

LEGAL ASPECTS OF PATENTING NANOTECHNOLOGICAL INVENTIONS

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1. INTRODUCTION

Innovations play a special role in the economic development nowadays. They are of key importance for the creation of better workplaces, development of environment-friendly society and the improvement of the quality of life as well as maintaining competitiveness on the global market. The European Commission identified technologies of strategic importance for the future development of the EU and called them Key Enabling Technologies (KETs). The Commission defines KETs as technologies that are “knowledge intensive and associated with high R&D intensity, rapid innovation cycles, high capital expenditure and highly-skilled employment”.¹ They enable process, goods and service innovation throughout the economy. KETs are micro- and nano-electronics, advanced materials, industrial biotechnology, photonics, nanotechnology and advanced manufacturing technologies. Nanoscience is currently the most dynamically growing branch of science; it is involved in research into phenomena and manipulation of materials on a nuclear, molecular and macromolecular scale. The objective of nanotechnology is to design, characterise, manufacture and use structures, devices, tools and systems, the features of which can be controlled by means of shape and size on a nanometre scale ($< 100 \text{ nm} = 10^{-7} \text{ m}$).² Nanotechnology is commonly considered to be the key technology of the 21st century; its importance results from its interdisciplinary nature. Application of nano-

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¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions, “A European strategy for Key Enabling Technologies – A bridge to growth and jobs”, COM/2012/341 of 26.06.2012.

² T. Dietl, *Nanotechnologie przyszłości*, Prace Komisji Zagrożeń Cywilizacyjnych Vol. 7, 2006, p. 3, http://www.ifpan.edu.pl/SL-2/articles/Dietl_PAU_KOM_ZAGR_06.pdf [accessed on 2/02/2017].

technology is very broad, inter alia, in medicine, IT, production and retention of energy, knowledge of materials based on nanotechnology and research into food, water and natural environment.³ Since the 1990s, a consistent growth in patent applications connected with nanotechnology has been recorded. The United States has been a leader in the field of patenting nanotechnological solutions. In 2017 the United States Patent and Trademark Office (USPTO) published 20,187 patents in the field of nanotechnology and 4,019 nanotechnological patents.⁴ Patent applications concern inventions in many sectors. However, it can be pointed out that the dominating nanotechnological inventions include computer technology and electronics, chemistry, biology, medicine, agriculture, materials, metrology and energy.⁵

The article aims to analyse the most important issues of patenting in the field of nanotechnology with special focus on the presentation of problems connected with matching patent requirements by nanotechnological inventions.

2. LEGAL ASPECTS OF NANOTECHNOLOGY DEVELOPMENT

Nanotechnology is currently a field that records an extremely dynamic development and creates opportunities to solve many civilizational problems. Particular states formulate strategies or programmes of nanotechnology development and increase the related investment. The United States is one of the most advanced countries in the field of regulating nanotechnology. Case law and jurisprudence have been occupied with the issues of patenting nanotechnological solutions for years. The European Union has also specified the objectives of legislation development in the field of nanotechnology. In accordance with Communication from the Commission "Regulatory aspects of nanomaterials", it is necessary to guarantee the community access to innovative nanotechnology applications and ensure the safety and protection of health and the environment.⁶ Due to the fact that the field is relatively new, there may also be potential risks posed by nanotechnological products. Many countries' regulatory bodies have already started work aimed at regulating and recognising the exposure to potential risks connected with nanoparticles. Some of them, like France, Belgium or the Netherlands, have already enacted legislation concerning nanomaterials. The current European Union law concerning nanomaterials applies to products, chemicals, the protection of workers and the environment. Special regulations apply to cosmetics, food and bactericides. Non-binding acts in

³ O.G. Schmidt et al., *Nanotechnology – Bottom-up meets top-down*, Springer-Verlag Berlin Heidelberg 2002, p. 231, http://bazy.pb.edu.pl:2083/full_record.do?product=WOS&search_mode=GeneralSearch&qid=5&SID=C1SV4bGglKVnrMBepQq&page=1&doc=8 [accessed on 28/06/2018].

⁴ *Top Ten Countries in Nanotechnology Patents in 2017*, Statnano.com: <http://statnano.com/news/62082> [accessed on 27/06/2018].

⁵ P. Ganguli, S. Jabade, *Nanotechnology, intellectual property rights, research, design, and commercialization*, Boca Raton, 2012, p. 15.

⁶ Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, "Regulatory aspects of nanomaterials", COM/2008/366 of 17.06.2008.

the form of recommendations and communications play an important role in regulating nanotechnology in the European Union. They specify, inter alia, the principles of doing research in nanosciences and nanotechnologies, and provide a definition of nanomaterials, which is important because of the already existing legislation. The European Commission recommends using this definition as a reference for determining whether a given material should be considered a nanomaterial for legislative purposes. It is important for all Member States to use a uniform definition. So far, there has been a big difference in the way states have used the term “nanomaterial” in individual cases in their legislation in order to identify particular substances.⁷

Due to the fact that the achievements of nanotechnology find applications in many fields of life, it is very probable that in the near future it will be necessary to regulate the solutions in this area that are subject to patent protection.

