Considerations on the patentability of nanotechnologies

Valerio Brizzolari *

SUMMARY: 1. The development and status of nanotechnologies in Europe and North America – 2. The relationship between nanotechnology regulation and intellectual property protection – 3. The peculiarities of nanotechnologies and the case law on their patentability – 4. The novelty – 5. The inherence and obviousness – 6. Implications of the current regulatory and jurisprudential context – 7. The outlook of intellectual property protection in nanotechnology.

1. – Nanotechnologies, defined as the manipulation of matter at the atomic and molecular scales, are revolutionizing strategic sectors, including medicine, energy, agriculture, and environmental protection. Their unparalleled versatility and transformative potential position them as one of the most promising scientific frontiers of the 21st century. However, this rapid evolution raises new legal challenges, both in terms of regulation and ensuring safety and sustainability. This paper aims to provide a concise analysis of the main legal issues posed by nanotechnologies, starting from their definition and the methods of protecting research in this field under the framework of intellectual property law.

The considerations presented in this brief work stem from research activities conducted within the *Samothrace Project – Sicilian Micro and Nano Technology Research and Innovation Center*. This initiative, supported by both public and private institutions, has funded research programs aimed at fostering the use and development of, among other domains, nanotechnologies. Specifically, the purpose of this work is to provide the perspective of a jurist on the challenges related to the intellectual property protection of devices, technologies, technical products, and similar innovations that utilize "nano" materials or measurements

The need to provide a contribution – albeit modest – to the topic under analysis stems from various factors, ranging from the scarcity of in-depth studies on the relationship between nanotechnologies and law to the obser-

* Associate professor of Private Law, University of Palermo.

vation of the substantial lag, at least from a legal perspective, in the regulatory frameworks governing nanotechnologies in the most representative European legal systems.

Those who delve into the study of this topic immediately notice the difference in terms of results and targets achieved between continental Europe and North America. The advanced development of nanotechnologies in North America can be attributed to several factors, foremost among them the strategic policy decisions implemented by the United States over two decades ago. Notably, in 2000, the U.S. inaugurated the National Nanotechnology Initiative (NNI), a federal program dedicated to promoting research and innovation in nanoscale material manipulation, also through the coordination of other governmental entities. In 2004, the United States Patent and Trademark Office (USPTO) introduced the first classifications for the protection of nanotechnologies.

Over the years, propelled by a highly favourable environment, the United States has become the global leader in the number of nanotech patents [1]. This has triggered a virtuous cycle: American universities have become a veritable goldmine of patents and have been compelled to employ highly specialized professionals in the intellectual property protection of nanotechnologies [2]. Consequently, legal practitioners have been required to address the challenges posed by nanotechnology, and today, American legal scholarship on the subject is significantly more specialized than that currently available in Europe.

It is not possible to conduct a comprehensive comparison, as this is not the correct approach for setting up research after all. There are simply too many areas and variables to claim that the scientific debate in one country is more advanced than in another. Moreover, nanotechnologies are, by defini-

[1] For an overview of the evolution of nanotechnologies, with reference to the number of patents, see. C.C. Jordan, I.N. Kaiser, V.C. Moore, *2012 Nanotechnology Patent Review*, in 10 *Nanotech. L. & Bus.* 2 (2013), 3 ff. It should be noted, however, that not everyone shares the enthusiasm on the subject; in fact, some, such as E. Michiko Morris, *The Irrelevance of Nanotechnology Patents*, in 49 *Conn. L. Rev.* 499 (2016), challenges the necessity of patenting nanotechnologies, arguing that in most cases, these patents are irrelevant or concern substances or items of little practical significance. B. Reese, M. Schmitt, *Small Changes, Big Opportunity: Nanotechnology and Intellectual Property Law*, in 16 *SciTech Law.* (2019-2020) 14, 19 state on the other hand that "It is clear that our world is in the middle of an NT revolution".

[2] M.A. Lemley, *Patenting Nanotechnology*, in 58 *Stan. L. Rev.* 601 (2005), 603 ff. has noted that universities, law firms, and the like have long established specialized teams focused on nanotechnology.

tion, a cross-disciplinary topic that encompasses regulation, safety, technology, and many other fields. However, a quick search of major legal databases, as well as the presence (or absence) of certain institutions dedicated to nanotechnologies, can easily provide a picture in which Europe appears to be a step behind North America. This still somewhat unsettled position, compared to other legal systems, concerns both the regulatory framework and the protection of intellectual property.

Regarding the former, the following sections will briefly examine the regulations adopted to define the methods and scope of research in nanotechnologies; regarding the latter, it is rare to encounter European doctrinal contributions specifically addressing the particularities that nanotechnologies require within the realm of intellectual property.

