

Starynskyi M.V.

*Dr. of Law, Prof.,
Professor of the Department of Administrative,
Commercial Law and Financial and Economic Security
Academic and Research Institute of Law
of Sumy State University
<https://orcid.org/0000-0003-2661-5639>*

Pogrebnyak O. D.

*Dr. of Phys.-Math. Sc., Prof.,
Head of the Department of Nanoelectronics and Surface Modernization
of the Faculty of Electronics and Information Technologies
Sumy State University
<https://orcid.org/0000-0002-9218-6492>*

THE CURRENT STATE OF LEGAL REGULATION OF THE USE OF NANOTECHNOLOGY IN THE MEDICAL FIELD AND PROSPECTS FOR ITS DEVELOPMENT

JEL Classification: K 19

SECTION "LAW": Право

Анотація. Інтенсивний розвиток інноваційних технологій, який постійно відбувається протягом останніх двадцяти років, є результатом того, що наноматеріали, створені з використанням нанотехнологій, все активніше входять в наше життя. Нанотехнології в сучасному світі впевненіше претендують на статус ще одного технологічного прориву, такого як електроенергетика та ядерні технології, які, поряд з величезною користю для людини, несуть у собі надзвичайно високі ризики потенційної небезпеки, особливо в сферах життя та здоров'я людей. Враховуючи ці властивості наноматеріалів, існує об'єктивна необхідність державного регулювання використання нанотехнологій у медичній сфері.

Автори статті аналізують проблемні аспекти використання нанотехнологій та їх правового регулювання. Проведений авторами аналіз дозволив зробити висновок, що в процесі використання нанотехнологій та наноматеріалів у медичній сфері існує велика кількість взаємозв'язків, які можна розділити на такі блоки: відносини у сфері інтелектуальної власності, об'єкт які є нанотехнологіями та наноматеріалами; відносини у сфері науково-технічної діяльності; відносини у сфері інноваційної підприємницької діяльності; відносини у сфері технічного регулювання використання нанотехнологій та наноматеріалів; відносини у сфері формування державної політики щодо використання нанотехнологій. Усередині виділених блоків відносин існує велика кількість проблем з їх правовим регулюванням. Автори стверджують, що основними причинами таких проблем є: а) відсутність інформації та відповідних знань фахівців-юридичних осіб про особливості нанотехнологій та властивості наноматеріалів; б) постійний інноваційний розвиток нанотехнологій та наноматеріалів.

За результатами дослідження автори пропонують встановити ефективний державний нагляд і контроль за використанням нанотехнологій, при розробці політики державного регулювання використання нанотехнологій у медичній сфері зосередити увагу на таких завданнях: а) розробити правові критерії визначення нанотехнологічних

галузей та критерії віднесення продукції до категорії «нано»; б) розробити критерії стандартизації та сертифікації нанопродукції, нанотехнологій та нанопродуктів; в) визначити правовий режим діяльності суб'єктів господарювання у сфері нанотехнологій; г) розробити ефективну модель спеціального режиму оподаткування для діяльності, пов'язаної з використанням нанотехнологій та наноматеріалів.

Ключові слова: медична сфера, право, правове регулювання, використання нанотехнологій, державне регулювання та контроль використання наноматеріалів.

Annotation. The intensive development of innovative technologies, which has constantly been taking place for the last twenty years, is the result of the fact that nanomaterials created using nanotechnologies are becoming more and more active in our lives. Nanotechnologies in the modern world are more confident in claiming the status of another technological breakthrough, such as electricity and nuclear technologies, which, along with the enormous benefits for humans, carry extremely high risks of potential danger, especially in areas of human life and health. Given these properties of nanomaterials, there is an objective need for government regulation in the use of nanotechnology in the medical field.

The authors of the article analyze the problematic aspects of the use of nanotechnologies and their legal regulation. The analysis conducted by the authors allowed us to conclude that in the process of using nanotechnology and nanomaterials in the medical field, there is a large number of relationships that can be divided into the following blocks: relations in the field of intellectual property, the object of which are nanotechnologies and nanomaterials; relations in the field of scientific and technical activities; relations in the field of innovative entrepreneurial activity; relations in the field of technical regulation of the use of nanotechnologies and nanomaterials; relations in the field of formation of state policy on the use of nanotechnologies. Furthermore, within the selected blocks of relations, there are many problems with their legal regulation. The authors argue that the main causes of such problems are: a) lack of information and relevant knowledge of legal professionals about the features of nanotechnology and the properties of nanomaterials; b) constant innovative development of nanotechnologies and nanomaterials.

