, representing a paradigm shift in European approval practice. The identification occurs via a verification process with national authorities. Category 2 (NGT2) plants, however, remain within the strict GMO regime. Herbicide tolerances are prohibited from Category 1; plants with such traits automatically fall under Category 2.

Plant variety protection is available for new plant varieties regardless of their origin – classical breeding, genetic engineering or NGT. In patent law NGTs are comparable to classical genetic engineering. The European Parliament, however, demanded a total patent ban for NGT plants to avoid dependencies on multinational seed corporations.[62] The compromise reached in December 2025 reads that patents on NGT processes and products remain possible but introduces measures to improve transparency concerning the existence of patent protection benefiting a plant for which the verification of NGT 1 status has been requested, including a publicly available database.[63] In line with EPO practice, natural traits are to remain free from patent protection by including disclaimers in the patents.[64]

The societal acceptance of NGT plants remains to be seen. Genetic engineering suffered from a lack of public acceptance in the European Union. Whether NGT will be perceived differently is also an interesting question for social sciences. In addition, the public perception of the interplay between sustainability issues, climate change and NGT plants as a potential mitigator should be researched.

60 CJEU, Grand Chamber, 25 July 2018, Case C-528/16, *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture, de l'agroalimentaire et de la forêt*, ECLI:EU:C:2018:583.

61 Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, COM(2023) 411 final, 5 July 2023. The agreement on new EU rules for plants obtained by using new genomic techniques (NGTs) was reached on 3 December 2025 by the Council and the European Parliament. See Council of the European Union, LIMITE doc. 16660/25, 11 December 2025. Accepted by the Council on 21 April 2026 (https://www.consilium.europa.eu/en/press/press-releases/2026/04/21/new-genomic-techniques-council-adopts-new-rules-to-boost-sustainable-and-competitive-eu-food-systems/, last accessed on 4 July 2026).

62 For a comprehensive overview of the public policy questions see *Kim/Kock/Lamping/Batista/Hilty/Slowinski/Steinhart*, New Genomic Techniques and Intellectual Property Law: Challenges and Solutions for the Plant Breeding Sector. Position Statement of the Max Planck Institute for Innovation and Competition, 2023.

63 Articles 6(3a), 7(2a), 9(1)(fa), and Recitals 16, 24.

64 Recital 46c: "[…] To ensure that patents on plants made by technical methods do not extend to plants that have been produced by essentially biological processes and carry the same characteristics, the European Patent Office requires that a disclaimer be included in the patent. Therefore, for a plant obtained by technical processes, the part of the patent claim defining exactly what is to be protected is required to specify that the patent does not include plants produced by essentially biological processes."

Genetic Resources

Genetic Resources are the subject of biodiversity law. For plants, the Nagoya Protocol on Access and Benefit Sharing and, as a special treaty for key crops, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) are of interest.[65] The Nagoya Protocol steps in at the research level when genetic resources are utilised – meaning researched (Article 3(5) of the Access and Benefit-Sharing Regulation[66]). In this context, digital technology has had an immense impact with the increasing use of Digital Sequence Information (DSI) and the resulting debate on how to treat DSI in biodiversity law.[67] Since COP16 in 2024, a multilateral mechanism for benefit-sharing in DSI is established (for the ITPGRFA, an update of the Multilateral System of Access and Benefit-Sharing is under negotiation). Companies developing new varieties based on publicly available gene sequences are expected to contribute to the so-called "Cali Fund". The legal difficulty lies in traceability: Breeders must document whether the sequence used falls under the Nagoya Protocol and whether Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) from the country of origin are in place. Violations of these due diligence obligations can lead not only to fines but even injunctions.[68]

Biodiversity is also linked to patent law, as the new WIPO agreement (GRATK Treaty)[69] provides for disclosure requirements regarding the origin of genetic resources.[70] However, this is not a patentability requirement.[71] While the treaty allows for sanctions for non-compliance, it protects against immediate patent revocation for bona fide errors, focusing instead on rectifying the disclosure (Article 5 GRATK Treaty).

Plant Protection and Fertilisers

The legal framework for innovation in plant protection is similar to pharmaceutical innovation law. Supplementary protection certificates are also available for plant protection products.[72] In addition, plant protection law provides for regulatory data exclusivity (Article 59 of the Plant Protection Products Regulation).[73] The reason for the similarity is the chemical technology basis.

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65 Fn. 18.

66 Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. Article 3(5) reads: "'utilisation of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention".

67 See *Klünker*, Die Tragödie des Access and Benefit-Sharings: Nutzungsregeln für genetische Ressourcen und digitale Sequenzinformation, 2024.

68 See § 2 of the German *Gesetz zur Umsetzung der Verpflichtungen nach dem Nagoya-Protokoll und zur Durchführung der Verordnung* (EU) Nr. 511/2014.

69 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge.

70 Similarly already § 34a PatG.

71 In Germany § 34a(1)(2) PatG stipulates that the disclosure of the geographical origin of biological material "is without prejudice to the examination of applications or the validity of rights arising from granted patents". However, § 34a(2) PatG stipulates that the German Patent and Trade Mark Office notifies the Federal Agency for Nature Conservation as the competent authority.

72 Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.

73 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. The data exclusivity rules are modified by general rules on the avoidance of duplicative testing and by rules on the (compulsory) sharing of tests and studies involving vertebrate animals (Articles 61 and 62)

Another important link between agriculture and chemistry is the supply of fertilisers.[74] Especially compounds which can be used as nitrogen fertilisers are energy-intensive to produce (see the section on basic chemicals). On the other hand, the use of fertilisers is environmentally sensitive and therefore strictly regulated.[75] Nitrogen fertilising is also linked to plant breeding, as some plants, with the help of microorganisms, are able to fixate nitrogen biologically. This offers an alternative to synthetic fertiliser.

Agriculture and Forestry

Land use and disuse are increasingly regulated at the European level, with a special focus on climate change. Not only must agriculture and forests adapt to climate change, but measures like rewetting peatlands can also contribute significantly to the reduction of hothouse gases in the atmosphere. Examples for European regulation include the LULUCF (land use, land use change and forestry) Regulation[76] and the Nature Restoration Law.[77]

Increasingly, the intersection with digitalisation is regulated. Drone use (e.g. for fawn rescue, plant protection or the precise application of fertilisers) is subject to aviation and data protection regulations. Agricultural data spaces are part of the Common European Data Spaces envisioned in the Data Governance Act. Agricultural data was also at the heart of the discussion that led to the *Data Act*. The rules on data sharing (Articles 3 – 7 of the Data Act) mean that farmers will have more rights to the data generated by deployed machines and sensors.