It is important to note that Europe faces an initial disadvantage, namely, its completely different legal structure compared to that of the United States. Therefore, it is only through the European Union that any form of competition (between legal systems) with North America can be envisaged.

In recent years, however, the trend seems to be reversing: since 2017, the *European Union Observatory for Nanomaterials* (EUON) has been established with the primarily informational task of providing a periodic overview of the state of nanotechnologies in Europe. As for the regulatory aspect, the EU is striving to catch up [3]. On March 15, 2024, Regulation (EU) 2024/858 on the regulation of nanomaterials in cosmetic products was published in the Official Journal of the European Union. This regulation amends Annexes II and III of Regulation (EC) No. 1223/2009, concerning the ban on the use of certain materials at the nanoscale.

As mentioned at the outset, nanotechnology is a cross-disciplinary field that affects multiple regulatory aspects, among others, and therefore it is difficult to imagine a regulatory framework entirely dedicated to the subject. On the contrary, in Europe, it has happened that EU institutions have addressed nanotechnologies incidentally [4], only when, for example, it was ne-

[3] As pointed put by E. Brosset, *The Law of the European Union on Nanotechnologies: Comments on a Paradox*, in 22 *Rev. Eur. Comp. & Int'l Envtl. L.* 155 (2013), 155 ff., until 2013 the European Union had no regulation concerning nanotechnologies. The evolution of European legislation over the past twenty years is outlined by M.B. Nielsen, L. Skjolding, A. Baun, S. Foss Hansen, *European nanomaterial legislation in the past 20 years – Closing the final gaps*, in 32 *NanoImpact* 1 (2023), 1 ff.

[4] Similarly, academic scholarship has addressed the topic only in relation to specific aspects or is-

cessary to establish bans on the use of certain substances. To understand the main issues concerning the relationship between nanotechnology and law, one must begin with the peculiarities that characterize the nanotechnology sector in general.

Meanwhile, before addressing this aspect, it is worth noting that the cross-disciplinary nature of nanotechnologies is reflected in the categorization of patents. The World Intellectual Property Organization (WIPO) and the European Patent Office (EPO) have updated the B82Y tag, an international classification used to identify patents under the Uniform Cooperative Patent Classification (CPC) system [5]. Specifically, the B82Y tag relates to nanotechnologies and inventions that exploit phenomena or technologies at the nanoscale, such as nanostructured materials, nanodevices, and other specific applications of nanotechnologies across various sectors (medicine, electronics, chemistry, etc.).

2. – Nanotechnology is a field of applied sciences and technologies that focuses on the control and manipulation of matter at the atomic and molecular scale, generally below 100 nanometres. A nanometer is one billionth of a meter. Under these conditions, materials behave differently compared to how they function when they are measurable and visible to the naked eye.

Nanomaterials may exhibit significantly different physical-chemical properties compared to their counterparts at the macroscopic scale. Nanotechnology, therefore, is essentially defined by scale and, in principle, could encompass any material that can be reduced to the previously mentioned scale and has some practical utility.

The challenges posed by nanotechnology, as mentioned earlier, primarily concern regulatory issues, since they span across various sectors (agriculture, computer science, medicine, industry, and so on). The approach adopted by European and North American legislators could be defined as "adaptive", meaning that primary legal sources are used, supplemented by sector-specific policies and guidelines developed by government agencies [6].

sues. For example, see M. Ahmadi, L. Ahmadi, *European Patent Law Framework regarding Nanotechnology Applications in Stem Cells*, in 10 *Nanotech. L. & Bus.* 65 (2013).

[5] See in this regard https://www.epo.org/en/news-events/in-focus/classification/nanotechnology.

[6] A summary of the regulatory aspects is provided by S. Ngarize, K.E. Makuch, R. Pereira, *The Case for Regulating Nanotechnologies: International, European and National Perspectives*, 22 *Rev. Eur.*

This is a regulation that embraces the precautionary principle [7], meaning that nanomaterials are included among the substances subject to evaluation and authorization when they come into contact with products consumable by individuals. Given the interdisciplinary nature of nanotechnologies, it makes sense to ask what rights a party holds when patenting a nanotechnology in a field that may find applications in different or currently unanticipated areas [8].

Starting from the definition of the phenomenon provided earlier, with the sole descriptive purpose, an immediate question arises: if "nanotechnology" essentially refers to the creation of smaller things or substances, when can it be said that the requirements for the patentability of something that has undergone a mere reduction in size are met? How does the law, particularly intellectual property law, regulate this phenomenon? Is the nanometric scaling of an existing technology an operation that can be protected with its own patent? These are just some of the questions that arise in the complex relationship between nanotechnology, regulation, and intellectual property.

