2. The Biomedical Sciences

2.1. The Concept and Position of the Biomedical Sciences in the 21st Century

As this study is based on the doctoral dissertation defended at Vilnius University in Lithuania, the selection of the term 'biomedical sciences' for this research was determined by the terms used in this country's national legal provisions. The Universal Lithuanian Encyclopaedia indicates that biomedical sciences are 'one of the scientific fields according to the European Union Commission's classification of the sciences. As of 2012, biomedical sciences include: biophysics, biology, botany, ecology (and environmental sciences), pharmacy, medicine, nursing, odontology, dentistry, public health and zoology'.[439]

This definition is in line with the former Order of the Ministry of Education and Science of the Republic of Lithuania of 16 October 2012 (the 'Order of 2012'), which divided science into the following fields: (1) humanities; (2) social sciences; (3) physical sciences; (4) agricultural sciences; (5) biomedical sciences; (6) technological sciences.[440] The Order of 2012 divided the field of biomedical sciences into: biology, biophysics, ecology and environmental sciences, botany, zoology, medicine, odontology, pharmacy, public health and nursing.[441] The Order of 2012 remained in force until 6 February 2019, when a new Order adopting the Classifications of the Fields of Science and the Fields of Art was approved (the 'Order of 2019'), which currently provides the following classification of the fields of science: (1) natural sciences; (2) technological sciences; (3) medical and health sciences; (4) agricultural sciences; (5) social sciences; (6) humanities.[442]

The term 'biomedical sciences' was chosen for this study because of the Order of 2012 that was in force in the Republic of Lithuania until 6

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439 Visuotinė Lietuvių Enciklopedija <https://www.vle.lt/straipsnis/biomedicinos-mokslai/> accessed 30 May 2023.

440 16 October 2012 Order 'On the Confirmation of the List of Study Branches Comprising Science Fields' (*Dėl mokslo krypčių patvirtinimo*). *Valstybės žinios (Official Gazette)*, 2012, No. V-1457 (Order of 2012).

441 ibid.

442 6 February 2019 Order 'On the adoption of the Classifications of the Fields of Science and of the Fields of Art' (*Dėl Mokslo krypčių ir Meno krypčių klasifikatorių patvirtinimo*). *Valstybės žinios (Official Gazette)*, 2019, No. V-93 (Order of 2019).

February 2019. However, after the new Order of 2019 was approved, the term 'biomedical sciences' disappeared from the legal rules. Although at first glance that does not seem a very favourable development for this research, the decision of the Lithuanian Government not to use the term 'biomedical sciences' can be considered rather rational, in both a national and an international context.

The Order of 2012 included the term 'biomedical sciences'. However, apart from referring to the above-mentioned ten areas,[443] it did not provide any definition of this term. That would have been useful, as different classifications of the fields of science are given in both scholarly[444] and practical[445] sources, making biomedical sciences, which are a part of the object of this study, even more difficult to define and distinguish from other scientific and technological fields. The situation was further complicated by the fact that, in principle, neither Lithuanian nor foreign sources[446] provide a definition of the Lithuanian term 'biomedicinos mokslai' or the English term 'biomedical sciences'. Also, the terms 'life sciences'[447] and 'biotechnology'[448] which, at first glance, seem to be related to the analysed field of science, are commonly used in both Lithuanian and foreign schol-

443 Biology, biophysics, ecology and environmental sciences, botany, zoology, medicine, odontology, pharmacy, public health and nursing (Order of 2012).

444 E.g. George A Cogswell, 'The Classification of the Sciences' (1899) 8 The Philosophical Review 494, 494.

445 E.g. Organisation for Economic Co-operation and Development, Directorate for Science, Technology and Industry, Committee for Scientific and Technological Policy, 'Revised Field of Science and Technology (FOS) Classification in the Frascati Manual' (26 February 2007) <http://www.oecd.org/science/inno/38235147.pdf> accessed 30 May 2023 (Revised Field of Science and Technology (FOS) Classification in the Frascati Manual).

446 E.g. the term in question is met more frequently in accidental sources, the purpose of which is not to provide the scientific definition of 'biomedical sciences', but to explain the term to the general public. For example, the University of Oxford, in its publicly available information on study programmes, provides a definition of the term 'biomedical sciences' which states that it is an interesting and dynamic field that can help in understanding and treating illnesses and that is focused on 'how cells, organs and systems function in the human body' (University of Oxford, Admissions, Undergraduate, Courses A-Z of courses, Biomedical Sciences <https://www.ox.ac.uk/admissions/undergraduate/courses-listing/biomedical-sciences?wssl=1> accessed 30 May 2023). The term 'biomedical sciences' is also used in other sources, but the definition is not given (e.g. Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 5).

447 In Lithuanian: 'gyvybės mokslai'.

448 In Lithuanian: 'biotechnologija'.

arly literature. This situation concerning the term 'biomedical sciences' has led this study to search for related categories and analyse their relationship. Therefore, the adoption of the Order of 2019, which removed the term 'biomedical sciences' from the legal provisions and introduced two fields, natural sciences (*inter alia* including chemistry, biochemistry, biology, biophysics, botany and zoology)[449] and medical and health sciences (*inter alia* including medicine),[450] as possibly closest to the biomedical sciences, has not changed the focus of this study.