3.1.3 Chemistry: Raw Materials and Basic Chemicals

Chemistry is the backbone of many economic activities, similar and closely linked to energy supply. Innovations in the chemical sector are therefore important enablers for innovations in other sectors, like biotechnology and digital technology but on an even more fundamental level.

Patents on chemical processes and products, especially compound protection, constitute an important part of patent law. Regulatory law is governed by Regulation 1907/2006 (REACH).[78] While it was set to be amended by REACH 2.0, the revision process is currently suspended.[79] There are also exclusivity rules concerning data submitted for registration purposes (Articles 10(a), 25(3) REACH).[80]

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74 *Metzger/Kusch*, Innovation Policy Beyond Patents: A Case Study on the Development of Climate-Friendly Fertilizers, GRUR International 2024, pp. 742 – 750.

75 In Germany by the Fertiliser Application Ordinance (DüV).

76 Regulation (EU) 2018/841 of the European Parliament and of the Council of 30 May 2018 on the inclusion of greenhouse gas emissions and removals from land use, land use change and forestry in the 2030 climate and energy framework, and amending Regulation (EU) No 525/2013 and Decision No 529/2013/EU.

77 Regulation (EU) 2024/1991 of the European Parliament and of the Council of 24 June 2024 on nature restoration and amending Regulation (EU) 2022/869.

78 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Com-mission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

79 See *European Parliament*, legislative Train Schedule: Revision of the REACH Regulation, available at: https://www.europarl.europa.eu/legislative-train/theme-a-new-plan-for-europe-s-sustainable-prosperity-and-competitiveness/file-revision-of-the-reach-regulation (last accessed on 15 May 2026): "On 27 April 2026, environment Commissioner Jessica Roswall said to the ENVI Committee that the long-delayed plan to overhaul the REACH Regulation would not go ahead: "We have come to the conclusion to not open REACH at this point"."

80 There are also rules on the (compulsory) sharing of existing data in the case of registered substances and on the sharing of data involving tests for phase-in-substances (Articles 27(6), 30(3) REACH).

The chemical sector has a strong link to biotechnology. Chemicals can often be produced using biotechnological methods or are utilized as starting materials in biotechnological processes. The sector is also a linked to digital technology due to its increasing relevance for the development and control of chemical processes. The sector-specific data law consists of the Common European Data Space for Chemicals with a new common data platform on chemicals, as part of the "One Substance, One Assessment" (OSOA) package which entered into force on 1 January 2026.[81]

Raw Materials and Basic Chemicals as the Foundation of Industrial Production

As already noted, the importance of chemistry for public welfare results from its function as a basis for many other relevant sectors. Innovations in chemistry can enable innovations in other sectors. Within the chemical sector itself, however, some chemicals serve as the fundamental building blocks of the chemical industry itself (basic chemicals)[82]. The availability of these chemicals is important for the whole economy. The production of basic chemicals, in turn, requires the necessary raw materials. Therefore, the entire value chain, from raw materials to basic chemicals, leading up to fine chemicals and finished products, must be considered.

Not only from a patent law, but also from an economic perspective, chemical compounds (and chemical products in general) can be analysed regarding their production and their applications. The uses comprise, as shown, the manufacturing of fine chemicals and finished products for many sectors, including digital technology and pharmaceuticals. Chemical innovations also have a special importance for energy innovations, such as rechargeable batteries and solar cells.

Major areas of production methods include petrochemical production (classical, having superseded coal-based chemistry), electrochemistry (an increasingly vital field, particularly due to its nexus with renewable energies) and biotechnological production (also garnering interest as an alternative to petrochemical methods). From a regulatory perspective, standard production methods or Best Available Techniques (BAT) for basic chemicals can be identified: Reference documents have been published by the European Integrated Pollution Prevention and Control Bureau (EIPPCB) as part of the information exchange carried out under Article 16(2) of Council Directive 96/61/EC (IPPC Directive).[83] This is an example of an information exchange organised by the state as a promoter of technology diffusion.

Besides the classical focus of chemicals regulation, health and environmental impact, two more aspects have gained importance: Availability problems due to energy-intensive production and due to raw-materials, which cannot be substituted (and are, in turn, difficult to source). Chemical innovations may lead to production methods with lower energy consumption or may enable the substitution of chemicals with more easily available materials, regarding the entire value chain from raw materials to finished products.

81 Regulation (EU) 2025/2455 of the European Parliament and of the Council of 26 November 2025 establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals.

82 Basic chemicals are key compounds on which the chemical industry is reliant, see: https://www.enargus.de/pub/bscw.cgi/d4629-2/*/*/Grundstoffchemie?op=Wiki.getwiki&search=Nutzenergie (last accessed on 15 May 2026).

83 *European Commission*, Reference Document on Best Available Techniques for the Manufacture of Large Volume Inorganic Chemicals – Solids and Others industry; Reference Document on Best Available Techniques for the Manufacture of Large Volume Inorganic Chemicals - Ammonia, Acids and Fertilisers.

Energy-Intensive Production: Hydrogen and Nitrogen Compounds

Many basic chemicals are energy-intensive to produce. The chemical industry, therefore, belongs to the most energy-intensive sectors (27.9 % of total industrial energy consumption in Germany).[84] The CBAM (Carbon Border Adjustment Mechanism), a climate policy tool that puts a fair price on carbon emitted during the production of carbon-intensive goods imported into the EU, is immensely important for the chemical industry. The Energy Efficiency Directive[85] with its energy efficiency targets directly influences energy-saving innovations in the chemical sector.

The energy sector itself, arguably, is a sector deserving closer analysis regarding its innovation regulation framework. However, in this area, state market problems and state intervention are complex enough to demand a research field of its own (energy economics). In addition, innovation exists (especially within renewable energies) but it is also highly driven by specific regulation. Finally, many assumptions hinge on the potential realisation of future technologies. Fission and fusion as potential technologies are politically highly contested. The realisation of fusion energy remains open but, interestingly, the sector is seeing a rise in privately financed research activities (at technology readiness levels 3 to 5). The Net-Zero Industry Act (NZIA)[86] aims to accelerate the production of clean technologies in Europe.