Two areas can be identified as worthy of further exploration: on one hand, how nanotechnology is regulated by authorities; on the other, how and in what forms inventions related to nanotechnology are protected. These two areas are interconnected, as the relationship between the regulation of nanotechnologies and their intellectual property (IP) protection is crucial to ensuring balanced development in the sector, fostering innovation, and simultaneously ensuring the safety of citizens and the environment. Both areas inevitably influence how nanotechnologies are developed, commercialized, and used. The regulation of nanotechnologies and IP protection are complementary: the former ensures that technologies are safe and acceptable for society, while the latter provides inventors with the means to reap economic benefits from their innovations. A balanced regulation, one that protects public safety

Comp. & Int'l Envtl. L. 131 (2013).

[7] On which one may see S. Heselhaus, *Nanomaterials and the Precautionary Principle in the EU*, in 33 *J. Consumer Pol'y* 91 (2010) and, as for Italy, I. Lincesso, *Nanotecnologie e principio di precauzione*, in *Contratti*, 2010, 12, 1093.

[8] Nanotechnologies are the field where the issue of patent overlap is most prominent, due to their transversal nature. In this regard, see A. Makker, *The Nanotechnology Patent Thicket and the Path to Commercialization*, in 84 *S. Cal. L. Rev.* 1163 (2011) and A. Lee, *Examining the Viability of Patent Pools for the Growing Nanotechnology Patent Thicket*, in 3 *Nanotech. L. & Bus.* 317 (2006).

without stifling innovation, can support the responsible development of nanotechnologies and promote the creation of economic value.

In light of these brief considerations, another question immediately arises: do nanotechnologies require a specific and distinct regulation compared to other sectors? In other words, we must ask whether the current legislation, which regulates the phenomenon incidentally, is sufficient, or if it is time to introduce a legislative framework (at least on a European scale) specifically dedicated to nanotechnologies. The current combined legislation, both European and North American, provides an important foundation for regulating nanotechnologies, but it appears to have some significant limitations, primarily because it was not specifically designed to address the unique characteristics of this sector.

Nanotechnology often depends on "upstream" research, meaning something that is already subject to a patent. The holder of this patent, for example, might not be able to develop a nanotechnology starting from the existing (and protected) technology, or, in the worst-case scenario, might not want anyone else to develop such a nanotechnology for personal reasons. This brings us back to the initial question regarding the "novelty" of nanotechnology derived from an existing technology. If the legal system does not consider such a creation to be "new" and, therefore, in summary, not protectable under intellectual property law, individuals would be disincentivized from conducting research in this field, as they would find themselves in an area already covered by someone else's rights and thus lacking incentives.

3. – The questions outlined in the previous paragraph lead to an investigation of the peculiarities of nanotechnologies and how they influence the scope of protection under intellectual property law.

One of the most critical and immediate issues concerns the applicability of existing macroscopic-scale patents to nanoscale inventions, particularly in cases where the original patent does not explicitly address size. Does the mere act of reducing an object to nanoscale dimensions justify the issuance of a new patent?

Generally, it is believed that the simple reduction in size is not enough to justify granting exclusive rights [9]. However, since nanotechnology involves

[9] C. Anderson, *Small Can Be Inventive: The Patentability of Nanoscale Reproductions of Macroscale*

the manipulation of matter at the atomic level and requires a research process that goes beyond mere size reduction, one must ask whether an invention resulting from the reduction to nanoscale is protectable.

The answer lies in analysing the requirements for patentability under European legislation, according to the European Patent Convention (EPC), and the 35 US Code. To be patentable, an invention must meet the following criteria: novelty (Article 54 EPC; § 102 35 US Code), inventive step and non-obviousness (Article 56 EPC; § 103 35 US Code), industrial applicability (Article 57 EPC), compliance with public order and morality (Article 53 EPC), and sufficiency of disclosure (Article 83 EPC). For convenience and brevity, the requirements for industrial applicability and legality will not be discussed, assuming that the nanotechnology invention is both useful and legal, and because, above all, it is the other requirements that provide the answer to the questions raised earlier.

The patentability of a nanotechnology invention thus requires determining whether it meets the "novelty" requirement compared to the existing macroscopic scale. If it is only a matter of size, can it be said that the larger device already encompasses itself at a smaller scale? A similar question arises with regard to "non-obviousness", based on the assumption that the smaller size might be considered a simple, obvious consequence of the larger size already existing. To answer these questions, it is useful to look at case law from both European and North American jurisdictions [10].