According to the classification of scientific and technological fields presented by the Organisation for European Economic Co-operation and Development (the 'OECD'), which is followed by the EU's statistics office (Eurostat), the following fields of science and technology exist: (1) natural sciences; (2) engineering and technology; (3) medical and health sciences; (4) agricultural sciences; (5) social sciences; (6) humanities.[451] Based on this classification, these fields are further divided into smaller areas (for example, natural sciences are comprised of mathematics, computer and information sciences, physical sciences, chemical sciences, earth and related environmental sciences, biological sciences and other natural sciences),[452] and then into even smaller units.[453]

In this international classification of the scientific and technological fields, the term 'biomedical sciences' is not used, and its definition is not available in any English-language sources. Based on a comparison of the content of the mentioned international documents and the Order of 2012,[454] it can be stated that, according to the classification outlined in the Order of 2012, the areas of science and technology that belong to the biomedical sciences fall under (1) the biological sciences that are part of the field of the natural sciences, and (2) the field of medical and health

449 Order of 2019.
450 ibid.
451 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 12.
452 ibid 6-7.
453 E.g. biological sciences are comprised of cell biology, microbiology, virology, biochemistry and molecular biology, biochemical research methods, mycology, biophysics, genetics and heredity, reproductive biology, developmental biology, plant sciences, botany, zoology, ornithology, entomology, behavioural sciences biology, marine biology, freshwater biology, limnology, ecology, biodiversity conservation, biology (theoretical, mathematical, thermal, cryobiology, biological rhythm), evolutionary biology, other biological topics (ibid 7).
454 Order of 2012.

sciences.[455] These are the areas listed in the current Order of 2019[456] which also seem to be closest to biomedical sciences.

The classification of the biomedical sciences as part of the two fields mentioned above (biology, as part of the natural sciences, and medicine) is supported by the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine), in the title of which biology and medicine are used as equivalents to 'biomedicine'.[457] The content of the aforementioned Convention on Human Rights and Biomedicine reveals that this legislation covers only actions related to the human body.[458] However, the definition of the term 'biomedical' provided by the Oxford Dictionary indicates that it should be understood 'as relating to both biology and medicine'.[459] The latter definition is also provided in Taber's Cyclopedic Medical Dictionary, where it is stated that the term 'biomedical' refers to the application of natural sciences in medical research.[460] In other sources, it is also indicated that the term 'biomedicine' is perceived as combining 'the traditional basic science of biology with the traditional technical practice of medicine',[461] adding that it is not clear where the said knowledge and medical practice begin and where they end: they are interconnected and interwoven.[462] In view of this, it can be held that the term 'biomedicine' can cover human, animal and plant-related aspects.

In the OECD Glossary of Statistical Terms, 'biomedical research' is described as: (1) the study of specific diseases and conditions (mental or physical), including the detection, cause, prophylaxis, treatment and rehabilitation of persons; (2) the design of methods, drugs and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions; (3) the scientific investigation required to understand the underlying life processes affecting disease and

455 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 7-9.
456 (1) natural sciences and (2) medical and health sciences (Order of 2019).
457 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) (adopted 4 June 1997).
458 ibid Articles 1-27.
459 Angus Stevenson (ed), 'Biomedical', *Oxford Dictionary of English* (3rd edn, OUP 2010) 168.
460 Donald Venes, 'Biomedical', *Taber's Cyclopedic Medical Dictionary* (2017) 266.
461 John M Ziman, *Science in Civil Society* (Imprint Academic 2007) 22.
462 ibid.

human well-being, including such areas as cellular and molecular bases of diseases, genetics and immunology.[463] Although this definition pertains to the aforementioned fields of biology and medicine, compared to the previously discussed sources, it can be viewed as narrower and limited to the activities related to human beings and their physical or psychological health.

The term 'life sciences' covers sciences that study living organisms: biology, botany, zoology, microbiology, physiology, biochemistry and related subjects.[464] According to the OECD classification,[465] all of these sciences belong to either biological or medical fields. As both of these sciences fall under the category 'biomedical sciences' outlined in the Order of 2012,[466] the term 'life sciences' can be equated with the biomedical sciences.

Scientific and technological advances affect not only the definition of biomedical sciences, but also the differentiation of their narrower constituent areas, for example, genetics, cell biology, ecology, microbiology, biochemistry and molecular biology.[467] It may be argued that this situation was influenced by the new tools and ideas that have emerged in the 21st century and have been used in biology in order to reveal new links between different fields of life sciences or erase the existing boundaries between them.[468] Organisations responsible for the policy of science indicate that the integration of science and technology will only increase, bringing more and more benefits to public health, food safety, environmental protection and other important socio-economic needs while extending beyond the biomedical sciences to areas such as information technology.[469] Therefore, biomedical sciences can be intertwined not only with related scientific fields, but also with branches of science and technology outside them.

463 OECD, *OECD Glossary of Statistical Terms* (OECD Publishing 2008).

464 Stevenson, *Oxford Dictionary of English* (n 459) 1021.

465 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 7-8.

466 Order of 2012. Currently, the sciences falling under the category 'biomedical sciences' according to the Order of 2012 are divided into two categories: (1) natural sciences and (2) medical and health sciences (Order of 2019).