3. NANOTECHNOLOGY: TERMINOLOGY

Nanotechnology covers manufacturing elements of matter and/or forming their morphology on a scale range from 1 to 100 nanometres (nm). The range is conventional and not always applied in practice.⁸ The terminology connected with nanotechnology is not uniform, which causes problems with applying for a patent. The definition of a nanomaterial and nanoscale is important in the examination whether an invention meets patent requirements, especially in the patent search. The International Organisation for Standardisation defined a nanomaterial as a material with any external dimension in the nanoscale or having internal structure or surface structure in the nanoscale. The term nanoscale was defined as a length range approximately from 1 nm to 100 nm. The number size distribution of particles makes it possible to take into account the fact that nanomaterials are usually composed of many particles in various sizes in a specific distribution. In case of no determination of the number size distribution of particles it would be difficult to recognise whether given material meets the requirements of the definition in a situation when some particles are smaller than 100 nm and others are not.⁹ The Commission Recommendation of 2011 provides a definition of a nanomaterial as a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and, where, for at least 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range from 1 nm to 100 nm. In specific cases and where warranted by concerns for the environment or health, the number size distribution threshold of 50% may be replaced by a threshold between 1% and 50%. Interpretational problems result

⁷ Commission Recommendation of 18 October 2011 on the definition of nanomaterials, OJ L 275 of 10.10.2011, p. 38.

⁸ A. Świdorska-Środa, W. Łojkowski, M. Lewandowska, K.J. Kurzydłowski (ed.), *Świat nanocząstek*, PWN 2016, p. 18.

⁹ Nanomaterials definition fact sheet, European Environmental Citizens Organisation for Standardisation, November 2014, http://ecostandard.org/wp-content/uploads/Nano_definition.pdf [accessed on 20/07/2016].

from imprecise concepts contained in patent applications, e.g. a nano-agglomerate or a nano-aggregate. In case of the European Union, the concepts were defined in the Commission Recommendation: “agglomerate” means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components, and “aggregate” means a particle comprising of strongly bound or fused particles. The lack of a uniform definition makes the patent search difficult, which may cause duplication of solutions and, consequently, may lead to their nullification. Interdisciplinary solutions of nanotechnology may create difficulties in examination of patentability, which may result in granting unjustified protection to inventions. The most important patent offices, such as the European Patent Office or the United States Patent and Trademark Office, train their employees in the field of examining patentability of nanotechnological solutions.¹⁰ At present, all patent offices throughout the world have started to classify nanotechnology in a uniform way within the International Patent Classification (IPC) and the Cooperative Patent Classification (CPC). A new symbol, B82Y, was introduced to IPC on 1 January 2011 to replace the formerly used Y01N.¹¹ The uniform marking of all nanotechnological solutions will facilitate patent search for solutions invented in the area and also will prevent doubling patents.

4. OBJECT OF PATENT PROTECTION

Patents are the key to the growth of economy based on modern technologies. Own technologies make it possible to develop competitive industry and benefit from licence agreements. At present, the patenting system is subject to assessment and a debate to what extent it really stimulates the development of new technologies. The system should be conducive to innovative entrepreneurs, and protect companies and their innovative solutions against appropriation and use of intangible goods. There is an opinion in literature that intellectual property rights may also have a negative impact on innovativeness; too broad scope of exclusive rights may lead to legal uncertainty as to what constitutes the existing state of patented technological solutions and whether a reported invention will not infringe somebody else’s rights.¹² Interdisciplinary nature of nanotechnology and its application in many fields creates a possibility of formulating a broad scope of reservations and, thus, obtaining too broad patent protection. The phenomenon is quite common in case of new technologies when there is no complete knowledge in the given area. It may also cause low technological value of reported inventions and excessively limit competitiveness as well as discourage innovation.

¹⁰ A. Watal, T.A. Faunce, *Patenting nanotechnology: Exploring the challenges*, WIPO Magazine, 2 April 2011, p. 26, http://www.wipo.int/export/sites/www/wipo_magazine/en/pdf/2011/wipo_pub_121_2011_02.pdf [accessed on 12/01/2017].

¹¹ European Patent Office, *Nanotechnology*, <http://www.epo.org/news-issues/issues/classification/nanotechnology.html> [accessed on 16/12/2016].

¹² D. Miąsik, *Stosunek prawa ochrony konkurencji do prawa własności intelektualnej*, Wolters Kluwer, Warsaw 2012, p. 137.