As a result of the study, the authors propose to establish effective state supervision and control over the use of nanotechnologies, in developing policies for state regulation of the use of nanotechnologies in the medical field, to focus on the following tasks: a) to develop legal criteria for determining nanotechnological industries and criteria for classifying products as “nano”; b) to develop criteria for standardization and certification of nanoproductions, nanotechnologies and nanoproductions; c) to determine the legal regime of business entities in the field of nanotechnology; d) to develop an effective model of the special tax regime for activities related to the use of nanotechnologies and nanomaterials.

Keywords: medical sphere, law, legal regulation, use of nanotechnologies, state regulation and control of nanomaterials use.

Introduction

The intensive development of innovative technologies, which has been constantly taking place for the last twenty years, is the result of the fact that nanomaterials created with the use of nanotechnologies are becoming more and more active in our lives. Nanotechnologies in modern world are more confident in claiming the status of another technological breakthrough, such as electricity and nuclear technologies, which, along with the huge benefits to humans, carry extremely high risks of potential danger. Nanomaterials, as the main product of nanotechnology, are increasingly seen not only as unique, unrivalled components of microelectronics, fuel cells or artificial tissues and organs, but also as extremely dangerous

to the world pollutants, the spread of which can lead not only to unforeseen ecological and sanitary consequences, but also to a direct threat to public health [17, с. 97].

Over the last twenty years, about two thousand varieties of nanomaterials have been created, which are used in various fields of industry, agriculture, medicine, pharmacy, etc. According to researchers, the size of the global nanotechnology market in 2020 is estimated at \$3 trillion [16, p. 10], and tends to increase.

At the same time, there are growing concerns in the world about the use of nanotechnology in the medical field and calls on states and the world community to take control of this process. This is due to the fact that nanotechnology is a completely unique phenomenon that can not only expand and change production capabilities, offer a broad technological platform for biomedicine, but also lead to serious social consequences, as it can lead to superhumans or cyborgs.

This indicates that the issue of the use of nanotechnology in the medical field and the regulation of this process by the state is extremely relevant and complex. Given this, *the purpose of the research* is to outline the problems of legal regulation of the use of nanotechnology in the medical field, and *the task* is to identify proposals for priority areas of legislation in the field of regulating the use of nanotechnology and nanomaterials.

Despite the fact that the use of nanotechnologies and nanomaterials is an extremely important topic for society and the state, research on its legal regulation in Ukraine is in its infancy. This is due to the fact that on the one hand nanotechnology and nanomaterials are quite new phenomena, and on the other hand – there are no clear boundaries of nanotechnology as an object of regulation.

An analysis of the domestic scientific literature on the regulation of the use of nanotechnology and nanomaterials in general and in the medical field in particular, shows that such research studies are isolated and general. Thus, Ya. Trynova in some works emphasizes the need for legal support for the use of nanotechnology on nanomaterials [21], while in others she draws attention to the prospects for the use of nanotechnology in criminal law [22]. The problems of legal regulation of relations in the field of nanotechnology are also pointed out by O.V. Pecherskyi [19]. V.Iu. Turanin and D.A. Serheeva also pointed to the problems in the legal regulation and development of nanotechnology in their research [23]. Researchers also pay some attention to the ethical aspects of the use of nanotechnology. In particular, O.V. Chumak [24] identified a number of ethical issues facing humanity as a result of the use of nanotechnology. The study of nanotechnology safety in medical, ecological, technological and legal aspects was also carried out by O.A. Husev, O.V. Zakharova and P.O. Baranchikov [17], I.M. Trakhtenberh and N.M. Dmytrukha [20]. In the foreign scientific literature, the situation is much better, because nanotechnology is an extremely promising industry in all senses. With this in mind, foreign scientists pay great attention to research in this area, as well as the publication of their results in professional scientific journals, which are directly devoted to the use of nanotechnology and nanomaterials. Thus, the most authoritative publications in the world are: American Journal of Nanosciences, American Journal of Nanomaterials, Journal of Nanobiotechnology, European Journal of Nanomedicine, Journal of Nanomaterials & Molecular Nanotechnology and others.

