NANOTECHNOLOGY & LAW IN THE 21ST CENTURY*

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Abstract in original language

Napjainkban a nanotechnológia az egyik legfontosabb és leggyorsabban fejlődő iparág. Ez az új terület rengeteg új kíhívást és kérdést vet fel, amelyek megoldásra várnak. A tanulmány célja, hogy röviden ismertesse az aktuális problémákat, tendenciákat és eredményeket. Az értekezés két fő része a nanotechnológiai találmányok szabadalmazhatósági kérdéseit, valamint az e találmányokra és kutatásokra vonatkozó európai szabályozási keretrendszert tárgyalja.

Key words in original language

Nanotechnológia, nanotudomány, szellemi tulajdon, szabadalom, akció terv, USPTO, 977-es osztály.

Abstract

Nowadays nanotechnology is one of the most important and most rapidly developing industry. With this new industrial field arise a lot of new challenges and questions, which are waiting for the answer. This paper aims to briefly give a description about the current problems, tendencies and results. The two main part of the study discusses the patentability issues of nanotechnology inventions and the European regulation framework of these inventions and researches.

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Key words

Nanotechnology, nanoscience, intellectual property, patent, action plan, USPTO, class 977.

1. INTRODUCTION

In the 21st century one of the most important technological industry branch is nanotechnology. With this new area of industry comes a lot of challenges, e.g. patentability issues and patent infringement, the national and regional regulatory of manufacturing nanotechnology-based devices, health and environmental issues, technology transfer and etc. This paper aims to lighten up the cornerstones of these new challenges in this rapidly developing industry.

In April 2005, Lux Research in partnership with Foley & Lardner, released a report entitled the „Nanotech Intellectual Property Landscape". The authors reviewed 1 084 patents in the United States – representing 19 485 claims – which are somewhat related to nanotechnology. They distinguished five main nanomaterial platforms: (1) dendrimers; (2) quantum dots; (3) carbon nanotubes; (4) fullerenes; and (5) nanowires.[1]

2. THE USE OF „NANO" TERM

Before I discuss about the patentability of these inventions, first of all it is necessary to define the so-called nanotechnology. This is an important step also, because the descriptive and precise terminology is essential to providing effective patent protection for the inventions in the field of nanotechnology. But the key difficulties in patenting is the absence of standard terminology to describe these inventions. The United States Patent and Trademark Office (USPTO) created an independent nanotechnology patent class (class 977, discussed later), but it has due to define nanotechnology. The USPTO didn't want a broad definition overlapping

[1] SERRATO, R. – HERMANN, K. – DOUGLAS, C. The Nanotech Intellectual Property Landscape, in *Nanotechnology Law & Business*, Vol. 2., Issue 2 (2005), 150.

with traditional molecular chemistry, nor didn't want a so narrow definition, which could exclude any areas of nanotechnology from patentability. [2]

In technology marketing nanotechnology refers to objects that have one or more physical and spatial dimensions on a nanometer scale, and other nano-parameters, such as nanograms or nanoseconds are excluded from nanotechnology.[3]

According to the class 977 class definition, this special nanotechnology patent class provides for disclosures related to a research and technology development at the atomic, molecular or macromolecular level, in the length of scale of approximately 1–100 nanometer range in at least one dimension, and that provides a fundamental understanding of phenomena and materials at the nanoscale and to create and use structures, devices, and systems that have novel properties and functions because of their small and/or intermediate size.

The European Commission on 18 October 2011 adopted the Recommendation on the definition of nanomaterial.[4] According to this, nanomaterial means: A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1nm – 100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness, the number size distribution threshold o f 50 % may be replaced by a threshold between 1 % and 50 %.

In the business, „nano" term is used in different meanings. While „nano" is a fix and precise scale, one-billionth of meter, in some cases „nano" is used in micro-range, which is larger than nano-range, and in some cases „nano" is used in the lower Angstrom range. The phenomena could be named nanoproliferation. Heines reviewed a big amount of US patent that includes a nano-term in their disclosure. The scope range of nanoparticles in these patents are between 1-100 000 nanometer.[5] These patents proof that the examining personnel in the USPTO allows a wide range of patent application with term of „nano" in their claims.

The imprecise use of terminology raises the problem of examination of novelty and nonobviousness. In the Texas Digital Systems, Inc. v. Telegenix, Inc. patent

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[2] MOUTTET, B. Nanotech and the U.S. Patent & Trademark Office: The Birth of a Patent Class, in *Nanotechnology Law & Business*, Vol. 2, Issue 3 (2005), 262.