Machines, in 9 *Wm. & Mary Bus. L. Rev.* 285 (2017), 288 and M. Costello-Caulkins, *Nanotechnology Patent Law: A Case Study of United States and European Patent Applications*, in 37 *Santa Clara High Tech. L. J.* 337 (2020), 344 ff. As for Europe, see C. Fulda, D. Weber-Bruls, J. Werth, *Nano is nano is nano or: nanotechnology – a European legal perspective*, in *Nanotechnol. Rev.* (2014) 401, 406 ff.

[10] Especially with reference to Europe, it is worth noting M. Schellekens, *Patenting Nanotechnology in Europe: Making a Good Start? An Analysis of Issues in Law and Regulation*, TILT Law & Technology Working Paper No. 008/2008 28 May 2008, available at http://ssrn.com/abstract=1139080. For a comparative analysis, see L. Escoffier, *Nanotechnology Under the Magnifying Lens from a European and U.S. Perspective: General Patent Statistics, Non-Obviousness Versus Inventive Step, and Two Case Studies in CNT Commercialization*, Stanford-Vienna Transatlantic Technology Law Forum Working Paper Series, Paper No. 3, 2009, available at https://law.stanford.edu/publications/nanotechnology-under-the-magnifying-lens-from-a-european-and-u-s-perspective-general-patent-statistics-non-obviousness-versus-inventive-step-and-two-case-studies-in-cnt-commercialization/. Finally, see B. Newberger, *Intellectual Property and Nanotechnology*, in 11 *Tex. Intell. Prop. L.J.* 649 (2003).

4. – It is not easy to find judicial disputes or cases specifically addressing the patentability of nanotechnologies. However, some European and North American precedents can be found, providing a glimpse of how courts approach the issues discussed earlier. The first aspect that comes to the forefront is that of novelty (Article 54 EPC; § 102 35 US Code).

An example of this is the case T 0547/99 of the Technical Board of Appeal (TBA) of the EPO, which ruled that a U.S. patent belonging to the state of the art [11] was limited to a minimum particle size of 111 nm. The TBA concluded that there was no implicit disclosure of particles in the range of 10 to 100 nm. However, this decision does not provide a definitive answer regarding the issue of size, as there was no overlap between the measurements of the two patents, making it easier to assess the novelty aspect. This case highlights that a nanometric size is not automatically included in a macroscopic patent, unless the description is sufficiently specific. However, this decision also emphasizes the importance of clearly defining the size limits in the patent documentation.

Another example is the case T 552/00 of the TBA, which dealt with the adjuvant properties in a vaccine. The claimed invention stated that the adjuvant effect could be enhanced by reducing the size of the lipid particles. The patent specified a range for the size of these particles that partially overlapped with ranges mentioned in prior state-of-the-art documents. However, the state of the art did not provide specific examples within the overlapping part of the range; thus, the TBA did not consider the overlap to be detrimental to novelty. In other words, when there is an overlap between the size range described in the patent for which protection is sought and that already known in the state of the art, the EPO has ruled that this does not automatically imply that the patent is not novel (and thus not valid). This is because, if the prior art document does not provide concrete examples within the overlapping range, the invention cannot be considered "already known" or "available to the public", which would destroy the novelty of the patent. Therefore, if the prior documentation mentions a similar size range but does not provide specific examples in the overlapping part of the range, the overlap is not sufficient to compromise the novelty of the subsequent patent.

[11] The term "state of the art" refers to the publicly available information prior to the filing date of a patent application, which is relevant in determining whether an invention is novel and non-obvious.

The EPO considers the invention to remain novel, as the information in the state of the art is not "sufficient" or "complete" enough to destroy the novelty. This case highlights that a partial overlap in dimensions does not necessarily invalidate novelty, unless the prior art provides concrete details and specific applications for that range.

A different view seems to emerge from a North American decision [12]. A case addressed issues related to the size range of nanotechnologies and established that a nanotechnology patent could infringe upon a non-nanotechnology patent when both patents specify particles with overlapping size ranges. This means that if two patents describe particles of similar or identical sizes, but are related to different technologies (one being nanotechnology and the other not), there could still be a patent infringement. Consider the case where a nanotechnology patent describes particles ranging from 1 to 100 nm, and another non-nanotechnology patent describes a particle size range that includes the same dimensions (e.g., 50 to 200 nm), but is not focused on nanotechnologies: an infringement could still occur if the overlapping-sized particles are used similarly or equivalently in both patents. In practice, even if the technologies are different, the overlap in particle sizes could lead to legal conflicts, as the non-nanotechnology patent might be considered protective for that size range as well, and the use of the same particles in another nanotechnology patent could violate the first one.

