The Patent Protection of Nanotechnological Inventions: The European View

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Abstract: The patent protection of nanotechnological innovations represents an exciting challenge for all those in the specialized circle. The scope of the present work is to highlight how the protection of nanotechnological inventions implies a new interpretation and application of the general requirements of patentability. By relying on the Case Law of the Board of Appeal of the European Patent Office, the author will illustrate with examples how the requirements of novelty, inventive step, industrial applicability, clarity, and sufficiency of disclosure apply in the nanotechnological platform.

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1. Introduction

What is a patent?

The patent is a "contract" involving three parties: inventor, authority, and public. The inventor makes the innovation and applies for a patent; the authority grants the patent, which confers exclusive rights to the inventor (i.e., a monopoly for the commercial exploitation of the invention); and the public is allowed, and must be enabled, to use and exploit the invention after expiry of the patent terms, normally 20 years. Therefore, the very concept of "patent" represents the compromise of two opposite interests: the inventor's interest and the public's interest.

2. The Patent Application

It is fundamental to diffuse the culture and knowledge of these innovative, environmentally friendly nanomaterials and nanotechnologies by scholastic teaching, together with the use of newspapers, television, and any other mean of mass media communication.

The patent application is a written document normally consisting of two sections: (i) the description of the invention and (ii) the claims.

(i) The description discloses the invention in all its technical aspects. The description may contain specific examples of concrete invention embodiments and make reference to drawings. In order that the public's interest (i.e., the possibility of exploiting the invention after expiration of the patent) is safeguarded, the patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the field, i.e., the public.

(ii) The "claims" are the legal section determining the extent of the protection conferred by the patent or patent application.

2.1. The Basic Principles of Patentability

In order for an invention to be patentable, it must be novel, involve an inventive step and be susceptible to industrial application.

Additionally, as seen above, the invention must be clearly and sufficiently disclosed.

An invention is considered to be new if it does not already form part of the state of the art; in other words, if it was not made available to the public by means of a written or oral description, by use, or by any other way before the date of filing the patent application.

An invention is considered to involve an inventive step if it is not obviously derivable from the state of the art and it is considered to have industrial application; if it can be made or used in any kind of industry, including agriculture.

3. Patentability in the Nanotech Field

This section evaluates how the usual requirements of novelty, inventive step, industrial applicability, clarity, and sufficiency of disclosure apply to inventions in the nanotechnology area [1].

First, it is necessary to identify an accepted and shared meaning of "nanotechnological invention". It seems there is a consensus in the scientific and patent literature, on the point that "nanotechnology" is not simply the science of the infinitesimally small (i.e., at least one dimension of less than 100 nm), but rather, the science of the infinitesimally small accompanied by at least one new property (physical, chemical, pharmaceutical, etc.) directly derived or caused by the nano-size.

Under this definition, a patentable nanotech invention may be reasonably considered as a patentable "selection-invention". A selection invention is an invention based on the recognition of a sub-range extracted from a previously known larger range, with said sub-range causing a technical effect not recognized or attributed to the whole larger range.

3.1. Novelty

If, prior to the filing date of the patent application seeking protection for an invention, the same invention had already been described in a written publication, oral presentation, or public prior use, then the invention no longer fulfils the requirement of novelty necessary for patentability. For example, if a natural product, such as chitin, is generically described in a scientific publication, with its chemical structure and some characterizing parameters, then this product will be excluded from subsequent patent protection since it is lacking novelty.

However the question is whether the same principle also applies when we move from the macro scale to the nano scale. For instance, if the invention consists of "nanocrystals" or "nanofibrils" of chitin, can this "nano-form" of chitin be considered novel over the chitin described in the prior art?

An indirect answer can be found in the case law of the Board of Appeal of the EPO, which laid down general principles in assessing the novelty of polymorphisms, but that also find application in the field of nanocrystalline substances.

For instance, the Board of Appeal recognized the novelty of a substance either in crystalline or in amorphous form, although the very same substance was known the prior art in a different physical form (either amorphous or crystalline, respectively) [2–4]. The Board of Appeal also recognized the novelty of Aspartame type IIa, whcih is a specific polymorphic form of aspartame, over Aspartame III, which is another polymorphic form of the same aspartame dipeptide [5].