A patent is an exclusive civil right that is property-related in nature, granted for an invention by the Patent Office by means of an administrative decision. Obtaining a patent, one is granted an exclusive right to use an invention in order to earn profits or in a professional way in the entire territory of the Republic of Poland. Patent claims contained in a patent description determine the scope of the patent object.¹³ Patent claims constitute the main element of a patent application because they determine the scope of the patent monopoly. In accordance with Article 33 para. 3 Industrial Property Law (hereinafter: IPL),¹⁴ the claims should briefly but clearly, by means of providing technical features of a solution, specify a reported invention and determine the scope of demanded patent protection.¹⁵ The European Union patent offices' experience indicates that patent claims concerning nanotechnological inventions are formulated with regard to such a broad scope that they also cover the existing solutions in other fields of technology. The lack of a uniform approach to the nanoscale is also a problem, which causes frequent cases of claims concerning the solutions on a macro scale.¹⁶ The patent protection term lasts 20 years from the day when an invention is reported to the Patent Office of the Republic of Poland. An entity applying for patent protection should take a decision concerning the territorial range of the protection because an invention protection covering only the country of the invention origin may turn out to be insufficient. That is why, it is necessary to take steps in order to obtain patent protection in other states; however, the choice should be based on the invention market potential.

In accordance with Article 24 IPL, an invention is an object of patent protection and patents are granted, regardless of the field of technology, for inventions that are new, involve an inventive step and can be applied industrially. There is no definition of an invention, which inter alia results from the fact that technologies are developing so fast and in such an unpredictable direction that it is not possible to formulate this definition. Therefore, most legal systems determine the requirements for granting invention protection. In case law, it is assumed that an invention is a solution to a problem with the use of nature in order to achieve a reasonably predictable result that is beyond the sphere of human intellectual influence. In the light of Polish law, an invention must be connected with the influence on matter by its new technical application and must result in a physical product of a new structure or composition or a new way of technical influence on matter.¹⁷

In order to obtain a patent, an invention must meet four basic requirements. It must be technical in nature, new, characterised by an inventive step and industrially

¹³ J. Sieńczyło-Chlabicz, *Prawo własności intelektualnej*, Wolters Kluwer, Warsaw 2018, p. 598.

¹⁴ Act of 30 June 2000: Industrial Property Law, Journal of Laws [Dz.U.] of 2001, No. 49, item 508.

¹⁵ K. Celińska-Grzegorzczak, *Postępowanie patentowe jako szczególne postępowanie administracyjne*, LexisNexis, Warsaw 2009, p. 210.

¹⁶ M.G. Poza, V. Balmaseda, *Examination practice at the OEPM in the field of nanotechnology*, [in:] *Patenting procedures in the field of nanotechnology*, Madrid 27–28 October 2015, http://www.oepm.es/export/sites/oepm/comun/documentos_relacionados/Ponencias/94_00_PatentingProceduresInTheFieldOfNanotechnology.pdf [accessed on 28/06/2018].

¹⁷ Judgement of the Voivodeship Administrative Court in Warsaw of 15 December 2009, VI SA/Wa 719/09, LEX No. 583588; the Supreme Administrative Court judgement of 16 March 2011, II GSK 374/10, Legalis No. 360713.

applicable. The technical requirement is laid down in Article 25 IPL which stipulates that patents are granted to inventions, regardless of the field of technology. This condition raises doubts because it is not defined in IPL in the same way as the conditions for novelty, innovativeness and industrial application. However, in accordance with §32 para. 1(1) Regulation concerning reporting and dealing with reports of inventions and utility designs¹⁸ (hereinafter: RIUD), the Patent Office does not recognise a reported object as an invention if it establishes that it does not concern any physical object that can be used, specified with the use of technical features referring to its construction or composition or the way of technical influence on matter, or a new application of a substance constituting part of the existing patented technologies. Thus, an invention cannot be abstract in nature; it must be within the sphere of technical sciences. The condition of technical features has not been defined in the European Patent Convention (henceforth: EPC),¹⁹ either. However, it results from the statement in Article 52 para. 1 EPC that patents must be granted for any inventions in all technical fields. Article 27 para. 1 Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter: TRIPS)²⁰ contains a similar formulation. The requirement of a technical nature of a solution also results from the provisions of implementing EPC regulations determining the rules of developing the European patent applications. According to them, a solution is technical in nature when it concerns a field of technique, a technical issue and is characterised by the use of technical means.²¹ Examination of the condition of technical features becomes an element of practice in the majority of states that are parties to EPC. This approach is also applicable in the light of IPL, which is confirmed in administrative courts' case law.²² Having recognised that an invention has a technical nature, the Patent Office examines whether the reported invention meets the three remaining requirements.