Hydrogen is an example of a basic chemical that is energy-intensive to synthesise. It also links to the energy sector because it can be used as an energy carrier and can be synthesised using electricity from renewable sources (using hydrolysers, the product being called "green" hydrogen). Currently, however, most hydrogen is produced from natural gas (by steam reforming, yielding "grey" hydrogen). Germany, through its National Hydrogen Strategy, directly intervenes to ensure the availability of sufficient hydrogen and the development of an efficient hydrogen infrastructure. With the Hydrogen Core Network, the existing pipeline network is to be enlarged. In addition, the Hydrogen Acceleration Act (WassBG) seeks to accelerate project planning, streamline environmental reviews, and simplify permitting of hydrogen production, storage, and pipelines.[87] From a technological point of view, innovations for hydrogen synthesis (inter alia, electrolysis, biotechnology, and artificial photosynthesis) and storage (inter alia, compressed gas, liquefied hydrogen, and metal hydrates) can be quite complex.

Ammonia (NH_3), the key starting chemical for nitrogen compounds, is another basic chemical which is energy-intensive to synthesise. Nitrogen, being part of the atmosphere, is chemically quite stable. Therefore, a considerable amount of energy and the assistance of catalysts are needed for nitrogen to react with hydrogen to produce ammonia. The Haber-Bosch process, having been further developed over time and still being used today, achieves this.

84 *VDI Magazin*, 23 January 2026, p. 15. Cement and steel making are two additional key sectors which are highly energy intensive. According to Federal Statistics Office (Destatis), available at: https://www.destatis.de/DE/Themen/Branchen-Unternehmen/Industrie-Verarbeitendes-Gewerbe/produktionsindex-energieintensive-branchen.html (last accessed on 15 May 2026) in 2021 the production of chemical products had the highest energy consumption of all sectors in Germany, followed by metal production and processing (second highest) and coking and mineral oil processing (third highest).

85 Directive (EU) 2023/1791 of the European Parliament and of the Council of 13 September 2023 on energy efficiency and amending Regulation (EU) 2023/955 (recast).

86 Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724.#

87 Gesetz zur planungs- und genehmigungsrechtlichen Beschleunigung von Erzeugung, Speicherung, Import und Transport von Wasserstoff (Wasserstoffbeschleunigungsgesetz - WasserstoffBG).

Alternatives, like ammonia synthesis directly from water with lithium nitride Li_3N (EP 4 001 212 A1) have not yet advanced to industrial application. Nitrogen fixation is important for agriculture, as the starting point for nitrogen fertilisers. Apart from manure, chemical nitrogen fertilisers can also be substituted by nitrogen fixating plants (normally plants harbouring nitrogen fixating microorganisms, such as legumes). As an alternative to hydrogen, ammonia is also discussed as an energy carrier.

Hydrocarbons (like methane, ethane, ethylene, acetylene, propane, etc.) may also be classified as energy-intensive basic chemicals. They are mainly produced from natural gas (methane being the main constituent of natural gas) or petrol. However, Carbon Capture and Utilization (CCU) may serve as an alternative to petrochemistry. Biofuels can also be produced using biotechnological methods.

The Problem of Substitution: Critical Raw Materials

The second problem concerns chemicals which rely on scarce and non-substitutional raw. This problem of substitution occurs especially where "exotic" elements, which are used in cutting-edge industries, are concerned. Well-known examples are gallium, tantalum, and rare-earth elements (REE).

The problem is addressed by the Critical Raw Materials Act (CRMA).[88] Critical raw materials are deemed of high economic importance for Europe but are also highly vulnerable to supply disruptions. A list of critical raw materials, which is to be updated by a delegated act, is found in Annex II, Section 1 of the CRMA (Article 4 CRMA).[89] Among the 34 listed materials are not only outlandish elements, but also more common materials like coking coal and phosphorus (which, like fixated nitrogen, is important for fertilisers).[90]

Chemical innovations could help address the problem by finding economically viable substitutes. Innovations could also happen in other sectors, such as mining or metallurgy, creating new sources for critical raw materials.

Health and Environmental Risks

The protection of human health and the environment represent the classical aim of chemicals regulation (compare Article 1(1) REACH). Innovations may lead to a use of chemicals, which are less problematic, or to production methods, which are better suited to these aims.

88 Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020.

89 The European Commission identified in its reports an increasing number of critical raw materials; see https://single-market-economy.ec.europa.eu/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en (last accessed on 15 May 2026). See also the reports by the Bundesanstalt für Rohstoffe on the raw materials situation in Germany, available at: https://www.bgr.bund.de/SharedDocs/Pressemitteilungen/DE/BGR/bgr-2025-12-22_bericht-zur-rohstoffsituation.html (last accessed on 15 May 2026).

90 These materials include: antimony, arsenic, bauxite/alumina/aluminium, baryte, beryllium, bismuth, boron, cobalt, coking coal, copper, feldspar, fluorspar, gallium, germanium, hafnium, helium, heavy rare earth elements, light rare earth elements, lithium, magnesium, manganese, graphite, nickel — battery grade, niobium, phosphate rock, phosphorus, platinum group metals, scandium, silicon metal, strontium, tantalum, titanium metal, tungsten, vanadium.

A current example of a whole class of chemicals, which, if possible, should be replaced by substitutes are organic fluorine compounds (per- and polyfluoroalkyl substances, PFAS). A proposal for a universal restriction in the EU is currently being assessed.[91] Such a ban on certain chemical compounds creates an incentive for finding substitutes, steering innovation towards health and environment goals.

An older example is nanotechnology. Nanotechnological materials were not subjected to a special regulation but are regulated under REACH.[92] By setting up the *European Union Observatory for Nanomaterials* (EUON), which monitors safety and market data, an indirect approach to regulation was taken.

3.2 Sectors with a Focus on Digital Technology

This chapter addresses research areas defined by sectors with a focus on digital technology. The European Union recently issued a "Technological Sovereignty Package" (Communication on *European Tech Sovereignty*)[93], focusing on digital technology sovereignty[94] and reflecting four initiatives: the Chips Act 2.0, the EU Cloud and AI Development Act (CADA), the EU Open Source Strategy and a Strategic Roadmap for Digitalisation and AI in Europe.