467 Jerome H Reichman, Paul F Uhlir and Tom Dedeurwaerdere, 'Uncertain Legal Status of Microbial Genetic Resources' in Jerome H Reichman, Paul F Uhlir and Tom Dedeurwaerdere (eds) *Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (Cambridge University Press 2016) 1-33, 20.

468 ibid 20 citing NAT'L RESEARCH COUNCIL (NRC), A NEW BIOLOGY FOR THE 21ST CENTURY (Natl'l Acads. Press 2009) at 41-42.

469 ibid 20-21.

One example of technologies related to the biomedical sciences is biotechnology, which has a large amount of definitions.[470] Scholarly literature indicates that biotechnology is not a completely new phenomenon.[471] Certain biological processes, for example the fermentation of cheese, wine and beer,[472] have been known for thousands of years, but the term 'biotechnology' was first used only in 1917, and modern biotechnology[473] (also known as new, innovative or advanced biotechnology)[474] appeared only around the 1970-1980, when scientists discovered a way to alter the genetic constitution of living organisms with the help of processes from traditional breeding practices.[475] The developed genetic engineering influenced both traditional spheres of biotechnology as well as further accomplishments in the fields of medicine and agriculture.[476]

Currently, modern biotechnology includes such processes as genetic modification carried out using recombinant DNA techniques, cell-fusion technologies and modern traditional biotechnological processes.[477] Hence, it is usually indicated in the literature that the manipulation of live organisms is the main tool of modern biotechnology.[478] This advancement in biotechnology has changed a long-standing perception of the surrounding environment, at the same time raising complex issues with regard to the regulation of the relevant field of technology, which leads to the necessity of comprehensive assessments of the impact of these technologies.

Essentially, this field of technology is described as the application of scientific knowledge and technologies to living organisms, as well as their segments, products or models, in order to modify animate or inanimate material in such a way that new goods and services may be produced or

470 There are sources that give several definitions of the term 'biotechnology'. See e.g. John E Smith, *Biotechnology* (5th edn, Cambridge University Press 2009) 3.

471 Smith, *Biotechnology* (n 470) 8.

472 *Netherlands v Parliament and Council* (n 90) para 10; Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 8.

473 Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 8.

474 Andrea Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience* (Edward Elgar Publishing 2015) 2.

475 Smith, *Biotechnology* (n 470) 4-5.

476 ibid.

477 ibid 3.

478 Martina Newell-McGloughlin and Edward Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (Springer 2006) xi.

new knowledge acquired.[479] According to the Convention on Biological Diversity of 5 June 1992, the term 'biotechnology' encompasses 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.[480] In other sources, biotechnology is understood as a range of enabling technologies which can be applied in different areas of industry,[481] for example by manipulating living organisms or individual components of their cells in order to create beneficial goods, products or services,[482] or as 'the use of biological processes, organisms or systems to manufacture products intended to improve the quality of human life or modernise industry'.[483] The OECD assigns this area of technology to the fields of medicine and health sciences, engineering and technologies as well as agricultural sciences.[484]

One of the most prominent features of biotechnology is its interdisciplinarity.[485] First, biotechnology is not only used in the field of biomedical sciences (medicine, veterinary, environmental protection,[486] pharmacy[487]) but also in agricultural sciences, engineering and other fields.[488] Second, biotechnology is also characterised by its interdisciplinarity because it is based on a wide range of disciplines, such as 'microbiology, biochemistry, molecular biology, cell biology, immunology, protein engineering, enzymology, classified breeding techniques, and the full range of bioprocess technologies'.[489] All this makes it reasonable to consider biotechnology as the

479 Organisation for Economic Co-operation and Development, Directorate for Science, Technology and Industry, Committee for Scientific and Technological Policy, 'A Framework for Biotechnology Statistics' (2005) <https://www.oecd.org/health/biotech/aframeworkforbiotechnologystatistics.htm> accessed 30 May 2023, 9 (A Framework for Biotechnology Statistics).

480 5 June 1992 Convention on Biological Diversity <https://www.cbd.int/convention/text/> accessed 30 May 2023.

481 Smith, *Biotechnology* (n 470) 4.

482 Newell-McGloughlin and Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (n 478) xi.

483 European Patent Office, 'Biotech patents' (2 November 2022) <https://www.epo.org/en/news-events/in-focus/biotechnology-patents> accessed 30 May 2023.

484 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 12; Smith, *Biotechnology* (n 470) 4-5.

485 Smith, *Biotechnology* (n 470) 6.

486 Newell-McGloughlin and Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (n 478) xi.

487 Smith, *Biotechnology* (n 470) 6.

488 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 12; Smith, *Biotechnology* (n 470) 4-5.