The methodological basis of the article is a set of philosophical (laws of dialectics and metaphysics), general scientific (logical method, systemic and structural-functional methods) and special legal research methods.

Results

Outlining the problems of legal regulation of the use of nanotechnologies and nanomaterials in the medical field requires, first of all, to pay attention to the fact that legal regulation is determined by the characteristics of these technologies and materials, and is essentially a form of objectification of state management capabilities. Given this, before describing the problems of legal regulation of the use of nanotechnology in the medical field, we pay attention to the features of nanotechnology.

It is difficult to define nanotechnologies because they are used in various fields of science, and sometimes at their junction. Almost all researchers agree that the term “nanotechnology” was introduced in 1974 by the Japanese physicist Norio Taniguti, describing the mechanisms-devices for probe microscopy smaller than one micron [18, p. 96], and this term entered the mass scientific lexicon thanks to E. Draxter, who predicted the role of nanotechnology as the main engine of creation [3, p. 412].

In the most general sense, nanotechnology is the technology of working with matter at the level of individual atoms. Norio Taniguti, who first used the term, noted that nanotechnology mainly consists of the processes of fission, union and deformation of materials atom by atom or molecule by molecule, and thus there is a transition from one level to another – from micro to nanoscale. This process can be described as an abrupt transition to the manipulation of individual atoms [16, p. 8].

Experts of the US National Nanotechnology Initiative perceive nanotechnology as research and technological development at the atomic, molecular or macromolecular levels on a scale of about 1 to 100 nm, conducted to gain basic knowledge about the nature of phenomena and properties of materials in the nanoscale, as well as for the creation and use of structures, devices and systems that acquire new qualities due to their small size. At the same time, nanotechnological research and development includes controlled manipulation of nanoscale structures and their integration into larger components, systems and architectures [5, p. 229].

Thus, nanotechnology is associated with the creation of materials, devices, systems, the useful properties of which derive from their size or associated with the ability to manipulate the elements of matter at the nanoscale. According to research, the use of nanotechnology can be of great benefit. Today, this benefit is mainly manifested in the creation of new materials and products with new properties. In addition, nanotechnology can be used to create chemicals with high chemical reactivity.

However, along with many useful properties, the use of nanotechnology can pose a significant threat, which in the vast majority of studies is not mentioned. Research shows that significant damage to human life and health and the environment is possible due to the properties of nanotechnology and nanomaterials. Among the most important are high chemical reactivity and toxicity [13], the ability to easily spread in space, between organisms, within a single organism [2], high penetrating ability (ability to penetrate tissues, organ walls and other barriers inaccessible to penetration of parts larger size) [6], insolubility in living organisms [13], the ability to accumulate in organs and tissues [13].

Given the above properties of nanomaterials, it is needed agreeing with the statement of researchers in the field of medicine that in addition to the large number of positive potential of nanotechnology can lead to harm to humans and their health [7]. It is also worth emphasizing that the use of nanotechnology and as a result of creating new materials and products is constantly continuing. As a result, new challenges will arise in the near future with the invention of new nanodevices, such as microrobots that deliver drugs to diseased organs, or microsystems such as microplants that produce nanorobots.

This indicates both a fairly wide range of applications of nanotechnology and nanomaterials, and a wide variety of relationships that arise in connection with the use of nanotechnology and the creation of nanomaterials in the emergence, change or termination of their legal regulation.

The study of this variety of these relations related to nanotechnology, makes it possible to identify their structural units within which legal regulation can and should be carried out by the state. Such separate but interconnected blocks can be identified based on the analysis of social relations, which are a sequence of stages of the innovation process in the field of nanotechnology. In particular, we can highlight:

- a) relations in the field of intellectual property, the object of which are nanotechnologies and nanomaterials;
- b) relations in the field of scientific and technical activities;
- c) relations in the field of innovative entrepreneurial activity;
- d) relations in the field of technical regulation of the use of nanotechnologies and nanomaterials;
- e) relations in the field of formation of state policy on the use of nanotechnologies.