The Communication on European Tech Sovereignty also mentions that fostering innovation in the digital sector must comprise the whole "technology stack", i.e. the whole value chain.[95] This idea also underlies the choice of sectors to be researched. At the same time, the sectors should be of high importance for Europe and Germany. Accordingly, three sectors, representing different tiers of the digital technology stack should be examined: semiconductors (2.1), data centres (2.2) and software and AI Models (2.3).

88 Regulation (EU) 2024/1252 of the European Parliament and of the Council of 11 April 2024 establishing a framework for ensuring a secure and sustainable supply of critical raw materials and amending Regulations (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1724 and (EU) 2019/1020.

89 The European Commission identified in its reports an increasing number of critical raw materials; see https://single-market-economy.ec.europa.eu/sectors/raw-materials/areas-specific-interest/critical-raw-materials_en (last accessed on 15 May 2026). See also the reports by the Bundesanstalt für Rohstoffe on the raw materials situation in Germany, available at: https://www.bgr.bund.de/SharedDocs/Pressemitteilungen/DE/BGR/bgr-2025-12-22_bericht-zur-rohstoffsituation.html (last accessed on 15 May 2026).

90 These materials include: antimony, arsenic, bauxite/alumina/aluminium, baryte, beryllium, bismuth, boron, cobalt, coking coal, copper, feldspar, fluorspar, gallium, germanium, hafnium, helium, heavy rare earth elements, light rare earth elements, lithium, magnesium, manganese, graphite, nickel — battery grade, niobium, phosphate rock, phosphorus, platinum group metals, scandium, silicon metal, strontium, tantalum, titanium metal, tungsten, vanadium.

91 See European Commission, Press Release, New EU Rules Limit PFAS in Drinking Water, 12 January 2026, available at: https://environment.ec.europa.eu/news/new-eu-rules-limit-pfas-drinking-water-2026-01-12_en (last accessed on 15 May 2026).

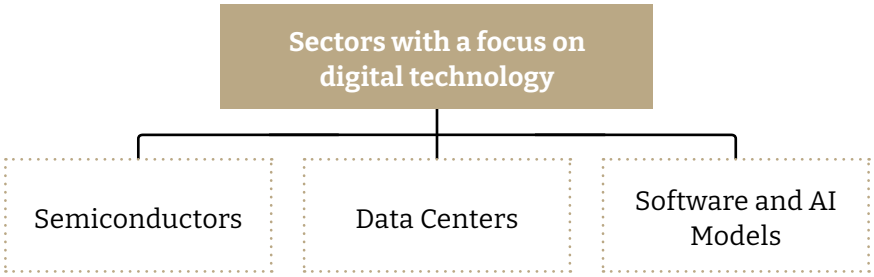
92 A definition of "nanoforms" of substances can now be found in Annex VI REACH. REACH requires manufacturers and importers to register nanomaterials and provide safety data. See Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances.

93 *European Commission*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Tech Sovereignty, accompanied by an EU Open Source Strategy, COM(2026) 503 final, 3.6.2026; cf. *European Council*, Meeting of 19 March 2026 – Conclusions, EUCO 1/26, No. 43(e).

94 The Communication defines technological sovereignty as follows: "Technological sovereignty denotes Europe's ability to develop, control and scale the critical technologies, infrastructure, services and data, including digital ecosystems, that underpin its economy, security and society, while derisking and diversifying supply chains and technological exposure to reduce strategic dependencies and resist foreign interference." (COM(2026) 503 final, p. 1, citing *Di Marco* et al., Open but Not Powerless: Towards a Common Understanding of EU Digital Sovereignty, European Commission, Joint Research Centre, 2025).

95 COM(2026) 503 final, p. 4: "A first lever is to build a 'European technology stack' to boost the EU 's capacity throughout the value chain."

Figure 6: Research on sectors with a focus on digital technology



3.2.1 Semiconductors

Semiconductors are the material backbone of digitalisation. As the example of TSMC shows, they have also become – much like critical raw materials – a major focus of geopolitical concern. Europe is not among the leading semiconductor developers. However, key basic technologies for cutting-edge semiconductors, such as lithographic machines (ASML), and the technologies underlying them, such as extreme ultraviolet (EUV) lasers (Zeiss/Trumpf), originate in Europe.

In a volatile geopolitical world, economic security has become a central pillar of legislation. The concept of "de-risking" aims to reduce strategic dependencies on systemic rivals – particularly China – without seeking full economic isolation. The most prominent example of this new industrial policy is the *European Chips* Act. It responds to global semiconductor shortages with the goal of strengthening European technological sovereignty. The legal framework rests on three pillars: strengthening innovation capacity (Pillar I), facilitating state aid for production facilities (Pillar II), and establishing a monitoring mechanism for crises (Pillar III).

Strengthening innovation capacity is mainly undertaken by focusing on bridging the gap between research and industrial application. This necessitates IP protection and licensing. Yet, the semiconductor industry is an example of an early misguided attempt to strengthen innovation in a specific sector by introducing a special IP right for semiconductor topographies.[96] Arguably, given the sector's short business cycles, lead time suffices to create competitive advantage for innovators. Accordingly, the Chips Act leaves IP protection unchanged and focuses instead on a Europe-wide design platform, pilot lines, competence centres, and financing. The *European Chips Act II*, which has yet to be proposed,[97] is expected to give the European Commission direct investment authority.

93 *European Commission*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Tech Sovereignty, accompanied by an EU Open Source Strategy, COM(2026) 503 final, 3.6.2026; cf. *European Council*, Meeting of 19 March 2026 – Conclusions, EUCO 1/26, No. 43(e).

94 The Communication defines technological sovereignty as follows: "Technological sovereignty denotes Europe's ability to develop, control and scale the critical technologies, infrastructure, services and data, including digital ecosystems, that underpin its economy, security and society, while derisking and diversifying supply chains and technological exposure to reduce strategic dependencies and resist foreign interference." (COM(2026) 503 final, p. 1, citing *Di Marco* et al., Open but Not Powerless: Towards a Common Understanding of EU Digital Sovereignty, European Commission, Joint Research Centre, 2025).

95 COM(2026) 503 final, p. 4: "A first lever is to build a 'European technology stack' to boost the EU 's capacity throughout the value chain."