5. SCIENTIFIC DISCOVERY VERSUS PATENTING

Sciences such as biotechnology or nanotechnology, which are constantly growing very dynamically, provide great opportunities to find new solutions. This leads to impressive discoveries that have extraordinary importance for mankind or are significant from the point of view of economic development. In case of nanotechnological

¹⁸ Regulation of the President of the Council of Ministers of 17 September 2001 on reporting and dealing with reports of inventions and utility designs, Journal of Laws [Dz.U.], No. 102, item 1119.

¹⁹ European Patent Convention of 5 October 1973, Poland became a party to the Convention on 1 March 2004, Journal of Laws [Dz.U.], No. 79, items 737 and 738.

²⁰ Agreement on Trade-Related Aspects of Intellectual Property Rights of 15 April 1994, Journal of Laws [Dz.U.] of 1996, No. 32, item 143; Annex to the Agreement of 14 July 1967 Establishing the World Trade Organisation (WTO), Journal of Laws [Dz.U.] of 1975, No. 9, item 49.

²¹ U. Promińska, *Prawo własności przemysłowej*, Difin, Warsaw 2005, p. 44.

²² K. Szczepanowska-Kozłowska, A. Andrzejewski et al., *Własność intelektualna, wybrane zagadnienia praktyczne*, LexisNexis, Warsaw 2013, p. 49.

solutions, special focus must be on scientific discoveries and theories. Based on the Polish Industrial Property Law (Article 28 IPL) as well as in the systems of many states, scientific discoveries are excluded from patent protection. Article 52 para. 1 of the Munich Convention on the Grant of European Patents of 5 October 1973²³ stipulates that European patents are granted for any invention provided that they are new, involve an inventive step and are susceptible of industrial application. In accordance with para. 2 of the Contention, discoveries are not regarded as inventions. The concept of a discovery has not been defined so determining what is one and, thus, is not subject to patenting must be analysed in the context of a particular technology. In literature, there are statements that discoveries are physical phenomena occurring in nature but have not been noticed and proved yet, and inventions are technical solutions that men come up with. Scientific discoveries are determinations of formerly unknown features or phenomena occurring in nature.²⁴ A discovery does not result in practical application and, thus, does not provide a ready solution to a technical problem.²⁵ A discovery may contribute to an invention but, on its own, it cannot be identified with one. Patent protection may also concern a new technology that has contributed to a discovery. However, there have been attempts to patent discoveries by attributing the features of an invention to them; this is what happened in case of a discovery in the field of biotechnology, i.e. the sequencing of the human genome.²⁶ It raises considerable controversies and has become subject to numerous litigations. The recognition and description of the functions of a given gene should be treated as a discovery. A gene isolated from the natural environment, cleaned or modified in the way in which it does not exist in nature can be patented. Also a gene that is identical to a natural one but produced in a technical way can be patented.²⁷ The above explanation concerns biotechnology but similar problems can be observed in the field of discoveries in nanotechnology. It is extremely difficult to grant exclusive rights to a discovery in the field of nature. In nanotechnology, discoveries concerning new features of carbon materials the basic elements of which are a few or several nanometres in diameter, e.g. carbon nanotubes, led to a technological and civilizational revolution. Carbon nanotubes, discovered by Sumio Iijima several years ago, constitute a basis for work on new composite materials, which have extraordinary mechanical strength or electrical conductivity.²⁸ Graphene is also

²³ Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as amended by the act revising Article 63 Convention of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998 and comprising the Protocols which constitute its integral part, Journal of Laws [Dz.U.] of 2004, No. 79, item 737.

²⁴ U. Promińska, *Prawo własności...*, p. 45.

²⁵ P. Kostański, *Prawo własności przemysłowej. Komentarz*, C.H. Beck, Warsaw 2014, citation after J. Sieńczyło-Chlabicz, *Prawo własności...*, p. 565.

²⁶ B. Fischer, *Ochrona patentowa produktów nanotechnologicznych*, Przegląd Prawa Handlowego No. 6, 2005, p. 50.

²⁷ G. Kawłatow, *Patentowanie ludzkich genów*, *Diametros* No. 32, 2012, p. 79, <http://www.diametros.iphils.uj.edu.pl/index.php/diametros/article/download/478/568> [accessed on 2/02/2017].

²⁸ A. Świdarska-Środa, W. Łojkowski, M. Lewandowska, K.J. Kurzydłowski (ed.), *Świat nanocząstek...*, p. 55.

a nanomaterial consisting of a single layer of carbon atoms, which is 100 times stronger than steel and has unique electrical properties. What can be patented is the production of graphene, which is a complicated technological process and which scientific centres all over the world try to improve. Both materials have an enormous potential in science and industry and, although their production is still difficult and expensive, patenting activity in the field of application of those two nanomaterials has increased especially since 2010.²⁹ Nano-scale production requires new complicated methods, which can meet the requirements of patentability. In most cases, solutions in nanotechnology are based on matter within which artificial interference has occurred, which has resulted in solutions unknown in nature and which can be patented, provided they meet the requirements of patentability.³⁰ In case of nanotechnological inventions, the problem results from the lack of regulations determining the object of protection. It is hindered, inter alia, by incoherent terminology (e.g. nanotechnology, nanoscale, nanomaterial) and incomplete knowledge of nanotechnology. In case of biotechnology, a regulation taking into account the specificity of patent protection of biotechnological inventions was included in the Industrial Property Law. Maybe, with the development of nanoscience, provisions determining conditions for patenting inventions in this field will be enacted. In the face of problems concerning the procedure of registering nanotechnological inventions, it seems that such a regulation is necessary.