Within the selected blocks of relations there is a large number of problems with their legal regulation. The main causes of such problems are a) lack of information and relevant knowledge of legal professionals about the features of nanotechnology and the properties of nanomaterials; b) constant innovative development of nanotechnologies and nanomaterials.

Lack of information from lawyers about nanotechnology and nanomaterials leads to the fact that today it is almost impossible to formulate a legal structure of the mechanism of legal regulation of relations related to nanotechnology. On the one hand, there is an object of regulation with blurred boundaries, on the other hand – it is constantly evolving and improving. As a result, the legislator either does not have time to legislate the state of regulation of certain relations related to nanotechnology, or attempts to use methods of legal regulation that are not typical for this object.

All of the above is fully consistent with the use of nanotechnology and nanomaterials in the medical field. At the same time, focusing on the medical field, experts have identified a number of basic and promising areas of use of nanotechnology in the medical field. These included: creation of fluorescent biological labels [1], delivery of drugs and genes [9, 14], biodetection of pathogens [4], detection of proteins [12], study of DNA structures [10], engineering of coating tissues [8], separation and purification of biological molecules and cells [11], phagokinetic studies [15].

Currently, all these areas are extremely relevant and can potentially bring great financial benefits. At the same time, almost every one of these areas, given their intensive development, is potentially dangerous, because in one way or another, directly or indirectly, associated with human and his body.

It should also be noted that the regulation of the right to use of nanotechnologies and nanomaterials in the medical field faces both the already mentioned problems, namely the lack of knowledge and intensive development of nanotechnology, and the problems that exist in the medical field. In particular, these are both problems related to the testing of new nanotechnologies and nanomaterials (medical experiments) and purely ethical issues affecting the existence of society as a whole (the use of nanotechnology to prolong life or gain immortality, create cyborgs).

This highlights the issue of controlling the use of nanotechnology to ensure the safety of people in the country. At the same time, given the intensive development of nanotechnologies and their use in the medical field, it is almost impossible to normalize the above relations at once. In this aspect, in our opinion, there are four main stages of formation and development of legal regulation of the use of nanotechnology.

At the first stage it is necessary, on the basis of scientific research and practice of nanotechnology use, to develop legal criteria for determining nanotechnological industries and criteria for classifying products as “nano”. This will provide an opportunity to formulate the foundation of effective legal regulation of the use of nanotechnology and create a basis for the innovative development of the state.

In the second stage, it is necessary to develop criteria for standardization and certification of new products, nanotechnologies and nanoproducts, which will allow to create a unified classification system in the field of nanotechnology. This will provide an opportunity to begin legal research on possible regimes for the legal regulation of various types of nanotechnology.

In the third stage, special attention should be paid to the problems of the legal regime of economic entities in the use of nanotechnology and nanomaterials. At the same time, special attention should be paid to the legal regime of economic entities engaged in the development of nanotechnologies and nanomaterials and economic entities engaged in the production of products using nanotechnologies.

In the fourth stage, after the establishment of a clear legal regime for the operation of economic entities in the field of nanotechnology, special attention should be paid to developing an effective model of special tax regime for activities related to the use of nanotechnology and nanomaterials.

Further development of an effective regime of legal regulation of the use of nanotechnology should be associated with the definition of the authorized body of the state, which will be responsible for the authority to control and supervise such activities. Given the fact that at the present stage of development of our state, today in Ukraine there is no such authorized body, in our view it should be formed, because only

the stable functioning of such a body as a single decision-making centre in the field of supervision and control over the use of nanotechnologies and nanomaterials will allow to develop and implement effective public policy in the field of nanotechnology.

Conclusions

Given the above, the following conclusions can be drawn. The intensive development of innovative technologies, which has been constantly taking place for the last twenty years, is the result of the fact that nanomaterials created with the use of nanotechnologies are becoming more and more active in our lives.

Nanotechnology is the technology of working with matter at the level of individual atoms. They are related to the creation of materials, devices, systems, the useful properties of which derive from their size or are associated with the ability to manipulate the elements of matter at the nanoscale. The use of nanotechnology can bring great benefits and cause significant harm. This situation is possible due to the properties of nanomaterials, in particular increased chemical reactivity and toxicity; the ability to easily spread in space, between organisms and within one organism; high penetrating power (ability to penetrate tissues, walls of organs and other obstacles that are inaccessible to the penetration of larger parts); insolubility in living organisms; ability to accumulate in organs and tissues.