489 Smith, *Biotechnology* (n 470) 4.

'integration of natural and engineering sciences'[490] or 'integration of natural sciences and organisms, cells, parts thereof, and molecular analogues for products and services'.[491]

In the light of the aforementioned interdisciplinarity and applicability of biotechnology in various fields as well its rapid development, it is not unexpected that the provision of a 'concrete legal *terminus technicus* in this area is impossible and unnecessary'.[492] The OECD publication 'A Framework for Biotechnology Statistics' highlights the difficulties in describing this field of technology with a single definition and, based on the analysis performed in the member countries and non-member countries, recommends the use of both a definition of the term 'biotechnology' and a list of technologies belonging to this branch in order to achieve reliable statistical results.[493] Therefore, biotechnology can be regarded as part of the biomedical sciences, which in this work are perceived as covering aspects related to both biology and medicine, but not limited to them and connected to other areas, for example those relating to information technology, such as bioinformatics.[494]

Considering all of the above, it can be concluded that, due to the rapid advancement of science and technology and their close interconnection, a precise definition of the term 'biomedical sciences' is difficult to achieve. However, according to the analysed sources, it may be stated that the term in question essentially covers the fields of biology and medicine and can be identified with the category 'life sciences' or, in certain particular cases, with biomedicine. One of the branches of technology based on the knowledge of the biomedical sciences is biotechnology, which has made significant progress in the second half of the 20th century and is recognised as an essential element in many fields of science, including the biomedical sciences. This means that the knowledge of biomedical sciences is crucial, both for the proper functioning of biotechnology and for the overall perception as well as the assessment of its actions. The term

490 Newell-McGloughlin and Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (n 478) 196.

491 Smith, *Biotechnology* (n 470) 2 citing European Federation of Biotechnology (EFB). Biotechnology in foods and drinks. Briefing Paper 2. Task Group on Public Perceptions of Biotechnology. Holland: EFB, 1994.

492 Paulius Jurčys, 'Biotechnologinių ir nanotechnologinių išradimų patentavimo teisiniai aspektai' (2006) 61 Justitia 68, 68.

493 A Framework for Biotechnology Statistics (479) 6-9.

494 ibid 7 and 9.

'biomedical sciences' in this study is therefore understood quite broadly and encompasses many areas of science, whose knowledge is essential for the proper assessment of biotechnology when examining inventions on the basis of Art. 53(a) EPC.

2.2. The Concept and Significance of the Biomedical Sciences as a Tradition

The term 'tradition' (in Latin: 'traditio' – 'transfer, narration')[495] is defined as the preserving and passing down of customs, rituals, images, ideas and symbols from generation to generation.[496] This term can also be used to describe 'the process of communication of knowledge, doctrine, or technique'.[497] In the anthropology of Western Europe, tradition is understood as 'beliefs, customs, values, behaviour, knowledge or experience that are passed down from generation to generation in a particular society'.[498] It can also be understood as a set of beliefs that is consistent throughout generations and that has a certain interpretation, perception and evaluation.[499]

According to A. MacIntyre, tradition is an argument extended through time, in which certain fundamental agreements are defined and redefined through two types of conflicts: (1) conflicts with critics and enemies, who do not belong to the tradition in question and reject all or certain substantive parts of those agreements; and (2) internal interpretative debates, through which the meaning of the fundamental agreements and the rationale behind them is expressed, allowing the tradition to progress.[500] Both definitions indicate that tradition can be described as having the following features: (1) certain substantive agreements, which can be expressed through customs, rituals, symbols, etc., and (2) the intergenerational *trans-*

495 Vaitkevičiūtė (ed), *Tarptautinių žodžių žodynas* (n 69) 603; H Patrick Glenn, 'Doin' the Transsystemic: Legal Systems and Legal Traditions' (2005) 50 McGill Law Journal 863, 873.

496 Vaitkevičiūtė (ed), *Tarptautinių žodžių žodynas* (n 69) 603. See also Saburo Ichii, 'On Innovation and Tradition' (1974) 21 Japan Quarterly 273, 274.

497 Glenn, 'Doin' the Transsystemic: Legal Systems and Legal Traditions' (n 495) 873 citing Romila Thapar, "Tradition" in Romila Thapar, Cultural Transaction and Early India: Tradition and Patronage (Delhi: Oxford University Press, 1994) 7 at 8.

498 Rasa Paukštytė-Šaknienė, 'Tradicijos sampratos šiuolaikinėje Lietuvoje' (2012) 88 Lituanistica 206, 206 citing SEYMOUR-SMITH, Charlotte. Macmillan Dictionary of Anthropology. London and Basingstoke: Macmillan Press LTD, 1987. 305 p. 280.

499 Edward Shils, *Tradition* (The University of Chicago Press 1981) 263.

500 Alasdair MacIntyre, *Whose Justice, Which Rationality?* (Notre Dame University Press 1988) 12.

mission of the said agreements with the possibility to rethink them in the long run.

According to E. Shils, a tradition is anything that is constant and repeated through transmission, irrespective of its content or institutional structure,[501] and regardless of how long and in what way (written or oral) it happens.[502] This means that the concept of tradition includes material objects, various beliefs, convictions about people and events, practices or institutions and encompasses 'buildings, monuments, landscapes, sculptures, paintings, books, tools, machines'.[503] Therefore, all accomplished patterns of the human mind, all patterns of belief, all modes of thinking, all achieved patterns of social relationships, all technical practices, all artefacts and all natural objects can be the objects of this *transmission* and can become a tradition.[504] Thus, traditionality can be compatible with any content.[505] Consequently, although we usually speak of artistic, political and similar traditions associated with the social sciences or humanities, it must be recognised that the natural sciences, of which the biomedical sciences are a part, as discussed in this study,[506] can also be regarded as a tradition.[507]

According to J. Jonutytė, the term 'tradition' in current public discourse is often used in ideological battles, making it 'the heart of the slogan for a single correct lifestyle or, on the contrary, the name for a dangerous form of backwardness'.[508] Due to such radical positions surrounding this term, the natural sciences, which are supposed to represent progress, cannot be identified with tradition.