96 Council Directive 87/54/EEC of 16 December 1986 on the legal protection of topographies of semiconductor products. This protection is mandated by Articles 35 – 38 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

97 European Commission, Proposal for a Regulation of the European Parliament and of the Council on a framework of measures for strengthening the Union's semiconductor ecosystem, repealing Regulation (EU) 2023/1781 (Chips Act 2.0), COM/2026/504 final.

3.2.2 Data Centres and Cloud Services: The Material Aspect of Digitalisation

Another hardware-related layer of the digitalisation "stack" is the construction and operation of data centres. This sector highlights not only the material dimension but also the energy dependency of digitalisation. A high number of data centres are located in the Frankfurt am Main region. Data centres are one of the few digital sectors where Germany is quite successful. It is therefore an interesting research subject to analyse how the existing legal and non-legal situation may have contributed to this success. Such research includes social sciences and economics. The key legal aspects comprise IT law but also energy law.

The Role of IP

Computer implemented inventions are patentable if they fulfil the requirements under the established COMVIK approach (especially regarding inventive step).[98] Business models, however, remain excluded from patentability. The microelectronics (semiconductors) basis has already been mentioned under 2.1.

Cloud Regulation, Data Protection, and Cybersecurity

Depending on the business model (lease of hardware versus cloud services), various layers of cloud regulation may apply. The Digital Services Act (DSA) applies to cloud computing services that qualify as hosting services (Articles 16-18 DSA). The Data Act contains rules enabling users to switch seamlessly between data processing services (Articles 23-31 DA).[99]

Data Protection applies whenever personal data are processed. However, a cloud service provider is generally deemed a data processor (Article 28 GDPR) because it processes personal data solely on behalf of the customer (the data controller).

Cybersecurity law applies primarily through the NIS 2 Directive.[100] Under the new German Federal Office for Information Security Act (BSIG), data centre operators, cloud providers and DNS service providers are categorised as "Digital Infrastructure" and are generally classified as "Essential Entities". Crucially, this classification is size-independent for data centre services. Unlike other sectors where regulation applies only to large enterprises, due to the systemic importance of data centres to the digital economy almost all commercial operators are subject to the highest tier of regulation.

98 EPO, Technical Board of Appeal, Decision of 26 September 2002, T 0641/00 (Two identities/COMVIK) of 26.09.2002, ECLI:EP:BA:2002 :T064100.20020926.

99 Council Directive 87/54/EEC of 16 December 1986 on the legal protection of topographies of semiconductor products. This protection is mandated by Articles 35 – 38 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

100 Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive). In Germany, the NIS 2 Directive was implemented via the NIS-2-Umsetzungsgesetz (NIS2UmsuCG), which in turn amended numerous legal acts, most notably the Gesetz über das Bundesamt für Sicherheit in der Informationstechnik und über die Sicherheit in der Informationstechnik von Einrichtungen (BSIG).

Energy Efficiency

Resulting from the immense power consumption of data centres, the legal framework governing energy efficiency is of paramount importance. The Energy Efficiency Directive (EED)[101] contains special rules for data centres with a power demand of the installed information technology (IT) of at least 500 kW, mandating them to report energy performance data (Article 12 EED). These reporting obligations are meant as a directed incentive to drive sustainability. However, they may also influence competitiveness.

In Germany, the EED was implemented via the Energy Efficiency Act (Energieeffiziengesetz, EnEfG). This broadened the scope of application for data centres and introduced substantive energy efficiency requirements. Prior to this legislation, energy efficiency was largely a voluntary pursuit driven by corporate social responsibility or operational cost reduction. The EnEfG transformed these objectives into legally binding mandates, establishing strict performance metrics for any facility with a non-redundant nominal electrical connected load of 300 kW or more (requiring high energy efficiency, mandatory utilization of waste heat, and the use of renewable energies).[102] This threshold effectively captures the vast majority of the German data centre market (including the colocation and hyperscale segments), leaving only the smallest edge deployments outside its immediate scope. As of May 2026, a new draft amendment is finalised to align these rules more closely with EU standards, potentially relaxing some of the initial targets.

3.2.3 Software and AI Models: The Immaterial Side

Despite prominent examples of strong European software firms like SAP, the main developers of software and especially AI models are predominantly located in the USA and China. This has led to a debate regarding Europe's lack of digital sovereignty. In the *Communication on European Tech Sovereignty*, the Commission mentions the importance of a functioning innovation ecosystem[103] and open source as a crucial contribution to achieving technological sovereignty (the open-source ecosystem forming part of a wider innovation ecosystem).[104] The legal framework concerning software and AI models no longer merely comprises IP law but also increasingly encompasses regulatory (cybersecurity) law.

The Role of IP

While IP protection for software is largely settled (with copyright protection,[105] patent protection for computer-implemented inventions,[106] and trade secret protection[107] serving as

101 Directive (EU) 2023/1791 of the European Parliament and of the Council of 13 September 2023 on energy efficiency and amending Regulation (EU) 2023/955 (recast).

102 Section 3, No. 24, and Sections 11-15 EnEfG.

103 See fn. 36.

104 *European Commission*, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Tech Sovereignty, accompanied by an EU Open Source Strategy, COM(2026) 503 final, 3.6.2026, p. 16.

105 Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs.

106 *European Patent Office*, Guidelines for Examination in the European Patent Office, Part G (Patentability), Chapter II (Inventions), 3. List of exclusions, 3.6 Programs for Computers: ""Computer-implemented invention" is an expression intended to cover claims which involve computers, computer networks or other programmable apparatus wherein at least one feature is realised by means of a computer program." The pivotal decision EPO Technical Board of appeal, 26 September 2002, T 0641/00 (Two identi-ties/COMVIK) of 26.09.2002 as the key jurisprudence outlining the patentability of computer-implemented inventions has already been mentioned. Cf. Guidelines for Examination in the European Patent Office, Part G (Patentability), Chapter VII (Inventive step), 5. Problem-solution approach, 5.4. Claims comprising technical and non-technical features.

107 Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.

the main pillars), IP protection for AI models and systems is still under debate (as already discussed in the section on AI at 2.2).

Regulatory Law

The transition from a phase of largely voluntary self-regulation to close-knit, risk-based legislation at the European level is fundamentally redefining the rules for innovation, market access, and liability. At the centre of this transformation are legislative acts such as the Artificial Intelligence Act (AI Act), the Cyber Resilience Act (CRA), and the modernised Product Liability Directive.