By translating the same principles, a substance in nano-form, such as nanocrystals or nanoparticles, may be considered novel, i.e., a different entity, over the same substance in macro-size form. This is indeed the case of the chitin nanofibrils (or chitin-whiskers), over the normal amorphous chitin or chitin long fibers obtained by electro-spinning. The same principles have been applied in assessing the novelty of composite materials, comprising a nano-sized particulate phase of a given chemical compound.

In a first decision [6], the Board acknowledged the novelty of a composite material comprising a layer of nanocrystalline nickel obtained by electrodeposition, on the basis of the size of the nanocrystals (less than 11 nm). Prior art documents disclosed essentially identical materials, yet comprising a layer of crystalline nickel having micro/macro-size crystals (>100 nm).

In a second decision [7], the Board of Appeal was faced with the problem of evaluating the novelty of a cigarette filter, consisting of a cellulose acetate tissue comprising nanoparticles of TiO_2 of size less than 100 nm as a photodegrating agent. A prior document disclosed essentially identical cigarette filters, but comprising TiO_2 particles of a much larger size, about 500 nm (pigment grade).

4. The Board Recognized the Novelty of the Invention

4.1. Inherency

The situation may prove even more intriguing when the down-scaling to nano-size confers to the "known" substance some novel properties, either chemical, physical, or biological.

In the macro world, it is a generally accepted rule that the discovery of a novel property of a known substance is unable to restore the novelty of this substance. It is in fact considered that the novel property was inherent to the substance itself.

In other words, if the novel property had been searched for in the substance, it would have been immediately revealed.

This does not necessarily happen to nanomaterial, since the novel properties characterizing the material in the form e.g., of a nanoparticle or a quantum-dot may directly result from the infinitesimal size of the material and, accordingly, could not be detected in the same material at the macro scale, even if it was purposely looked for. For this reason, the inherency approach, and its impact on the novelty of macro materials, no longer applies when we move from the macro to the nano scale.

4.2. Inventive Activity

The claimed subject matter is considered to involve an inventive activity if, for the skilled person, it is not obviously derivable from the state of the art.

This requirement, applied to nanoscience, raises a number of questions, specifically in consideration of the interdisciplinary nature of the nanotech platform. For example, which should be the reference technical field for inventions overlapping different technical fields, such as biotechnology, electronics, and semiconductors? Also, who should be the skilled person?

The case law of the EPO in the biotechnological field already offers some answers, which can be extended to the nanotech field.

The Board has recognized in many cases in the biotech field that the skilled person is indeed represented by a team of persons, each of whom is an expert on a different aspect of the same technical field. Furthermore, in the nanotech platform it is likely that this fictitious person will be embodied by a team of persons, each of whom is an expert on a different technical field: for instance, gene technology and semiconductors. Yet, this multidisciplinary approach raises the bar in assessing the requirement of inventiveness, making this requirement more difficult to meet. In fact, what seems to be inventive to one single "expert", may prove obvious when evaluated in the light of the combined knowledge of two or more experts.

A further question is whether the miniaturization of an object can in itself endow said object with an inventive step. In the macro domain, the answer is in the negative. The Board of Appeal has already set forth [8] that the easy miniaturization of devices or equipment is suggested by the well-known industrial need of optimizing space and materials.

However, moving into nano-size can be regarded as an obvious step only if the necessary tools and technology are available to the skilled person. It is well known that the top-down method has technical limits. Overtaking these limits by an alternative top-down method or by novel bottom-up methods could never a priori be regarded as obvious.

Moreover, as already seen above, miniaturization to the nano scale is very often accompanied by a novel and unpredictable effect. Under these circumstances,

the result of miniaturization should always be considered inventive, regardless of the apparent obviousness of the means used to achieve the result.

5. The New Technical Effect Directly Caused by the Nano-Size

There are in the patent literature many examples of "novel properties" or "novel effects", caused by miniaturization, that justified the patentability of nano-substances or nanomaterials already known in macro-form.

For instance, chitin nanofibrils show, in addition to optimal mechanical properties, a surprising resistance to hydrolytic enzymes as compared to natural amorphous chitin. See Table 1 (kindly provided by Prof. Pierfrancesco Morganti—Mavi Sud S.r.l.).