[3] HEINES, M. H. „Nano-Aerobics" and the Patent System, in *Nanotechnology Law & Business*, Vol. 2, Issue 4 (2005), 335.

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF, 2013.04.28.

[5] HEINES, 336–340.

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case the »court stated that claim terms bear a „heavy presumption" that they mean what they say and have the ordinary meaning that would be attributed to those words by persons skilled in the relevant art.«[6] The so-called ordinary meaning of claim terms should be ascertained by using dictionaries, encyclopedias, treatises and official guidelines. While the dictionary-based approach gives a „full-range meaning protection" to the patentees, it presents more difficulties. From one side, the existing terms could have a special and unique meaning in the multidiscipline field of nanotechnology. From the other side, the technological development brings a mass of terms waiting for the exact and final defining. So the dictionaries have to keep pace with the new researches.[7] In the area of nanotechnology the dictionaries can't help too much yet. The „nano" prefix is simply defined as one-billionth of the scope of the root word, but obviously there isn't so much patent claims with exactly one nanometer dimensional scale. For nanotechnology term the American Heritage Dictionary of the English Language gives the following explanation: the science and technology of building electronic circuits and devices from single atoms and molecules. According to the Merriam Webster's Collegiate Dictionary nanotechnology is the art of manipulating materials on an atomic or molecular scale especially to build microscopic devices (as robots).[8] In the better case, the lack of precise terminology leads to a false interpretation of the desired scope of the claim, in the worse case it could result a full misunderstanding around the claimed invention.

3. THE U.S. AND INTERNATIONAL CLASSIFICATIONS OF NANOTECHNOLOGY INVENTIONS

In 2004 the USPTO began a new project to create the first searchable nanotechnology patent class. In that year 1 000 of the 350 000 patent applications were related to nanotechnology, but there hadn't been any adequate patent class, and especially there had been no centralized resource or group of patent examiners assigned to handle nanotechnology.[9]

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[6] MOLENDA, J. J. The Importance of Defining Novel Terms in Patenting Nanotechnology Inventions, in *Nanotechnology Law & Business*, Vol. 1, Issue 2 (2004), 175.
[7] MOLENDA, 175.
[8] HEINES, 341.
[9] MOUTTET, 261.

The newly created nanotechnology class is different from the traditional classes. A traditional U.S. patent class is designed around a specific technological area. For example the class 063 is the designated area of jewelry, the class 310 is for electrical generators. Every class is divided into subclasses, and these subclasses are arranged in mainlines and more indent levels.

In the most cases the new classes are based upon an earlier class or classes. When a subclass within a class starts to grow rapidly and an imbalanced situation arises, within the frames of reclassification this subclass will be separated and gain an own class number. This evolutionary growth characterized the U.S. patent classification system. However nanotechnology broke this pattern because it is not simply a refinement of an older technology, but, rather a fundamentally new way of doing things for which the pertinent patent literature is scattered in dozens of different classes.[10]

Class 977 has at this moment 5 subclasses, these are the followings:

- Nanostructure, with 138 subclasses.
- Mathematical algorithms, e.g. computer software, etc., specifically adapted for modeling configurations or properties of nanostructure, without subclasses.
- Manufacture, treatment or detection of nanostructure, with 60 subclasses.
- Specified use of nanostructure, with 59 subclasses.
- Miscellaneous, without subclasses.

The class 977 is not a traditional original classification area, but it is designated as a „cross-reference classification" area. This means that patent and other documents related to this class are placed first in the areas related to the specific technology involved, and the secondary class could be the nanotechnology class. So this way the class 977 gives a supplemental search base specific to nanotechnology.[11]

The U.S. nanotechnology classification model was taken by pattern to the international patent classification (IPC) system, managing by the World Intellectual Property Organization. The class B82 – which was created in the 7th version of IPC and restructured in 2011 – covers the inventions in the field of nanotechnology. In the scope of this class – similar to the U.S. class 977 – the „nano size" or „nano-scale" terms relate to a controlled geometrical size below 100 nanometers in one or more dimensions, and „nano-structure" means an entity having at least one

[10] MOUTTET, 261.
[11] MOUTTET, 261.