However, the differences between legal systems do not end here. A study [13] focused on a patent application regarding the structuring of carbon nanotubes encountered several difficulties during its examination both in the United States and in Europe. In the United States, the application was examined, and the applicant was asked to limit the patent to one of the two inventions originally proposed and to make minor formal changes to the application. Subsequently, the applicant submitted a supplemental European search report, but this had no impact on the final outcome of the application in the United States. Ultimately, the application was granted as a patent. In Europe, however, the application was rejected for lack of novelty,

[12] Elan Pharma Int'l Ltd. v. Abraxis Bioscience Inc., No. 06-438 GMS, 2007 WL 6382930, D. Del. Dec. 17, 2007.

[13] Escoffier, *Nanotechnology Under the Magnifying Lens from a European and U.S. Perspective*, cit., 22 ff.

based on two existing patents that had also been cited in the U.S. patent. Despite the applicant slightly modifying the claims, the outcome changed when the European Patent Office considered a new non-patent reference that had been cited in the supplemental search report. This new reference negatively impacted the application, which was eventually abandoned. This case illustrates the significant differences in evaluation criteria between the European and U.S. patent offices, with the EPO tending to consider a broader range of prior art documents, including non-patent literature.

Regarding again European case law, the case T 0006/02 TBA can be mentioned. It concerns a patent related to a degradable agent in cigarette filters, specifically titanium dioxide. The issue at hand was the overlap in particle size between the patent under examination and a prior document, which referred to a particle size range between 10 and 1000 nm, while the patent claimed a range of less than 100 nm. The TBA decision states that, although there was an apparent overlap between the two particle size ranges, it was not sufficient to destroy the novelty of the patent. This was because the prior document did not specify a mean particle size, but rather a distribution of sizes. Furthermore, the prior document only provided a specific example of a mean particle size of 300 nm, which fell outside the range claimed in the patent. Therefore, although there was an overlap between the two ranges, the patent office considered that the overlap was not sufficient to invalidate the patent's novelty, as the prior document did not seriously consider the application of the invention within the overlapping range. Considering this case, it can be stated that the EPO does not solely focus on the extreme limits of ranges, but rather evaluates the relevance of the different parts of a range in relation to the prior art. If the prior document does not seriously consider the application of the invention within the overlapping range, there is no issue in claiming a range that overlaps with the known one. The decision reiterates the importance of evaluating the specificity of the information available in the prior art and its impact on the claim to the size range.

Another example is the case T 1051/11 which dealt with a patent application for a method to produce nanoparticle formulations for drug delivery. The application was rejected by EPO on the grounds of lack of novelty and obviousness. The board considered that while the formulation was new, the method used was an obvious combination of existing techniques. The de-

cision emphasized that merely applying existing knowledge to nanoparticles at a smaller scale does not automatically lead to an inventive step. This case highlighted the challenge of determining inventive steps when working within the established knowledge of nanotechnology. Simply scaling down existing formulations was not enough to overcome the obviousness hurdle.

In the case T 0204/13 the patent application involved nanomaterials with specific surface coatings. The EPO considered the novelty of the claims, particularly focusing on whether the use of specific coating techniques at the nanoscale was inventive compared to the state of the art. The board ruled that the claimed invention lacked an inventive step because the prior art already disclosed the use of similar coatings, albeit at a larger scale. The novelty and inventive steps were challenged based on whether the nanoscale coating represented a significant technological difference or if it was just an application of well-known techniques to smaller particles.

This brief overview of case law regarding novelty demonstrates the different approaches adopted by European and North American institutions regarding the patentability of nanotechnologies. In particular, the last case exemplifies how the differing outcomes in patent grant decisions can be detrimental to businesses.

5. – Another problematic aspect concerns the inherence. Specifically, one must ask whether the patent also covers what implicitly derives from it. Is nanotechnology, understood solely as a reduction in size, inherent in an already existing patent? In short: is an existing object, when reduced to "nano" dimensions, patentable [14]?

The issue arises particularly in relation to substances used in pharmaceuticals, where it may occur that an existing molecule (already patented) reduced to the nanoscale exhibits new or otherwise unknown properties compared to the original molecule. The answer to these questions should be to admit the patentability of the substance that is already known but scaled down if it has different or previously unknown properties and functions. The novelty lies in the fact that miniaturization opens up the possibility of

[14] Anderson, *Small Can Be Inventive*, cit., 303 ff. rightly states that there is no doubt about the patentability of nanotechnologies. However, the more complex issue arises when prior art related to a device of much larger dimensions calls into question a patent on nanotechnology.

utilizing the substance in areas previously ignored or not feasible due to its size. As for inherence, it must be stated that if a substance at the nanometric level exhibits properties that fundamentally differ from those of its larger-sized counterparts, the analysis of inherentness should not strip the nanometric substance of its novelty, since such properties are not inherently present in the substance at larger sizes [15].