6. NOVELTY AND INVENTIVE LEVEL REQUIREMENTS

In accordance with Article 25 IPL, an invention is recognised as a novelty if it is not part of the actual state of technology, i.e. everything that before the date determining the priority to obtaining a patent was disclosed to the public in the form of a written or oral description, by application, display or reveal in any other way. In literature, there is an opinion that the state of technology is a legal term and never reflects a particular person's actual knowledge. Thus, a novelty of an invention in an objective sense is required and not an inventor's subjective opinion on his solution.³¹ The state of technology may be basic or extended. The basic state of technology concerns solutions that have been sufficiently revealed before the date of priority to obtaining a patent. The date of priority to a patent is a date of reporting an invention to the Patent Office of the Republic of Poland, the date of reporting in a patent office of another country or a priority date resulting from the disclosure of an invention at an official international exhibition or one officially recognised.

²⁹ D. Jost, T. Cottler, *Broad concerns about nanotechnology patents: Symptoms and diagnosis*, Working Paper No. 2012/13, June 2012, p. 15, http://www.wti.org/media/filer_public/13/c5/13c527f4-019e-4172-9f0d-27bec3ca53d1/nccr_wp2012_13_nanopatentssymptomsdiagnostic_jost_cottier2012june.pdf [accessed on 11/01/2017].

³⁰ M. Balcerzak, *Zagadnienia nanotechnologii w prawie. Czy nanotechnologia może czerpać z doświadczeń biotechnologii?*, [in:] D.M. Trzmielak (ed.), *Innowacje i komercjalizacja w biotechnologii*, Poznań–Łódź 2013, p. 159, http://www.proakademia.eu/gfx/baza_wiedzy/455/innowacje_i_komercjalizacja_w_biotechnologii_2.pdf [accessed on 20/06/2018].

³¹ K. Celińska-Grzegorzczak, *Postępowanie patentowe...*, p. 26.

The extended state of technology concerns information contained in inventions or utility designs reports making use of a former priority, not disclosed to the public, provided they are revealed in the way determined in statute.³² This means that if a report has not been formerly disclosed, the requirement of a novelty is not frustrated.³³ A new wording of Article 25 para. 4 IPL entered into force on 1 January 2015. It lays down that a patent can be granted for an invention of substances or mixtures constituting part of the state of technology applicable or that can be applied in a strictly specified way in treatment or diagnostic methods, provided that such an application does not constitute part of the state of technology. A new para. 5 was also added to Article 25 IPL, which determines that it will be possible to obtain a patent, regardless of an invention disclosure by third parties. However, there is a requirement that the invention should not be reported later than six months after the disclosure, which is an obvious abuse of the person reporting or his legal predecessor. The provision should facilitate obtaining patent protection, especially in a situation when one fails to protect oneself with former secrecy agreements against unauthorised use of knowledge about one's solution.

As far as the solutions in the field of nanotechnology are concerned, some problems with the global patent search arise in the course of the requirement of novelty examination. The problems result from the lack of complete knowledge about nanotechnology or no access to it. Apart from that, it is an interdisciplinary field linked to such sciences as biology, medicine, chemistry, electronics or mechanics. Thus, patents may be doubled. The same or a similar solution may be reported by different entities to different units in the Patent Office. The World Intellectual Property Organization (WIPO) observes such a phenomenon concerning nanotubes, nanofibres, nanocrystals or nanoemulsions.³⁴ A question is also asked whether the fact of reporting a solution on a scale exceeding 100 nm³⁵ does not annihilate a condition of a novelty for the same solution in a nanoscale reported later. The European Chemicals Agency believes that "nanomaterials may have different characteristics compared to the same materials without nanoscale features. Therefore, the physico-chemical properties of nanomaterials may differ from those of the bulk substances or particles of a larger size".³⁶ This statement indicates that the size has impact on the features of a material; however, it is the same material as one already patented. Still, there is no uniform approach to meeting the requirement of novelty because of the difference in size (dimensions and capacity) in comparison with the former inventions. Patent offices of the United States or Japan and the

³² A. Niewęgłowski, *Wynalazki, wzory użytkowe i wzory przemysłowe*, [in:] T. Demendecki et al., *Prawo własności przemysłowej*, Komentarz LEX, Wolters Kluwer Business, Warsaw 2015, pp. 116–117.