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nano-sized functional component that makes physical, chemical or biological properties or effects available, which are uniquely attributable to the nano-scale.[12] The B82 class has two subclasses:

- B82B, nano-structures formed by manipulation of individual atoms, molecules, or limited collections of atoms or molecules as discrete units; manufacture or treatment thereof,
- B82Y, specific uses or applications of nano-structures; measurement or analysis of nano-structures; manufacture or treatment of nano-structures.

The B82B subclass does not cover chemical or biological nano-structures per se, provided elsewhere in other classes. The B82Y subclass covers applications and aspects of nano-structures which are produced by any method, and is not restricted to those that are formed by manipulation of individual atoms or molecules. The cross-reference classification works in the IPC too. Those nano-structures that have specialized features or functions are further classified in appropriate places in other subclasses provided for those features or functions. Moreover, class B82Y is for obligatory supplementary classification of subject matter already classified as such in other classification places. In this subclass multi-aspects classification is applied, so that aspects of subject matter that are covered by more than one of its groups should be classified in each of those groups. Because of that the classification symbols of this subclass are not listed first when assigned to patent documents.

4. NANOTECHNOLOGY REGULATIONS IN THE EUROPEAN UNION

Articles 179 to 190 of the Treaty on the Functioning of the European Union (hereafter TFEU) are the current foundations of the EU research and space policies. Article 179 section 1 TFEU lays down the principles:

The Union shall have the objective of strengthening its scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry, while promoting all the research activities deemed necessary by virtue of other Chapter of the Treaties.

[12] http://web2.wipo.int/ipcpub/#&viewmode=a&lang=en&version=20130101&symbol=B82&notion=scheme&refresh=showdeleted&indexes=yes&showdeleted=yes, 2013.02.28.

But a few years before the adoption of the TFEU there were initiatives in the field of nanotechnology. In 2002, the Directorate General for Research of the Commission published a working paper on nanotechnology advances in Europe. This 28 page long document gave an overall outlook about nanotechnology and its funding concerns, and focused on the special research areas of the nanotechnology.[13]

In 2003, the EuroNanoForum gathered participants from civil society, industry and policy-makers. The conclusion of the series of conferences was an idea to establish a code of conduct at global level.[14] A few months after the first EuroNanoForum, the European Commission launched the communication Towards a European Strategy for Nanotechnology. The aim of the communication was to determine some common principles, which could be embodied in a voluntary framework between the countries, who are active in nanotechnology researches. The communication calls it a „code of good conduct".[15]

On June 7, 2005 the European Commission, the European Parliament and the Economic and Social Committee adopted an Action Plan (based on the Commission's Communication Towards a European Strategy for Nanotechnogy) for the term 2005–2009 for the implementation of a strategy for European nanoscience and nanotechnology development.[16] The financial background of this strategy goes back to 2000, when the member states of the European Council at Lisbon expressed commitments to develop a knowledge-based economy and to bring research funding up to 3 % of their GDP.[17]

The action plan handle nanosciences and nanotechnology together (hereafter N&N). According to the definition of N&N in the action plan it is a new approach

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[13] *Nanotechnology advances in Euorope*, 2002, European Parliament, Directorate-General for Research, Scientific and Technological Options Assessment Series. http://www.europarl.europa.eu/RegData/etudes/etudes/join/2002/311204/DG-4-JOIN_ET(2002)311204_EN.pdf, 2013.04.28.

[14] BOCHON, A. Evaluation of the EC Recommendation for a Code of Conduct for Responsible Nanotechnology Research, in *Nanotechnology Law & Business*, Vol. 8. Issue 2 (Summer 2011), 119.

[15] It was adopted on 12. May 2004. Within this document a safe, integrated and responsible strategy was proposed, wich aimed to reinforce the EU's leading position in N&N R&D and innovation while addressed any environmental, health, safety and societal conerns upfront.

[16] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2005:0243:FIN:EN:PDF, 2013.03.02.

[17] COLLIN, J. European Commission Action Plan on Nanotechnologies: A Brief Presentation with a Viev on Intellectual Property, in *Nanotechnology Law & Business*, Vol. 3, Issue 1, (2006), 80.

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to R&D that concern the study of phenomena and manipulation of materials at atomic, molecular and macromolecular scales, where properties differ significantly from those at a larger scale. These advances can address the needs of citizens and contribute to the EU's competitiveness and sustainable development objectives for example in the field of public health, nanobiotechnology, employment and occupational safety and health, information society, energy, transport, security and space.