Nevertheless, these extreme views discussed above can be regarded as unfounded, and, as M. Krygier states, the contrasting of tradition with the categories of 'change', 'progress' and 'modernity' is based on a deep misunderstanding of its nature and behaviour.[509] According to B. Russell, scientific and technological advancement, which is contrasted with tradition, often was the reason behind the worst living conditions in a society or parts of it.

501 Shils, *Tradition* (n 499) 16.
502 ibid 12.
503 ibid.
504 ibid 16.
505 ibid.
506 See '2.1. The Concept and Position of the Biomedical Sciences in the 21st Century'.
507 Shils, *Tradition* (n 499) 262.
508 Jonutytė, *Tradicijos sąvokos kaita* (n 39) 7 (translated from Lithuanian into English by the author of this study). See also Shils, *Tradition* (n 499) 3.
509 Martin Krygier, 'Law as Tradition' (1986) 5 Law and Philosophy 237, 251.

For example, the industrial revolution brought about by scientific advancement initially caused 'unspeakable misery' for both adults and children in England and the U.S.: child labour in appalling conditions, handicraftsmen being thrown out of work because of the advent of machines, etc.[510] Currently, with the Fourth Industrial Revolution under way, characterised by unprecedented digital changes and radical biotechnological advances,[511] the question arises as to what impact these innovations will have, not only on the economy, business and trade around the world, in various regions and in individual countries, but also on governance, international security, questions of morality and ethics or even interpersonal relationships.[512]

The aforementioned misunderstanding as regards tradition can be also illustrated by the fact that the biggest and most destructive acts of intolerance of the 20th century were performed by revolutionary regimes based on the ideas of scientific progress, which suggests that the latter, although more progressive, were hardly less intolerant than reactionary regimes.[513] Considering this, it can be agreed that tradition does not necessarily contain more dogmatism and intolerance than scientism, rationalism and secularism.[514] Consequently, tradition cannot be strictly and continuously contrasted with progress, be it social, cultural or even empirical, such as in the natural sciences. Thus, both the approach in favour of existing tradition and the approach denying or refusing it must be treated with caution.

The idea that the natural sciences, including the biomedical sciences, may be also considered a tradition is supported by the ideas of current scientific development. Scholarly literature indicates that in recent centuries, and especially in modern times, the development of the natural sciences has been perceived as a continuous process of accumulation of knowledge, where certain discovered scientific truths after a while are gradually com-

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510 Bertrand Russell, *The Impact of Science on Society* (George Allen & Unwin LTD 1952) 31.

511 Klaus Schwab, *The fourth industrial revolution* (World Economic Forum 2016) 21-27.

512 ibid 32-98. The relevance and importance of the latter questions are shown by the fact that that the ethical and social aspects of patenting of inventions which involve artificial intelligence were discussed at the Conference 'Patenting Artificial Intelligence' of the European Patent Organisation (European Patent Organisation, 'Patenting Artificial Intelligence' (Conference summary, Munich, 30 May 2018) <https://e-courses.epo.org/pluginfile.php/23523/mod_resource/content/2/Summary%20Artificial%20Intelligence%20Conference.pdf> accessed 30 May 2023.

513 Shils, *Tradition* (n 499) 5.

514 ibid.

plemented by others, forming a coherent body of knowledge.[515] As the foundations of the classical natural sciences established by G. Galileo, I. Newton and other scientists became the basis on which new generations of explorers could build their knowledge, the view that scientific knowledge is constantly being accumulated gained even more supporters.[516] The development of science seemed unproblematic: 'it is as natural as the growth of a tree'.[517] It was also considered that in the future, all scientific problems will be solved and this growth will come to an end.[518]

However, the scientific achievements at the turn of the 19th and 20th centuries, i.e. the theory of relativity and quantum mechanics, could not be conceived of as new truths to complement the old ones of Newtonian mechanics.[519] This changed the attitude towards the existing fundamental knowledge on the nature and development of science itself. Despite the fact that the idea of accumulating knowledge into a single whole has not been refuted, the perception has emerged that new knowledge might contradict old knowledge, thus making uninterrupted growth of the body of knowledge not possible at all times.[520] Therefore, at present, the cumulative approach to the development of the natural sciences is not the only one, as there is also a non-cumulative perception of the development of these sciences. The latter is based not only on the accumulation of knowledge, but also on its revision, radical renewal and the formulation of new theories that may be incompatible with the preceding ones.[521]

One of the most influential theories[522] on the aforementioned situation regarding the development of natural sciences[523] was proposed by T. Kuhn,