³³ M. du Vall, *Prawo patentowe*, Wolters Kluwer, Warsaw 2008, p. 186.

³⁴ A. Watal, T.A. Faunce, *Patenting nanotechnology...* [accessed on 8/02/2017].

³⁵ International Organization for Standardization (ISO) defined the term nanoscale as a length range approximately from 1 nm to 100 nm, and a nano-object as a material with one, two or three external dimensions in the nanoscale. Source: ISO/TS 80004-2:2015: "Nanotechnologies – Vocabulary – Part 2: Nano-object".

³⁶ European Chemical Agency, *Nanomaterials*, <http://echa.europa.eu/pl/regulations/nanomaterials> [accessed on 20/12/2016].

European Patent Office tried to introduce a uniform terminology in order to limit patent applications in which applicants defined different nanoscales for the reported solutions, which hindered patent search.³⁷ According to the European Patent Office, the change of scale to the nanosize does not have to be sufficient to treat a solution as a novelty.³⁸ The solutions can be patented, provided that an additional circumstance that has occurred as a result of the change of size is proved. "This circumstance may mean obtaining the same effect but at a surprisingly higher level or obtaining a completely different effect from expected as a result of miniaturisation".³⁹ Thus, one should approve of a statement that it is necessary to prove that a nanotechnological invention differs from its macro-scale "counterpart" as far as the set objectives or doubts about the obtained effects are concerned.⁴⁰

After the recognition of technical features of a given solution, it is necessary to establish whether an expert in the given field, having to solve a technical problem, would be able to modify or adapt the closest patented solution and to obtain the effects of an invention in this way. If the solution to the problem is surprising in the light of the global state of technology, one can recognise that an invention involves an inventive step. However, the examination of the inventive level concerns only those solutions that have already been determined to be new. The examination of inventiveness requires that the object reported should be compared with the entire patented technology.⁴¹ Article 26 IPL uses a category of "an expert", which in the face of the fast progress in technology may undergo changes, especially in the context of new technologies such as nanotechnology. The term "expert" may suggest it is a person who has extraordinary knowledge of the given field of technology. Case law indicates, however, that it is, inter alia, "a specialist who knows the closest patented solutions in the given field";⁴² "an ordinary specialist having commonly available knowledge in the given field of technology"⁴³. The practice of patent offices indicates that it is an average graduate working in the given research field.⁴⁴ However, it should be emphasised that the assumption of "ordinariness" of the level of knowledge in relation to new technologies such as biotechnology or nanotechnology may be wrong. The fields impose special requirements on experts to be employed in patent offices.⁴⁵ There is no uniform approach to the interpretation of the term "expert" in the context of nanotechnology. Since it is an interdisciplinary field, a question is asked in which fields an expert should have

³⁷ A. Watal, T.A. Faunce, *Patenting nanotechnology...* [accessed on 8/02/2017].

³⁸ European Patent Office, *Nanotechnology and patents*, [http://documents.epo.org/projects/babylon/eponet.nsf/0/623ECBB1A0FC13E1C12575AD0035EFE6/\\$File/nanotech_brochure_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/623ECBB1A0FC13E1C12575AD0035EFE6/$File/nanotech_brochure_en.pdf) [accessed on 10/01/2017].

³⁹ M. Balcerzak, *Zagadnienia nanotechnologii w prawie...*, p. 161.

⁴⁰ B. Fischer, *Ochrona patentowa produktów...*, p. 51.

⁴¹ U. Promińska, *Prawo własności...*, p. 62.

⁴² Judgement of the Voivodeship Administrative Court in Warsaw of 12 March 2010, VI SA/Wa 2079/09, CBOSA.

⁴³ The Supreme Administrative Court judgement of 19 April 2012, II GSK 1140/11, CBOSA.

⁴⁴ M. Balcerzak, *Zagadnienia nanotechnologii w prawie...*, p. 161.

⁴⁵ D. Kasprzycki, *Kontrowersje wokół zdolności patentowej wynalazków biotechnologicznych*, Repozytorium Uniwersytetu w Białymstoku 2015, p. 149, https://repozytorium.uwb.edu.pl/jspui/bitstream/.../1/BSP%2019_D_Kasprzycki.pdf [accessed on 28/06/2018].

sufficient knowledge.⁴⁶ Thus, it is right to state that the level of knowledge of an expert who is involved in a narrow specialisation may be naturally high because it is the knowledge selected from a bigger whole, which specialists in other fields may know less. What is also important, imposing strict requirements of the level of average knowledge on experts may have impact on the examination of patentability criteria.⁴⁷ Thus, the assessment of an inventive step in case of a solution in the field of nanotechnology may cause a problem because of novelty and sophistication of such solutions for experts with general knowledge in the field.