The Cyber Resilience Act (CRA)[108] establishes mandatory cybersecurity requirements for all hardware and software products connected to the internet placed on the EU market. Interestingly, Free and Open-Source Software (FOSS) is explicitly regulated with the aim to foster the development and deployment of free and open-source software, in particular by micro-enterprises and small and medium-sized enterprises (Recital 17 CRA). To support this, the framework introduces the concept of "open-source software stewards" (Article 24 CRA).

Research is required into the effects of this new regulatory background in the domestic European and German software industry. Arguably, the European sector previously faced difficulties in competing with the US Big Tech companies. The introduction of a regulatory framework might create a level playing field, favouring domestic industries. Conversely, the additional regulatory burden might stifle economic activity. The software industry is therefore a critical testing ground for determining the best approach to regulating highly innovative industries.

Liability Law

The modernised Product Liability Directive[109] now encompasses software and AI systems as products and even services as components.[110] However, under general German tort law, liability for negligence already existed for software providers. The new product liability regime may shift the dynamics concerning the burden of proof.[111] Like with other software-related European legal acts, the Directive does not apply to free and open-source software that is developed or supplied outside the course of a commercial activity (Article 2(2) Product Liability Directive).

108 Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act).

109 Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC.

110 See the corresponding discussion on the Product Liability Directive above in fn. 31. Under the old product liability framework, the question of whether product liability applies to computer programs that are not embedded in hardware was heavily debated; this question has now been resolved.

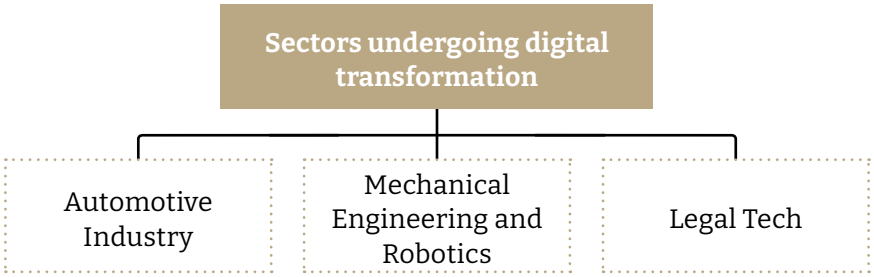
111 See Article 10(4) of the Product Liability Directive.

3.3 Exemplary Sectors Undergoing Digital Transformation

The third and last chapter focuses on sectors undergoing digital transformation. This encompasses sectors that traditionally did not focus on digital technology but are currently undergoing digital transformation as their key driver of innovation, such as automotive and mechanical engineering. Key sectors of the European and the German economy are rooted in traditional technology and face the dual challenge of digitalisation and the risk of a "mid-tech trap." A problem that occurs when excessive effort is devoted to evolving existing technologies at the expense of developing revolutionary solutions.

As an important part of the classical industry, the automotive sector, should be addressed (3.1). Mechanical engineering and robotics form another sector where products become ever smarter (3.2). Legal tech, on the other hand, represents a service sector undergoing digital transformation (3.3).

Figure 7: Research on sectors undergoing digital transformation



3.3.1 Automotive Industry

In Germany, the most preeminent example for a transforming sector is the automotive industry. It is not only undergoing digital transformation but also a simultaneous transformation of its core technology – shifting from combustion engines to electric motors (and potentially other technologies like hydrogen fuel cells). However, this industry is subject to extensive sector-specific regulation (similar to the energy sector). Alongside these rules, the AI Act, the Data Act, and the Cyber Resilience Act form critical new components of the applicable legal framework. An attempt to derive legally binding obligations concerning climate-relevant actions or omissions of individual companies and consumers from German civil law was rejected by the Federal Court of Justice (BGH).[112]

In IP law, the car manufacturing industry played a pivotal role in the debate about standard-essential patents (SEPs) and in the introduction of Section 139(1), Sentence 3 of the German Patent Act (PatG), which codified the principle of proportionality in patent injunctions. This shows that IP protection, for the car industry, is not only an innovation promoter but also a potential hindrance, particularly regarding digital technology.

112 Federal Court of Justice (4th Civil Senate), Judgment of 23 March 2026 – VI ZR 334/23.

In data law, the automotive sector has served as a pioneer, notably in the handling of personal data in cars and through special rules for mandatory data sharing in the Type Approval Regulation.[113] The latter imposes obligations on manufacturers to provide vehicle On-Board Diagnostics (OBD) information and vehicle repair and maintenance information (Article 61). Currently, the Data Act obligates manufacturers to share data from connected cars directly with users and third-party service providers.[114]

In the debate over liability for autonomous systems, self-driving cars have been a central focus. With the new product liability regime, clear rules for manufacturers of cars and components (both hardware and software) were created, enhancing legal certainty.

These aspects show that car manufacturing is not only important economically but is also an interesting case study where a classic industry is undergoing digital transformation and therefore multiple regulations apply.

3.3.2 Mechanical Engineering and Robotics

Mechanical engineering is another sector of the German economy, which is both economically important and undergoing digital transformation.

Machinery Perspective

The most important regulation for mechanical engineering is the Machinery Regulation (replacing the old Machinery Directive).[115] One of the most significant changes concerns the definition of safety components, which now explicitly includes software (Article 3(3) Machinery Regulation).

The software aspect also plays a major role in product liability. With the new Product Liability Directive not only the physical machines but also software as such fall within the definition of product or component.[116] In addition, digital manufacturing files (for 3D printing/additive manufacturing) will also qualify as products.[117] However, Product Liability does not cover damages to property used exclusively for professional purposes or damages to data used also for professional purposes (whereas general German tort law does).[118] Arguably, contractual liability is and will be the most important liability regime for machine manufacturers in business-to-business relationships.

112 Federal Court of Justice (4th Civil Senate), Judgment of 23 March 2026 – VI ZR 334/23.

113 Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC.

114 See *European Commission*, Communication, Guidance on Vehicle Data, Accompanying Regulation 2023/2854 (Data Act), C(2025) 6119 final, 12 September 2025.

115 Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC. Full applicability is set for 20 January 2027.

116 See the discussion on product liability referenced above in fn. 31.

117 Article 4(1) of the Product Liability Directive.

118 Article 6(1)(b)(iii) Product Liability Directive: "property used exclusively for professional purposes" is excepted. Article 6(1)(c): only "destruction or corruption of data that are not used for professional purposes" is encompassed.