In the process of using nanotechnologies and nanomaterials in the medical field, a large number of relationships emerge, which can be divided into the following blocks: relationships in the field of intellectual property, the object of which are nanotechnologies and nanomaterials; relations in the field of scientific and technical activities; relations in the field of innovative entrepreneurial activity; relations in the field of technical regulation of the use of nanotechnologies and nanomaterials; relations in the field of formation of state policy on the use of nanotechnologies. Within the selected blocks of relations there are a large number of problems with their legal regulation. The main causes of such problems are: a) lack of information and relevant knowledge of legal professionals about the features of nanotechnology and the properties of nanomaterials; b) constant innovative development of nanotechnologies and nanomaterials.

To establish effective state supervision and control over the use of nanotechnology, the implementation of the following tasks should be focused on: a) to develop legal criteria for determining nanotechnological industries and criteria for classifying products as “nano”; b) to develop criteria for standardization and certification of nanoproductions, nanotechnologies and nanoproducts; c) to determine the legal regime of business entities in the field of nanotechnology; d) to develop an effective model of the special tax regime for activities related to the use of nanotechnologies and nanomaterials.

References

1. Bruchez M., Moronne M., Gin P., Weiss S., Alivisatos A. P. Semiconductor nanocrystals as fluorescent biological labels. *Science*. 1998, 281: 2013-2016. 10.1126/science.281.5385.2013.
2. Donaldson K., Stone V., Tran C. et al. *Nanotoxicology // Occupational and Environmental Medicine*. 2004. № 61. URL: <https://oem.bmj.com/content/oemed/61/9/727.1.full.pdf>
3. Drexler E. *Engines of creation: The coming era of nanotechnology*. N.Y.: Anchor press / Doubleday, 1986. P. 412.
4. Edelstein R., L., Tamanaha C. R., Sheehan P.E., Miller M.M., Baselt D.R., Whitman L.J., Colton R.J. The BARC biosensor applied to the detection of biological warfare agents. *Biosensors Bioelectron*. 2000, 14: 805-813. 10.1016/S0956-5663(99)00054-8.
5. Gordon A.T., Lutz G.E., Boninger M.L., Cooper R.A. Introduction to nanotechnology: potential applications in physical medicine and rehabilitation. *Am. J. Phys. Med. Rehabil.*, 2007. 86(3): 225–241. DOI: 10.1097/PHM.0b013e318031ee1a .
6. Koops, Bert-Jaap and Leenes, Ronald E. and Leenes, Ronald E. and Marbus, Rachel and Stuurman, Kees and Verschuuren, Jonathan, *On Small Particles and Old Articles - An Exploration of Legal and Regulatory Issues of Nanotechnologies* (November 13, 2008).