Another problem concerns the requirement of disclosure of the basic knowledge about an invention in the patent description. One of the conditions for a patent grant is the disclosure of an invention in a patent application. The disclosure must be complete and should enable an average expert in the given field whose task is to solve a technical problem to copy the invention based on the description in the application. An inventor does not have to reveal detailed information about how the invention works or present a theoretical model. The only requirement is the disclosure of information in the manner sufficient for it to be carried out by a person skilled in the art (Article 83 EPC). In some cases, an applicant may be obliged to reveal the scientific theory based on which he has made the invention, e.g. if an invention contradicts general rules of physics and adopted theories, an inventor must prove that industrial application of his invention is possible and this is connected with a more detailed patent description.⁴⁸ The requirement of a more detailed description may occur in case of nanotechnological solutions because of the lack of complete knowledge about nanomaterials. That is why, a patent application must contain a representative number of examples in relation to the predictability of the field of science concerned.⁴⁹

7. ETHICAL ASPECTS OF PATENTING NANOTECHNOLOGICAL INVENTIONS

In 2009, a report on regulatory aspects of nanomaterials was presented in the European Parliament.⁵⁰ It took into account the Commission Communication of 17 June 2008 "Regulatory aspects of nanomaterials". The report suggests that the European Commission notices the advantages of the growth in nanotechnology and, at the

⁴⁶ M. Schellekens, *Patenting nanotechnology. Are we on the right track?*, [in:] M.E.A. Goodwin, B.J. Koops, R.E. Leenes (ed.), *Dimensions of technology regulation*, pp. 107–124, Wolf Legal Publishers, Nijmegen 2010, p. 6, https://pure.uvt.nl/ws/files/1225655/Schellekens_Patenting_nanotechnology_100526.pdf [accessed on 28/06/2018].

⁴⁷ A. Niewęglowski, *Wynalazki, wzory użytkowe i wzory przemysłowe...*, p. 125.

⁴⁸ M. Cisneros, *Patentability requirements for nanotechnological inventions*, Munich Intellectual Property Law Center 2009, p. 19.

⁴⁹ B. Fischer, *Ochrona patentowa produktów...*, p. 54.

⁵⁰ Report on regulatory aspects of nanomaterials (2008/2208(INI)), the Committee on the Environment, Public Health and Food Safety, document adopted at the European Parliament session, PE418.270v02-00, www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A6-2009-0255+0+DOC+XML+V0//PL [accessed on 19/08/2016].

same time, is aware of hazards resulting from this development to people and the natural environment. The European Commission confirms the lack of complete knowledge of potential threats posed by nanomaterials, concerns raised over evidence that some nanomaterials carry a risk and a general shortage of methods of proper assessment of threats connected with nanomaterials.

Pursuant to EPC, patents should not be granted for inventions the exploitation of which would be contrary to *ordre public* or morality (Article 53(a) EPC). On the other hand, in accordance with TRIPS, "Members can exclude from patentability invention, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law" (Article 27 para. 2 TRIPS). Exclusion from patenting inventions that are in conflict with *ordre public* and morality is also possible in accordance with the Polish law, which results from Article 29 para. 1(1) IPL. However, such exclusion would be possible only in case there is information at the moment of taking such a decision that the given nanoparticle might cause damage to the environment or human health.⁵¹ Today, the main fears concern artificially manufactured nanoparticles and control over them. They easily penetrate a living organism through the lungs, the digestive system and skin, and may even reach the brain.⁵² The presence of nanoparticles in food, cosmetics or pharmaceuticals must be given appropriate attention. Consumers should be provided with an opportunity to learn that a given product contains nanoparticles in order to be able to make a conscious decision whether they want to buy it. The EU regulations determine the requirements in this area in relation to cosmetics, food, bactericides, plant protection products and pharmaceutical products. Regulations in this area contain definitions of nanomaterial and requirements for marking such products with information that a given product contains a nanomaterial.

Before patents were granted for biotechnological inventions, a ban on patenting inventions contrary to *ordre public* and morality had not been the subject of a lively debate. The ban was seldom applied then, e.g. to some types of ammunition, bombs sent in letters and anti-personnel mines.⁵³ With the dynamic growth of biotechnology and controversies over inventions in this area, the debate over this issue revived. It concerned, inter alia, patenting transgenic organisms the introduction of which to the environment might disturb ecological balance, and thus, pose a threat to the natural environment. The appeals boards of the Patent Office of the Republic of Poland and of the European Patent Office discussed the issue.⁵⁴ Therefore, it is possible that one day there will be a regulation excluding inventions in the field of nanotechnology

⁵¹ M. Cisneros, *Patentability requirements...*, p. 22.