Concerning IP protection, mechanical engineering is one of the classical fields of technology eligible for patent protection. Additive manufacturing may raise special problems, e.g., the question whether digital manufacturing files may constitute a direct infringement of product patents.[119] Another important area is data access rights and trade secrets protection.

Data Perspective

The data perspective has gained prominence due to the increasing interconnectedness of things. This increase led to technology debates surrounding the Internet of Things (IoT) or cyber-physical systems, which, when applied in manufacturing, were discussed as "Industrie 4.0" or Industrial Internet of Things (IIoT). A further development is the use of "Digital Twins," which strive to replicate physical machines with increasingly detailed digital models, dynamically reflecting changes in the physical machines. The interconnectedness of machines led to an increasing availability of data (which at first were supposed to be used in Big Data applications and now are being used as training data for AI).

The most important legal consequence of this factual availability of data (and a perceived underuse thereof) is the Data Act. This legal act, especially the rules on data sharing (Articles 3-7 Data Act), was developed specifically for IoT data. The rules on data sharing a huge challenge for the data holders (often identical with the machine manufacturers), as they place the user in a linchpin position to decide whether to share data generated by the use of a connected product.[120] An important question from an IP perspective will be the relationship between these mandates and trade secret protection.

Another consequence of this connectivity is the applicability of cybersecurity regulation in the form of the Cyber Resilience Act (CRA). The CRA applies to *products with digital elements made available on the market, the intended purpose or reasonably foreseeable use of which includes a direct or indirect logical or physical data connection to a device or network* (Article 2(1) CRA). Both, software and hardware products qualify as products with digital elements (Articles 3(1) CRA). This encompasses interconnected machines. The increasing connectivity of machines in the IIoT therefore makes cybersecurity (covering the entire lifecycle of digital products) a mandatory prerequisite for product safety. For machine manufacturers, this means a fundamental expansion of their risk assessment, which must now go beyond physical safety to anticipate cyber threats.

119 See *Abegg-Vaterlaus*, Die Patentverletzung durch additive Fertigung (3D Druck), 2018.

120 Cf. *Zech*, in: Sattler/Zech (eds.), The Data Act: First Assessments, 2024, p. 53-66 (at 61-64).

Robotics and AI

Robotics is the key driver of innovation in manufacturing. Whereas highly automated robots (and manufacturing facilities) already exist, increasingly AI is used to control these machines. Physical AI is regarded as one of the key future developments in AI. For industrial applications this means a shift from automation to autonomy. It is also of high strategic relevance for the future of industrial production (especially when labour is scarce). For domestic companies, domain-specific AI (specifically trained, less prone to hallucination, e.g., industrial AI) will offer a compelling business opportunity.

One of the legal consequences is the applicability of the AI Act. Often, physical AI will be regarded as high-risk AI (according to Article 6(1) AI Act). High-risk AI systems in machinery may include AI systems intended to be used as a safety component of a machine (Article 6(1) lit. a AI Act). If the machine is required to undergo a third-party conformity assessment under the Machinery Regulation the second requirement for being considered high-risk is also fulfilled (Article 6(1) lit. b, Annex I number 1 AI Act). Such a requirement may follow from the categorisation under Annex I, Part A of the Machinery Directive, especially numbers 5 and 6, mentioning self-evolving behaviour.[121] An initiative to exempt industrial AI from the AI Act (in the European Parliaments position for a Digital Omnibus on AI) illustrates the tensions in this regulatory area.[122] Currently (as of 7 May 2026), a compromise was found to exempt the machinery regulation from the direct applicability of the AI Act.[123]

3.3.3 Legal Consulting

As an example of the use of Domain-specific Language Models (DSLMs) in a service sector, legal consulting is particularly interesting. Legal consulting is a regulated sector which currently is undergoing dramatic changes due to AI. Further, it is an interesting sector for lawyers due to the proximity to their profession. Potential competitive advantages may arise from the use of proprietary training data in the form of copyright protected legal literature. One example of an enterprise undertaking the development of such a domain-specific model is Noxtua,[124] having access to literature from major German legal publishers. However, this business model is not undisputed.[125]

121 Annex I, Part A Machinery Regulation: "Categories of machinery or related products to which a procedure referred to in Article 25(2) shall be applied: […] 5. Safety components with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions. 6. Machinery that has embedded systems with fully or partially self-evolving behaviour using machine learning approaches ensuring safety functions that have not been placed independently on the market, in respect only of those systems."

122 *European Parliament*, P10_TA(2026)0098, Simplification of the Implementation of Harmonised Rules on Artificial Intelligence (Digital Omnibus on AI), Amendments adopted by the European Parliament on 26 March 2026 on the proposal for a regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) (COM(2025)0836 – C10-0304/2025 – 2025/0359(COD)).

123 See *Council of the European Union*, Press Release, Artificial Intelligence: Council and Parliament Agree to Simplify and Streamline Rules, 7 May 2026, available at; https://www.consilium.europa.eu/en/press/press-releases/2026/05/07/artificial-intelligence-council-and-parliament-agree-to-simplify-and-streamline-rules/ (last accessed on 15 May 2026). See also Council of the European Union, Interinstitutional File: 2025/0359 (COD), Proposal for a Regulation of the European Parliament and of the Council amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence - Letter sent to the European Parliament, 13 May 3036.

124 See the official website of the Noxtua platform, available at: https://www.noxtua.com/de/ (last accessed on 15 May 2026).

125 For arguments against the licensing practices of a major publisher regarding AI training see *Grünberger*, Warum ich den KI-Vertragsergänzungen des Beck-Verlags nicht zustimme, Verfassungsblog, available at: https://verfassungsblog.de/warum-ich-den-ki-vertragserganzungen-des-beck-verlags-nicht-zustimme/ (last accessed on 15 May 2026).

Apart from this competitive perspective, Large Language Models have opened up the possibility for machines to apply legal rules with unprecedented success. The "Law as Code" initiative (sponsored by SPRIND) serves as an example.[126] Although the idea to automating the application of legal rules is quite old and largely depending on structuring legal rules into a clear logic form, AI allows to cope with the inherent imprecision of legal rules due to their natural language nature. Nevertheless, critical questions regarding the transparency (understandability) of legal decisions and effective judicial control remain to be addressed.[127]

4 Potential Outcomes

The results of the proposed research activities cannot be foreseen in their entirety. Ideally, new interrelations between different legal frameworks and successful or unsuccessful innovation policies will become clear. At the very least, the comparison between different sectors and varying legal approaches will allow for a more structured understanding of the existing legal framework and ongoing legislative projects.