515 Evaldas Nekrašas, *Filosofijos įvadas* (Mokslo ir enciklopedijų leidykla 1993) 117.
516 Nekrašas, *Filosofijos įvadas* (n 515).
517 ibid.
518 ibid.
519 ibid 118.
520 ibid.
521 ibid.
522 Feldman, 'Historic Perspectives on Law & Science' (n 72).
523 When using the term 'science' in his works, T S Kuhn refers to the field of science commonly referred to as 'natural sciences' (e.g. when speaking of scientific revolutions and the nature of normal science, T S Kuhn only presents examples related to natural sciences: discoveries of Nicolaus Copernicus, Isaac Newton, Max Planck or Albert Einstein) (see Kuhn, *The Structure of Scientific Revolutions* (n 70) 6-8, 11-15, 25-34). Also, the Introduction to *The Structure of Scientific Revolutions* suggests that his work seeks to separate natural sciences from social sciences (Kuhn, *The Structure of Scientific Revolutions* (n 70) viii). This position is also presented in his other works: Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition*

who perceived natural sciences as consisting of: (1) so-called ‘normal science’, which is regarded as being cumulative[524] research that is firmly based on one or more scientific achievements of the past, and recognised by a particular scientific community for a certain period of time as a basis for its further practice;[525] and (2) revolutions, i.e. non-cumulative episodes in the development of science when the old paradigm is completely or partially replaced by a new one that is incompatible with the old one.[526] The first part emphasises convergent and the second part divergent thinking, both of which complement each other.[527] Also, according to T. Kuhn, these two ways of thinking are inevitably conflicting, and therefore the ability to withstand the tension arising between them, which may become unbearable, is a fundamental requirement for any research of good quality, which is why both ways of thinking are important for the progress of the natural sciences.[528]

As T. Kuhn indicates, the concept of ‘normal science’ relates closely to the category of ‘paradigm’,[529] which is perceived as universally acknowledged scientific achievements that, at a given point in time, provide problem-solving models and solutions to the community of practitioners.[530] The aim of a paradigm-based scientific approach is not to provide fundamentally new theories, but to ensure that research is in line with what already exists,[531] i.e. to analyse whether it corresponds to a particular prevailing tradition. Therefore, although cumulative ‘normal science’, which follows the tradi-

and Change (n 104). Moreover, the fact that T S Kuhn speaks specifically about the natural sciences is also confirmed by the following authors: David C Lindberg, *The Beginnings of Western Science* (Chicago University Press 1992) 359; Algimantas Valantiejus ‘Thomas Kuhno istorinė-sociologinė mokslo raidos koncepcija’ (2004) 1 Sociologija. Mintis ir veiksmas 126, 126; Esther van Zimmeren, ‘Towards a New Patent Paradigm in the Biomedical Sector? Facilitating Access, Open Innovation and Social Responsibility in Patent Law in the US, Europe and Japan’ (PhD thesis, Katholieke Universiteit Leuven Faculty of Law Centre for Intellectual Property Rights, 2011) 7; Sandra Halperin and Oliver Heath, *Political Research: Methods and Practical Skills* (OUP 2012) 61.

524 Kuhn, *The Structure of Scientific Revolutions* (n 70) 52.

525 ibid 10.

526 ibid 92.

527 ibid 8.

528 ibid 226.

529 ibid 10.

530 ibid viii.

531 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 233.

tion, increases efficiency, it does not lead to fundamental innovations and does not provide answers when a new atypical problem arises and requires resolution within the existing paradigm.[532]

Despite the fact that during the period of 'normal science' the scientific community 'does not aim at novelties of fact or theory',[533] they still occur. If 'normal science' is unable to explain them, they become anomalies, which are viewed 'with the recognition that nature has somehow violated the paradigm-induced expectations that govern normal science'.[534] Thus, the emergence of the said anomalies indicates that paradigms have reached their limits and no longer fulfil their function.[535] When their number reaches a critical limit, 'normal science' faces a crisis which can only be resolved by a fundamental paradigm shift. In such cases, in order to respond to new problems that cannot be explained by 'normal science', the tradition-bound approach requires a tradition-shifting update[536] which leads to fundamental changes, i.e. scientific revolutions,[537] that do not occur often but are of vital importance for the renewal of scientific tradition.

The concept of scientific development discussed above may be associated with A. MacIntyre's theory that every tradition has the following stages of development: (1) texts, beliefs and authorities are not questioned; (2) texts, beliefs and authorities are questioned, which leads to the occurrence of inconsistencies; (3) there is a desire to answer the aforementioned inconsistencies, and thus texts, beliefs and authorities are reviewed.[538] The first two stages can be attributed to the concept of 'normal science' proposed by T. Kuhn, whereas the last one can include the paradigm-shifting stage, where the scientific revolution is most evident.

Nevertheless, even in the non-cumulative stages of the development of the natural sciences, there are arguments for considering this scientific field, including the biomedical sciences, as a tradition. This can be inferred from T. Kuhn's rather restrained position regarding the effectiveness and process of scientific revolutions. '[R]evolutionary changes in the scientific

532 Kuhn, *The Structure of Scientific Revolutions* (n 70) 233.
533 ibid 52.
534 ibid 52-53.
535 ibid 92.
536 ibid 227.
537 ibid 92.
538 MacIntyre, *Whose Justice, Which Rationality?* (n 500) 355.

tradition'[539] he perceives as short and scarce stages of radical paradigm shift, which interfere with the relatively static and prolonged stages of question-solving in the context of 'normal science', because '[a]lmost none of the research undertaken by even the greatest scientists is designed to be revolutionary, and very little of it has any such effect'.[540]

Furthermore, scientific revolutions are not necessarily monumental, but rather encompass events affecting only a narrow subsection of the community of natural sciences.[541] In principle, it is enough for a change to have an impact on a small group of scientists to be recognised as a scientific revolution. As indicated by T. Kuhn, to astronomers, the discovery of X-rays can be only an addition to existing knowledge which does not affect their paradigm, but for Lord Kelvin, W. Crookes or V. H. Röntgen, whose studies involved radiation and cathode-ray tubes, it was an event leading to a new paradigm.[542] Hence, the extent and the importance of scientific revolutions can vary.