- TILT Law & Technology Working Paper No. 009/2008, Available at SSRN: <https://ssrn.com/abstract=1300925> or <http://dx.doi.org/10.2139/ssrn.1300925>.
7. Lin A.C. Size Matters: Regulating Nanotechnology // Harvard Environmental Law Review. 2007. Vol. 31. URL: <http://ssrn.com/abstract=934635>.
 8. Ma J., Wong H., Kong L.B., Peng K.W. Biomimetic processing of nanocrystallite bioactive apatite coating on titanium. *Nanotechnology*. 2003, 14: 619-623. 10.1088/0957-4484/14/6/310.
 9. Mah C., Zolotukhin I., Fraites T.J., Dobson J., Batich C., Byrne B.J. Microsphere-mediated delivery of recombinant AAV vectors in vitro and in vivo. *Mol Therapy*. 2000, 1: S239-10.1006/mthe.2000.0174.
 10. Mahtab R., Rogers J.P., Murphy C.J. Protein-sized quantum dot luminescence can distinguish between "straight", "bent", and "kinked" oligonucleotides. *J Am Chem Soc*. 1995, 117: 9099-9100.
 11. Molday R.S., MacKenzie D. Immunospecific ferromagnetic iron dextran reagents for the labeling and magnetic separation of cells. *J Immunol Methods*. 1982, 52: 353-367. 10.1016/0022-1759(82)90007-2.
 12. Nam J.M., Thaxton C.C., Mirkin C.A. Nanoparticles-based bio-bar codes for the ultrasensitive detection of proteins. *Science*. 2003, 301: 1884-1886. 10.1126/science.1088755.
 13. Onichenko G., Arachkov A. et al. Risk assessment of nano materials: methodological approaches. *Methodological Problems of Study and Assessment*. https://ec.europa.eu/health/scientific_committees/opinions_layman/en/nanotechnologies/l-3/8-risk-assessment.htm
 14. Panatarotto D., Prtidos C.D., Hoebeke J., Brown F., Kramer E., Briand J.P., Muller S., Prato M., Bianco A. Immunization with peptide-functionalized carbon nanotubes enhances virus-specific neutralizing antibody responses. *Chemistry&Biology*. 2003, 10: 961-966.
 15. Parak W.J., Boudreau R., Gros M.L., Gerion D., Zanchet D., Micheel C.M., Williams S.C., Alivisatos A.P., Larabell C.A. Cell motility and metastatic potential studies based on quantum dot imaging of phagokinetic tracks. *Adv Mater*. 2002, 14: 882-885. 10.1002/1521-4095(20020618)14:12<882::AID-ADMA882>3.0.CO;2-Y.
 16. Butko B.O. Tendentsii rozvytku sivtovoho rynku nanotekhnologii i nanoproduktii [Trends in the development of the sowing market of nanotechnologies and nanoproductions]. *Scientific notes of V.I. Vernadsky Taurida National University. Series: Economics and Management. Volume 30 (69). №4, 2019. P. 7–12. (in Ukrainian).*
 17. Husev A.A., Zakharova O.V., Baranchikov P.A. Bezopasnost nanotekhnologiy: mediko-ekologicheskoye, tekhnologicheskoye i yuridicheskoye storony [Safety of nanotechnology: medico-ecological, technological and legal aspects]. *State legal research*. 2020 №3. P. 96–100. (in Russian).
 18. Gusev A.I. Nanomaterialy, nanostruktury, nanotekhnologii [Nanomaterials, nanostructures, nanotechnology]. M.: FIZMATLIT, 2007. 416 p. (in Russian).
 19. Pecherskyi O.V. Problemy pravovoho rehulivannia vidnosyn u sferi nanotekhnologii v Ukraini [Problems of legal regulation of relations in the field of nanotechnology in Ukraine]. *Law and security*. 2016. №3 (62) P. 56–59. (in Ukrainian).
 20. Trakhtenberh I.M., Dmytrukha N.M. Do pytannia bezpeky nanotekhnologii i nanomaterialiv [On the safety of nanotechnologies and nanomaterials] // *Bioethics: from theory to practice*. K.: VD «Avitsena» 2-21. 144 p. (in Ukrainian).
 21. Treneva Ya. Nanotekhnologii – «tabula rasa» v sfere normativnogo obespecheniya [Nanotechnology – «tabula rasa» in the field of regulatory support]. *Lega si viata*. 2013. № 12. P. 207-211. (in Russian).

22. Treneva Ya. Nanotekhnologii i sovremennoye ugolovnoye pravo: perspektivy razvitiya obshchikh problem dlya respubliki Moldova i Ukrainy [Nanotechnology and modern criminal law: prospects for the development of common problems for the Republic of Moldova and Ukraine]. *Lega si viata*. 2013. № 11. P. 210-214. (in Russian).
23. Turanin V.Yu., Sergeyeva D.A. K voprosu o pravovykh osnovakh razvitiya nanotekhnologiy v Rossii [On the issue of the legal framework for the development of nanotechnology in Russia]. *Scientific statements. Series Philosophy, Sociology, Law*. 2012. №2 (121). Issue 18. P. 87-90. (in Russian).
24. Chumak O.V. Etychni problemy vprovadzhenia nanotekhnolohii v umovakh rozvytku innovatsiinoho suspilstva [Ethical problems of nanotechnology implementation in the conditions of innovation society development]. *Humanitarian Bulletin ZDIA*. 2009. Issue 37. P. 96-104. (in Ukrainian).