In case T 1227/17 the decision focused on the patentability of a process for the synthesis of carbon nanotubes. The invention was challenged for obviousness, arguing that the process was a natural extension of known methods for producing carbon-based materials. The EPO Technical Board concluded that while the method was new, it was not sufficiently inventive, as it merely scaled up existing methods to a new scale. This case demonstrates how existing methods can be applied at the nanoscale, but unless there are clear, novel effects or properties resulting from this application, the invention may lack an inventive step.

However, case law, at least in the North American context, seems to take a different view. In the past, a pharmaceutical composition of a compound was deemed invalid because the pharmacokinetic properties at a threshold of 200 microns were considered obvious in light of a previously known compound [16]. The patent was invalidated on several grounds. One key element was that a French company had developed and sold compositions of the same substance with similarly sized particles prior to the priority date of the patent. Although the patent holder argued that the previous patent had not fully understood the benefits of using smaller particles, it was decided that the prior knowledge of the substance constituted relevant prior art. Moreover, the patent was considered obvious, as it was already known in the industry that a smaller particle size improves the dissolution and bioavailability of the substance in question [17].

The consequence of this approach is that the standard for implicit obvi-

[15] This is the prevailing view in the literature. See Schellekens, *Patenting Nanotechnology in Europe*, cit., 4 and once again Anderson, *Small Can Be Inventive*, cit., 305 ff.

[16] Apotex, Inc. v. Cephalon, Inc., Civ. No. 2:06-cv-2768, 2011 U.S. Dist. LEXIS 125859.

[17] For further references to North American case law, see K.E. Fehlan, *Does Size Matter? Nanoscale Particle Size as an Indicator of Inherency in Nanopharmaceutical Patent Validity*, in 38 *Ga. St. U. L. Rev.* 1057 (2022), 1075 ff. For Europe, see C. Kallinger, V. Veffkind, R. Michalitsch, Y. Verbandt, *Patenting Nanotechnology: A European Patent Office Perspective*, in 5 *Nanotech. L. & Bus.* 95 (2008), 102 ff.

ousness appears to be the following: if a combination of prior art elements naturally leads to an unknown property, that property is considered inherent, unless the opposing party can demonstrate that it was unexpected. However, this approach is not convincing, and it is preferable to argue that patents on nanotechnology should not be considered invalid solely due to the existence of prior art on a larger scale.

The policy underlying the recognition of obviousness in intellectual property, particularly in patents, is to limit patent protection to matters that are truly non-obvious, which depends on whether a person having ordinary skill in the art would have known how to combine the prior art references to create the invention. However, when an inherent property is "secret" or unknown in the prior art, how could an inventor know how to combine prior art references in such a way as to produce the claimed invention? When a property is not obvious in the prior art, the inventor cannot reasonably predict that it will emerge from the combination of known elements. This raises the issue of whether such innovations can truly be considered obvious, given that the property is not "inherent" to the prior art.

Consequently, at this point, the problem shifts to another level: what are the ways to confer inventiveness to an invention on a nanometric scale? One solution is to consider that different processes must be used to obtain products on a nanometric scale compared to those employed for larger-sized products. These processes, of course, must not be obvious to a person skilled in the art, in light of the challenges associated with manufacturing on a nanometric scale.

6. – The European legal framework concerning the patentability of nanotechnologies presents several significant implications for inventors and businesses working in this field, particularly regarding novelty, inventive step, and disclosure requirements. The challenges outlined by European case law reflect the complexity of protecting inventions that operate on a nanoscale, and can have broad legal and commercial consequences.

As for novelty and the nanoscale, European patent law mandates that an invention must demonstrate novelty, meaning it must differ significantly from the prior art. The application of existing technologies to the nanoscale is not sufficient to establish novelty unless it results in new properties or functions

that are not anticipated by prior art. Patents that simply apply well-known techniques to nanoscale materials may fail to satisfy the novelty requirement if the underlying principles have already been disclosed at a larger scale. Consequently, to meet the novelty threshold, applicants must show that their nano-scale innovations provide distinct and non-obvious advancements over existing knowledge, rather than merely scaling down previous technologies.