The key areas of the European Strategy and Action Plan are the followings: research, industrial innovation, infrastructures, education, societal aspects/ethics, risk assessment, regulation, international cooperation. Summarizing this key factors, we can state, that it is a goal to bring together public and private organizations across Europe to perform collaborative research and development for the interdisciplinary approach, which is a key factor in the nanotechnology. For nanotechnology it is crucial that a favorable environment for innovation is created, in particular for small and medium sized enterprises. To remain competitive in nanotechnology, the European Union has to create a world-class research infrastructure. It requires a huge amount of resources that could far beyond the regional or national governmental and industrial possibilities. To maintain the high competitiveness in research, the EU has to promote the up-to-date education, the lifelong learning of researchers and engineers. It is required to strengthen the mobility across state borders and disciplines and between academia and industry. The societal and ethical aspects have to taken account too. The society has the right to know the risks and benefits of the nanotechnology, because that way can the people make their own decisions to buy or use these inventions. Risk assessment is an important factor. The EU permanently investigates the current and potential impacts of nanotechnology based products on human health and the environment. Due to the foregoing, making the regulation framework is obviously one of the most important job of European Commission. And finally, because the scientific and technical challenges are huge and expand all over the world, it is essential to maintain international cooperation, both with industrially advanced and less advanced countries.[18]

The European Strategy and Action Plan made such a policy, which brings together the innovative development, the proactive stance, the human health and environmental issues and ethics or societal considerations.

In February 2008 the European Commission adopted a Code of Conduct for Responsible Nanosciences and Nanotechnology Research (hereafter Code of Conduct). The Code of Conduct is the part of the EU strategy towards nanotechnolo-

[18] http://ec.europa.eu/nanotechnology/pdf/nano_action_plan2005_en.pdf, 2013.04.28.

gies, which is adoptable on a voluntary basis, therefore it offers ethical toolkit as a soft law instrument.[19]

The Code of Conduct covers the so called nano-objects, which are – in the absence of recognized international terminology – nanoparticles and their aggregation at nanoscale, nano-systems, nano-materials, nano-structured materials and nano-products.[20] The above-mentioned recommendation on the definition of nanomaterials was published after two years than the Code of Conduct.

The Code of Conduct has two main role. First, to be a common reference for all the people and organizations interested or involved in nanosciences and nanotechnologies. Second, to be a European basis for dialogue with third countries and international organizations.[21]

At the center of the Code of Conduct is a set of general principles aimed at guaranteeing their respect by all stakeholders. The principles briefly are the followings:

a) Meaning: The N&N research activities should be comprehensible to the public.
b) Sustainability: N&N research activities should be safe, ethical and contribute to sustainable development serving the sustainability objectives of the Community as well as contributing to the United Nations's Millenium Development Goals.
c) Precautionary: N&N activities should be conducted in accordance with the precautionary principle, anticipating potential environmental, health and safety impacts of N&N outcomes.
d) Inclusiveness: Governance of N&N research activities should be guided by the principles of openness to all stakeholders, transparency and respect for the legitimate right of access to information.
e) Excellence: N&N research activities should meet the best scientific standards, including standards underpinning the integrity of research and standards relating to Good Laboratory Practices.
f) Innovation: Governance of N&N research activities should encourage maximum creativity, flexibility and planning ability for innovation and growth.

[19] BOCHON, 118.
[20] http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf 2013.04.28.
[21] BOCHON, 123.

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g) Accountability: Researchers and research organizations should remain accountable for the social, environmental and human health impacts that their N&N research may impose on present and future generations.

5. CONCLUSION

Unfortunately the first revision of the Code of Conduct and the public consultation of the Strategic Nanotechnology Action Plan (hereafter SNAP) 2010–2015 was a failure. The responses to the SNAP public consultation showed a global ignorance concerning the Code of Conduct. Of the respondents 33 % did not know of its existence, 30 % knew of its existence but have not read it, and 25 % have read it but do not used it. Only 12 % of the respondents use the Code of Conduct. [22] This ignorance shows, that different ethical aspects and scientific innovations can't be strictly handled, it has to be compromise between the stakeholders. Without it, a soft law instrument will be just a paper law, and nothing more. Maybe the financial and economical crisis had a role in strengthening the ignorance, and maybe because of that get stucked the adoption of SNAP 2010–2015.

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[22] BOCHON, 140.

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