The proposed mapping of the European legal frameworks for innovation serves as a necessary accompaniment to the intense legislative activities of the European Union. The comparison with other approaches, like those taken by the US and China, will provide an important source of arguments in the ongoing debate over how Europe can maintain and strengthen its position in the face of global competition from other innovation powerhouses.

From a German perspective, the contrast between the European extensive and detailed legislative approach and the traditional German ordoliberal thinking (which has itself been partially superseded by highly detailed regulations, for instance concerning energy-related innovations) stands out. Comparing these approaches represents a valuable contribution not only to legal and economic sciences, but also to social and political sciences.

126 See Federal Agency for Disruptive Innovation (SPRIND), Strategic Projects: Law as Code, available at: https://www.sprind.org/taten/strategische-projekte/law-as-code (last accessed on 15 July 2026).

127 For the perspective of the judiciary see: Einsatz von KI und algorithmischen Systemen in der Justiz, Grundlagenpapier der Präsidentinnen und Präsidenten der Oberlandesgerichte, des Kammergerichts, des Bayerischen Obersten Landesgerichts und des Bundesgerichtshofs, 2026, available at https://www.justiz.bayern.de/media/images/behoerden-und-gerichte/oberlandesgerichte/bamberg/pressemitteilungen/pressemitteilungen2026/ki-grundlagenpapier_2026.pdf (last accessed on 15 May 2026).

Annex: European Legislative Acts on Law and Innovation

Area of Technology	Legislative Act (Title)	Status (planned/proposed/ agreed/in force)
Life Sciences and Chemistry	Biotech Act I	*Announced*
	BiotechAct II	*Announcement planned for the end of 2026*
	NGT Regulation	*Adopted on 17 June 2026*
	Pharma Package	*Political agreement*
	Regulation (EC) No 1394/2007 on advanced therapy medicinal products (ATMP Regulation)	*In force*
	Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use	*In force*
	Regulation (EC) No 726/2004 laying down Union procedures for authorisation/ supervision of medicinal products and establishing EMA	*In force*
	Regulation (EC) No 1901/2006 on medicinal products for paediatric use	*In force*
	Critical Medicines Act (CMA)	*Provisional political agreement*
	Directive 2001/83/EC / Community code relating to medicinal products for human use	*In force*
	Regulation (EC) No 2100/94 / Community Plant Variety Rights Regulation	*In force*
	PRM Regulation Proposal, COM(2023) 414 final	*Provisional deal*
	Directive 2001/18/EC / GMO Directive	*In force*
	Regulation (EU) No 511/2014 / Access and Benefit-Sharing Regulation	*In force*

	Regulation (EC) No 1610/96 / SPCs for plant protection products	*In force*
	Regulation (EC) No 1107/2009 / Plant Protection Products Regulation	*In force*
	Regulation (EU) 2024/1991 / Nature Restoration Law	*In force*
	Regulation (EU) 2018/841 / LULUCF Regulation	*In force*
	Regulation (EC) No 1907/2006 / REACH	*In force*
	REACH 2.0 / Revision of REACH Regulation	*Suspended*
	Regulation (EU) 2025/2455 establishing a common data platform on chemicals ("One Substance, One Assessment" (OSOA) package)	*In force*
	Regulation (EU) 2024/1252 / Critical Raw Materials Act / CRMA	*In force*
	PFAS universal restriction under REACH	*Under assessment*
	Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council	*In force*
Digital Technology	Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act)	*In force*
	Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance (Data Governance Act)	*In force*
	Directive (EU) 2019/790 of the European Parliament and of the Council of 17 April 2019 on copyright and related rights in the Digital Single Market and amending Directives 96/9/EC and 2001/29/EC.	*In force*

	Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.	*In force*
	EU Quantum Act	*Announced*
	Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information.	*In force*
	Council Directive 87/54/EEC of 16 December 1986 on the legal protection of topographies of semiconductor products	*In force*
	Directive (EU) 2022/2555 of the European Parliament and of the Council of 14 December 2022 on measures for a high common level of cybersecurity across the Union, amending Regulation (EU) No 910/2014 and Directive (EU) 2018/1972, and repealing Directive (EU) 2016/1148 (NIS 2 Directive)	*In force*
	Directive 2009/24/EC of the European Parliament and of the Council of 23 April 2009 on the legal protection of computer programs	*In force*
	Regulation (EU) 2024/2847 of the European Parliament and of the Council of 23 October 2024 on horizontal cybersecurity requirements for products with digital elements and amending Regulations (EU) No 168/2013 and (EU) 2019/1020 and Directive (EU) 2020/1828 (Cyber Resilience Act)	*In force*
	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a framework of measures for strengthening the Union's semiconductor ecosystem, repealing Regulation (EU) 2023/1781 (Chips Act 2.0) COM/2026/504 final	*Proposal adopted on 3 June 2026*

	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a framework of measures for strengthening Europe's cloud and AI ecosystem (Cloud and AI Development Act) COM/2026/502 final	*Proposal adopted on 3 June 2026*
	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689 and (EU) 2018/1139 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI) COM/2025/836 final	*Proposal adopted on 19 November 2025*
	Regulation (EU) 2016/679 / General Data Protection Regulation / GDPR	*In force*
	Regulation (EU) 2024/1689 / Artificial Intelligence Act / AI Act	*In force*
Other	European Research Area Act	*Announced*
	Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC and Council Directive 73/361/EEC.	*In force*
	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.	*In force*
	Directive (EU) 2023/1791 of the European Parliament and of the Council of 13 September 2023 on energy efficiency and amending Regulation (EU) 2023/955 (recast).	*In force*

	Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure.	*In force*
	Directive (EU) 2024/2853 of the European Parliament and of the Council of 23 October 2024 on liability for defective products and repealing Council Directive 85/374/EEC	*In force*
	Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC	*In force*
	Regulation (EU) 2023/956 of the European Parliament and of the Council of 10 May 2023 establishing a carbon border adjustment mechanism (CBAM)	*In force*
	Regulation (EU) 2024/1735 / Net-Zero Industry Act / NZIA	*In force*

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