As for inventive step and non-obviousness, for a nanotechnology invention to be patentable, it must exhibit an inventive step, meaning it must not be obvious to a person skilled in the field, considering the prior art. This becomes a challenge when nanotechnologies are perceived as mere extensions of known principles. In cases where the nanoscale application is viewed as an incremental improvement, it is often found to be obvious, and thus fails to satisfy the inventive step requirement. This leads to what follows: to overcome the obviousness objection, inventors must demonstrate that their nano-sized innovations are not only new in scale but also yield unexpected or surprising results that could not be foreseen by applying existing techniques at the nanoscale.

The case law analysis of the previous paragraphs also shows a recurring issue in European patent decisions which is the extent to which existing methods can be applied to nanotechnologies. Merely using known methods to produce nanomaterials does not guarantee patentability if those methods are considered obvious or routine extensions of existing practices. In this regard, patent applicants must provide evidence that the nano-scale adaptation results in unpredictable and novel effects that justify granting a patent, distinguishing their inventions from routine applications of known techniques.

The brief comparison with the U.S. also shows that patents for nanotechnologies are subject to differing standards across jurisdictions. In particular, the European and U.S. patent systems have distinct approaches to novelty and inventive steps. While the EPO is known for its rigorous standards, particularly concerning incremental innovations, U.S. patent law may provide more leeway in granting patents on nano-sized adaptations of existing technologies, especially in fields like pharmaceuticals. Patent applicants in the nanotechnology sector must navigate these jurisdictional variances to develop effective global patent strategies. Differences in the treatment of novelty and obviousness could lead to divergent patent outcomes depending on

the jurisdiction, necessitating careful legal planning to ensure broad and enforceable protection for innovations.

The legal landscape for nanotechnology patents in Europe emphasizes the need for substantial innovation rather than mere application of existing knowledge at the nanoscale. To succeed in securing patent protection, inventors must demonstrate that their inventions not only meet the technical requirements for novelty and inventive step, but also provide sufficient and detailed disclosure to enable replication. As nanotechnology continues to evolve, patent applicants must stay informed about the strict criteria imposed by patent offices and plan their strategies accordingly to ensure the long-term commercial viability of their innovations

7. – The brief overview provided in the previous sections presents legal practitioners with a fragmented and, in some respects, unsettling picture. This uncertainty is, however, inherent in some of the characteristics of nanotechnologies, as highlighted at the beginning of this work. Additionally, it should be considered that when it comes to patenting devices, the patent concerns the object in itself, which utilizes or is based on a nanotechnology, and not the nanotechnology per se. Thus, due to the aforementioned cross-cutting nature of nanotechnologies, there may be aspects of inventions that are not fully protected by intellectual property laws. The settlement of all issues related to the patentability of nanotechnologies inevitably impacts the market. A clear and well-defined regulatory framework, combined with certainty regarding the practices of patent offices, enhances the value of inventions [18].

As seen, one of the biggest issues when patenting nanotechnology is determining whether the mere miniaturization of something existing is sufficient. However, in order to obtain protection from the legal system, new technical benefits are required. In this regard, it should be emphasized that a patent should be granted whenever, despite a simple reduction to the nanoscale of an existing object, "new" properties of that object, previously unknown or non-existent at the macroscopic scale, are discovered.

On the other hand, when patent applications are rejected by the relevant offices, an overprotection occurs that, in most cases, is entirely unnecessary

[18] This aspect is analysed by L. Radomsky, S. Maebius, *Patent Ownership Challenges for Nanotechnology*, in 1 *NANOTECH. L. & Bus.* 159 (2004).

because it is highly unlikely that the inventors of the macroscopic and nanoscale versions would experience any competition from their respective inventions, precisely because of the differences in uses or properties depending on the scale of operation. Conversely, there is the risk of attributing too much significance to the first inventor who patented the invention without considering its properties or potential at a much smaller scale. In this regard, it should be noted that, to be fair to the inventor of the macroscopic scale, it is highly likely that they never considered the applications of their invention at the nanoscale. Therefore, granting him the rights while denying those who have developed the technology at other scales would not only give them excessive power but would also recognize an undeserved advantageous position.

Coming now to the regulatory aspects of nanotechnologies as summarized at the outset, it should be noted that nanotechnologies can encompass a wide range of applications, from medicine to materials science, and the legal considerations may vary accordingly. Given that nanotechnology is a relatively recent field, it is understandable that European legislators are still aligning with ongoing scientific advancements [19]. Nevertheless, numerous nanotechnology-based products have already entered the EU's internal market.