Moreover, according to T. Kuhn, scientists themselves are not inclined to change the paradigm immediately: the new paradigm will be taken on by the younger colleagues, and the old one will exist until scientists who support it die out.[543] Thus, the result of the scientific revolution, i.e. which paradigm will be chosen in the face of their competition, will depend on the decision of the community concerned.[544] This suggests that these revolutions are not always sudden and frequent, and that the development of the natural sciences is determined by the scientific community and not by a self-contained process isolated from society.

The difficulties faced when abandoning old theories and adopting new ones can be influenced by the teaching of the natural sciences. According to T. Kuhn, considering how the natural sciences are taught, it is clear that the convergent way of thinking is emphasised much more than the divergent way.[545] The latter theorist also claims that young scientists study the most

539 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 227.
540 ibid.
541 Kuhn, *The Structure of Scientific Revolutions* (n 70) 49.
542 ibid 93.
543 ibid 150-151. He was supported by M Planck (see Cohen, *Revolution in Science* (n 70) 467-468).
544 Kuhn, *The Structure of Scientific Revolutions* (n 70) 94.
545 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 228.

prominent paradigm at a particular time and, based on it, are trained to discover the 'right' answer.[546] Generally, students are taught only from textbooks and are not encouraged to get acquainted with classical works in certain fields of the natural sciences as well as the theories mentioned in them, which T. Kuhn believes would give them the opportunity to see the questions discussed in the textbooks from a different perspective and allow them to familiarise themselves with the concepts, problems and solutions that have already been refuted long ago.[547] Thus, young natural scientists do not have to rediscover everything, but rather follow what has already been discovered and presented in the textbooks, i.e. rely on solutions to problems that are in line with the existing paradigm,[548] which may lead to a reluctance to abandon prevailing scientific theories.

E. Shils supports the idea of the dominance of convergent thinking in the natural sciences, suggesting that patterns of reason and the scientific method are not created by each participant of a tradition, but 'are mostly inherited'.[549] All of this can reasonably affect the identification of a research topic, its formulation and the process of research itself, which makes the effect of tradition on natural sciences quite evident. According to the aforementioned theorist, in the natural sciences there is also a tradition outside the laboratory controlling the research and publications, and although, as E. Shils argues, the scientific approach does not officially bind scholars, many still follow it.[550]

Also, in the course of a scientific revolution, knowledge of the prevailing paradigm is essential even for the revolution itself, in order to recognise anomalies. According to T. Kuhn, only with sufficient knowledge of current 'normal science' is it possible to determine whether it is functioning inadequately, and what is the cause of these anomalies.[551] This situation can be illustrated by the corpuscular theory of thermal phenomena and states of matter developed by chemist R. Boyle, which replaced Aristotle's and Paracelsus' perception of these aspects.[552] Instead of relying on Aristotle's

546 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 228.
547 ibid 228-229.
548 ibid 229.
549 Shils, *Tradition* (n 499) 21.
550 ibid 272.
551 Kuhn, *The Structure of Scientific Revolutions* (n 70) 65.
552 Science History Institute, Robert Boyle <https://www.chemheritage.org/historical-profile/robert-boyle> accessed 30 May 2023.

definition of physical reality and analysing changes in both matter and form as the classical elements of earth, air, fire and water, or, based on Paracelsus' ideas, as three elements – salt, mercury and sulphur, R. Boyle did it in a completely new way, by using particles and their motion.[553] This led to a shift from non-empirical, logically based theories of the natural sciences to empirical ones that seek to determine if the aforementioned theory really works,[554] which seems to be routine today.

In order to propose these new ideas, R. Boyle was supposed to be well acquainted with the theories of the aforementioned ancient and medieval scholars and to question them. This reveals the existence of continuity between old and new theories of science. According to A. F. Chalmers, a similar situation exists in relation to A. Einstein's theory of relativity: identifying the problems to which this scientist proposed solutions required two hundred years of meticulous 'work in I. Newton's paradigm and a hundred years of work in limits of the theory of electricity and magnetism'.[555] This shows that scientific knowledge does not come from nowhere and no scientist can investigate or consider everything anew. Anomalies are only recognisable against the backdrop of a prevailing paradigm; therefore, knowledge of the general concepts of earlier periods is necessary for the emergence of scientific knowledge which changes the tradition. All this shows that even the revolutions of natural sciences are closely linked to traditionality.

In this context, it can be agreed with T. Kuhn that a successful scientist must have the characteristics of both a traditionalist and an iconoclast.[556] Scientists must be fully committed to the tradition, which they will abandon if the research is successful.[557] The two approaches mentioned above (tradition-bound and tradition-shifting) and the relationship between them, which was called 'the essential tension' by the latter scientist,[558] are considered to be the most prominent features of the natural sciences, and

553 Science History Institute, Robert Boyle <https://www.chemheritage.org/historical-profile/robert-boyle> accessed 30 May 2023.