⁵² S. Bujak-Pietrek, *Narażenie na nanocząstki w środowisku pracy jako zagrożenie dla zdrowia*, *Medycyna Pracy* No. 61 (2), 2010, p. 186, <http://lodz.pip.gov.pl/f/v/93622/07%20Nanocząsteczki%20i%20nanomaterialy%20charakterystyka.pdf> [accessed on 2/02/2017].

⁵³ U. Promińska, *Prawo własności...*, p. 51.

⁵⁴ R. Witek, *Czy patentowanie może być niemoralne?*, <http://wtspatent.pl/wp-content/uploads/2014/05/pl4.pdf> [accessed on 15/12/2015].

because of their non-compliance with *ordre public* and morality in a situation when harmfulness of a nanomaterial is identified. However, it is a complicated issue and, although legal norms concerning patents for biotechnological inventions were established, the assessment of ethical aspects of new technologies by the employees of patent offices remains controversial.

8. CONCLUSIONS

At present, we observe activities aimed at regulating nanotechnology. In the European Union, some states undertake steps to introduce legislation directly concerning nanomaterials. Due to the use of nanotechnology in many fields, this regulation does not constitute a separate branch of law. It is indicated that there is a need to adjust legislation to particular sectors with respect to untypical features of nanomaterials. In the field of patenting nanotechnological solutions, some problems occurred connected with meeting patentability requirements for this type of inventions. Due to the interdisciplinary nature of nanotechnology and incomplete knowledge of the field, there are difficulties with determining whether the reported solutions constitute a novelty. The differences in the size of the reported nanotechnological inventions also result in difficulties with the recognition of a novelty. The experience of patent offices indicates that different nanoscales are determined for reported solutions and this also hampers patent search. As far as the recognition of an inventive step is concerned, there are difficulties with ambiguity of the concept of an expert, especially in the context of nanotechnology. New technologies such as nanotechnology or biotechnology require that patent office experts should have more specialist knowledge, which cannot be described as average knowledge in a given field of technology. It seems that ethical issues connected with patenting nanotechnological inventions are also important. Although, at present, there is mainly a debate in literature over biotechnological inventions, attention should be also drawn to this issue in relation to nanotechnology. With learning the features of nanoproducts and possible confirmation of harmfulness of some of them, there may be a necessity of referring the provisions excluding the possibility of patenting inventions that are contradictory to *ordre public* and morality to this kind of solutions. It is possible that in the future the EU legislator will decide to regulate nanotechnology in the context of intellectual property rights, especially as the problem occurred when the uniform European patent was developed. The European Commission is of an opinion that the present conditions for the protection of the achievements of nanosciences and nanotechnology are less favourable than in other patent systems.⁵⁵

⁵⁵ M. Balcerzak, *Zagadnienia nanotechnologii w prawie...*, p. 169.

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LEGAL ASPECTS OF PATENTING NANOTECHNOLOGICAL INVENTIONS

Summary

Nanotechnology uses a basic unit of measure called a "nanometre" (nm). It is one-billionth of a metre. Nanotechnology is a very vast field, which includes a range of nanoscale technologies, such as pharmaceutical sciences, biotechnology, genomics, neuroscience, robotics, information technologies, etc. In the 1990s there was a significant growth in the number of nanotechnological patents. Patenting nanotechnological inventions is not the same as that of other technologies as there are some problems with patent requirements. The difficulties concern fulfilling patentability criteria for novelty, inventiveness and industrial applications. The lack of a standardized definition of nanomaterials has implications for patent search and classification. The aim of this article is to analyse the main problems with patenting nanotechnological inventions.

Keywords: nanotechnology, nanomaterial, patent, patentability requirements, industrial property

PRAWNE ASPEKTY PATENTOWANIA WYNAŁAZKÓW NANOTECHNOLOGICZNYCH

Streszczenie

Nanotechnologia wykorzystuje podstawową jednostkę miary zwaną „nanometr” (nm). Jest to jedna miliardowa część metra. Nanotechnologia jest bardzo rozległą dziedziną, która dotyczy technologii w skali nano, takich jak farmacja, genetyka, biotechnologia, neurologia, robotyka czy technologie informatyczne. W 1990 roku nastąpił znaczny wzrost liczby patentów w dziedzinie nanotechnologii. Patentowanie wynalazków nanotechnologicznych różni się jednak od patentowania innych technologii. Istnieje kilka problemów związanych ze spełnieniem wymagań patentowych. Trudności dotyczą przesłanek zdolności patentowej, nowości, nieoczywistości i zastosowań przemysłowych. Brak znormalizowanej definicji nanomateriałów ma wpływ na poszukiwania w stanie techniki i klasyfikację patentową. Celem artykułu jest analiza zagadnień problematycznych w zakresie patentowania wynalazków nanotechnologicznych.

Słowa kluczowe: nanotechnologia, nanomateriał, patent, przesłanki zdolności patentowej, własność przemysłowa

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