Nanotechnology researchers are not only driving technological progress but are also shaping an evolving legal landscape. In Europe, the regulatory framework has progressively matured, leveraging scientific insights while adopting pragmatic, policy-driven approaches to address emerging challenges. The patent system is on the verge of unprecedented harmonization and integration, presenting numerous opportunities with new challenges on the horizon.

As the European patent system intersects with European Union legislation for the first time, a convergence between regulatory and patent law approaches to defining nanomaterials is likely to emerge over time. It should also be mentioned the REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals) and CLP (Classification, Labeling, and Packaging) that are two important European Union regulations. Both REACH and CLP regulations are applicable to nanotechnologies and nanomaterials.

[19] More than ten years ago, Ngarize, Makuch, Pereira, *The Case for Regulating Nanotechnologies*, cit., 145 observed that the European Union was considering the introduction of specific regulations for nanotechnologies. Unfortunately, to date, it seems that this has not occurred, and we must question why. Along the same lines, see Brosset, *The Law of the European Union on Nanotechnologies*, cit., 162.

The inclusion of nanomaterials within the scope of REACH and CLP reflects the EU's commitment to ensuring the safe use of these materials and providing information about their potential hazards.

The regulatory frameworks are designed to adapt to advancements in science and technology, including those in the field of nanotechnology. However, nanotechnologies introduce some unique challenges and considerations within patent law due to the specialized and interdisciplinary nature of this field. Here are some specific characteristics of nanotechnologies that require in-depth scientific studies.

Scale and definition issues: nanotechnology deals with materials and structures at the nanoscale, and traditional definitions and classifications may not always be suitable. Patent offices face challenges in establishing clear boundaries and definitions for nanotechnologies, especially as the technology evolves. Consequently, the difficulty in providing a sufficient and precise description by the inventor of the nanotechnological product or process may hinder the ability to obtain a patent, which requires an adequate disclosure of the invention.

Interdisciplinarity: nanotechnology often involves a combination of knowledge from various scientific disciplines, such as physics, chemistry, biology, and engineering. Patent applications in nanotechnology may need to address a broad range of scientific and technical aspects, requiring collaboration between experts from different fields.

Rapid technological evolution: nanotechnology is characterized by rapid advancements and continuous innovation. Patent offices must adapt to the fast-paced nature of nanotechnology to ensure that the patent system remains effective in protecting intellectual property.

Safety and ethical concerns: nanotechnology raises unique safety and ethical concerns, such as potential health and environmental impacts. Patent applications in nanotechnology may need to address these concerns, and patent examiners may need expertise in assessing the safety aspects of nanomaterials.

Utility and enablement challenges: nanotechnologies sometimes face challenges in meeting the utility and enablement requirements for patentability. It may be more complex to demonstrate the practical utility and provide sufficient information for someone skilled in the art to carry out the invention, especially when dealing with intricate nanoscale processes.

Global standardization: nanotechnologies often involve international collaboration and may be subject to different regulatory standards in various jurisdictions. Patent applicants may need to navigate a complex landscape of global standards and regulations.

Patent thickets: the convergence of different technologies in nanotechnology can lead to the creation of "patent thickets", i.e. a dense web of overlapping patents. This can pose challenges for innovation and market access, as navigating through numerous patents may become cumbersome for researchers and businesses.

These problematic aspects of nanotechnologies have not yet been adequately explored, likely because the phenomenon addressed in this article has not reached considerable scale. In any case, it is advisable that all parties involved be prepared when nanotechnologies become widespread. The unanimous hope of the doctrine is still to implement existing regulations [20].

[20] Nielsen, Skjolding, Baun, Foss Hansen, *European nanomaterial legislation in the past 20 years*, cit., 12.

Abstract

L'articolo esplora lo sviluppo e lo stato attuale delle nanotecnologie in Europa e Nord America, con particolare attenzione alle sfide legate alla regolamentazione e alla protezione della proprietà intellettuale (IP). Esso analizza le peculiarità delle nanotecnologie in relazione alla loro brevettabilità, esaminando i concetti di novità, inerenza e ovvietà e come questi sono applicati dalla giurisprudenza attuale. L'articolo discute inoltre le implicazioni del contesto normativo e giuridico esistente, offrendo una panoramica delle prospettive future per la protezione della IP nel settore delle nanotecnologie.

This article examines the development and current status of nanotechnologies in Europe and North America, with a particular focus on the interplay between nanotechnology regulation and intellectual property (IP) protection. It explores the unique characteristics of nanotechnologies, addressing key issues in patentability case law, such as novelty, inherency, and obviousness. The article also analyses the implications of the existing regulatory and legal framework and offers a forward-looking perspective on the future of IP protection in the nanotechnology sector.