554 L Pearce Williams and Henry John Steffens, *The History of Science in Western Civilization*, vol 2 (University Press of America 1978) 1.

555 Chalmers, *Kas yra mokslas?* (n 71) 143 (translated from Lithuanian into English by the author of this study).

556 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 227.

557 ibid 235.

558 ibid 227.

are essential for both systematic research and technological development as well as the progress of radical new innovation.

K. Popper claimed that in the field of the empirical sciences, a scientist 'constructs hypotheses, or systems of theories, and tests them against experience by observation and experiment'.[559] In view of this, he argued that, for human knowledge to be considered a scientific theory, it must be capable of being tested by experience,[560] and that 'every genuine test of a theory is an attempt to falsify it, or to refute it'.[561] Thus, 'the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability'.[562]

If the conclusions prove acceptable or '*verified*',[563] for a certain period of time there is no way to reject the theory, whereas if the 'conclusions have been *falsified*, then their falsification also falsifies the theory from which they were logically deduced'.[564] In the latter case, it becomes apparent that, as T. Kuhn would argue, the theory contains anomalies and can therefore be rejected. Only when a theory stands up to extensive and rigorous testing, and is not superseded by another theory in the course of scientific progress, is it considered '*corroborated*'.[565] Still, according to K. Popper, although a scientific theory is currently tested, this does not mean that it will not be disproved in the future: a positive decision can only provide temporary support for a theory, because later negative decisions can always refute it.[566] Thus, similarly to the above-mentioned tradition-bound and tradition-shifting approaches, verification and falsification are constantly interacting with each other in the field of the empirical sciences to determine the scientific status of a theory.

The natural sciences also follow the tradition-specific characteristics presented by M. Krygier: (1) pastness, which means that the content of every tradition was formed at a certain time in the past; (2) authoritative presence, which indicates that particular practices, doctrines and convictions, formed in the past, affect the lives, thoughts and actions of the current participants of the same tradition; (3) transmission, which means

559 Karl Popper, *The Logic of Scientific Discovery* (2nd edn, Routledge 2002) 3.
560 ibid 18 and 26.
561 Karl Popper, *Conjectures and Refutations: The Growth of Scientific Knowledge* (reprint edn, Routledge 2004) 48.
562 ibid.
563 Popper, *The Logic of Scientific Discovery* (n 559) 10.
564 ibid.
565 ibid.
566 ibid.

that a tradition is deliberately or unknowingly transmitted from generation to generation, rather than being suddenly transferred from the past to the present without any link with the latter.[567]

Based on the above-mentioned characteristics and all that has been discussed above, it can be held that the natural sciences are characterised by pastness: for example, the origins of many of the natural sciences can be found in the works of classical ancient philosophers.[568] Also, in their continuous research, scientists are always influenced by their predecessors and their work, i.e. every scientist sees the object of research not only through his/her own perspective, but also from the view of his/her predecessors and colleagues.[569] Even if they are later refuted or changed, they still serve as a starting point for creating new results. While looking at the natural sciences, E. Shils points out that each generation of scientists acquires what was achieved by their predecessors through consistent research and analysis, after rigorous rational reflection and refined articulation.[570] This means that the results of these actions and experiences are transferred to the subsequent generations.

The recognition of the natural sciences, including the biomedical sciences, as a tradition, discussed in this part of the study, suggests that the preservation of the prevailing theories of the natural sciences or, on the contrary, their denial and refusal, is a decision of the scientific community, often shaped by the existing tradition, but is not always a self-contained and objective scientific process based on scientific knowledge. This understanding that the development of the natural sciences can be determined by social factors is particularly important in shaping the response of the legal system to the changing environment which we understand with the help of the natural sciences. This allows the legal system to take a more cautious and critical look at the environment – which may be required to assess the consistency of the commercial exploitation of biotechnological inventions on the basis of Art. 53(a) EPC from the perspective of the biomedical sciences.

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567 Krygier, 'Law as Tradition' (n 509) 240.

568 Marshall Clagett, *The Science of Mechanics in the Middle Ages* (The University of Wisconsin Press 1959) xix.

569 John M Ziman, *Public knowledge: an essay concerning the social dimension of science* (Cambridge University Press 1968) 9.

570 Shils, *Tradition* (n 499) 22.

2.3. Preliminary Conclusion

Although it is difficult to find a definition of the term 'biomedical sciences', it can be argued that this scientific field essentially covers the spheres of science falling under the categories of biology and medicine, and can be identified with life sciences or, where appropriate, with biomedicine. Biomedical sciences are also closely linked to biotechnology, which can be used in the field of biomedical sciences and evaluated on the basis of knowledge in this field. In view of the rapid advancement in science and technology, and the interconnections between different disciplines and branches, such a broad concept of biomedical sciences can be considered reasonable.

The natural sciences, including the biomedical sciences, can be perceived as phenomena encompassing both cumulative and non-cumulative development. This makes it possible to claim that tradition and revolution exist side by side in this field of science. Therefore, in the case of both normal natural sciences and scientific revolutions, the knowledge and assessment of the environment and its processes is influenced by the attitude of the scientific community, which is usually shaped by the existing traditions and may not always objectively reflect reality. This may encourage the European patent system to be more cautious about the knowledge provided by biomedical sciences and to make decisions only after a more careful assessment of the surrounding environment and its knowledge.