Table 1

	CHITIN NANOFIBRILS		Weight variation		CHITIN NATURAL		Weight variation	
	INITIAL	FINAL	g.	%	INITIAL	FINAL	g.	%
CELLULASE	0.10028	0.10021	-0.00007	0.07%	0.10060	0.10004	-0.00056	0.56%
LYSOZYME	0.09999	0.09991	-0.00008	0.08%	0.10010	0.09900	-0.00110	1.09%
PECTINASE	0.10110	0.10109	-0.00001	0.0099%	0.10234	0.10120	-0.00114	1.11%
AMYLASE	0.10031	0.10029	-0.00002	0.02%	0.10905	0.10305	-0.00600	5.5%
COLLAGENASE	0.02563	0.02560	-0.00003	0.12%	0.10958	0.10008	-0.00950	8.67%

This unexpected property makes chitin nanofibrils a very promising material in dermatology and cosmetic surgery, for protecting wounds or damaged skin or as filler in the treatment of wrinkles, showing a high resistance to hydrolytic endogenous enzymes.

Thank to this novel effect, chitin nanofibrils have been claimed for use in dermo-cosmetic surgery and in therapy [9]. They have been claimed in complexes with negatively charged polymers for use as carriers for medicament [10], for the preparation of films comprising anti-bacteria metals, as well as for many cosmetic and therapeutic applications and food supplementation or preservation [11].

Other examples include nano-constructs with pharmacological activity comprising an inorganic metallic nanoparticle with an amphiphilic polymeric coating and an active antiviral peptide bound thereto [12]. The nanoparticles used as a carrier of the medicament enable an effective transportation of the active molecule through the cellular membrane and directly into the cell cytosol, thus escaping the endosome pathway and accordingly the lysosomal degradation, i.e., an unpredictable behavior caused by the nano-structure.

Yet another example is the "antireflective coating for use in photolithography" of Advanced Micro Devices Inc. [13,14]. An antireflective Titanium Nitride (TiN) layer with a thickness between 25 and 40 nm minimized the percent of reflected radiation to less than 5%. Thickness values below 25 or above 40 nm, as disclosed in the prior art, resulted in a significant increase of the reflected radiation up to 30%, as illustrated in Figure 1.

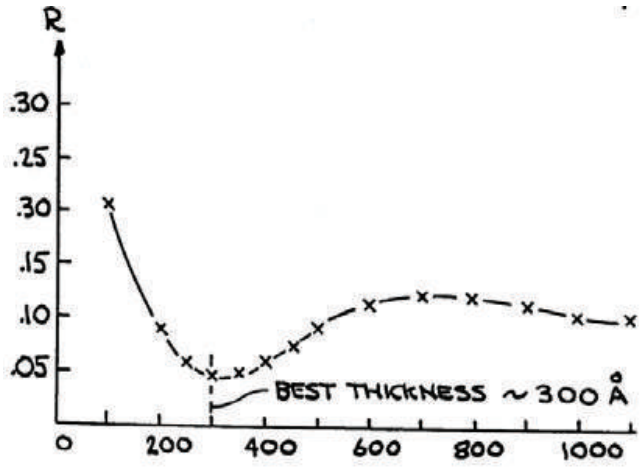

Figure 1. Reflected radiation of about 5% for 25 to 40 nm (i.e., 250–400 Å).

An additional case [15,16] (Rohm and Haas Company) related to a coating composition comprising a dispersion of copolymer particles having a size range of 20 to 70 nm. The miniaturization of the particles to 70 nm or less, although achieved by "normal" methods, was able to endow the claimed coating with an unpredictable optimal effect, namely with excellent transparency and clarity, where the effect was lost for larger particle-sizes. The closed prior art document described comparable coating compositions comprising polymer particles spread along a much broader range (10–1000) and preferably along the range of 100–500 nm. Accordingly, the Board of Appeal recognized the novelty and the inventive step involved in the selection of the range of 20–70 nm over the coating compositions described in said prior document.

6. The Reasonable Expectation of Success

Another important factor playing a role in evaluating the existence of an inventive step is the "reasonable expectation of success". This principle, which was developed and frequently applied in the biotechnology field, may give a strong support to inventiveness in any pioneer field such as nanotechnology. In fact, the prejudicial effect, for the patentability of an invention, represented by an earlier suggestion of the invention in the prior art depends on the circumstances. In a traditional technical field, all procedures and tools needed for realizing a "suggestion" are normally known and available to the skilled person and thus the results easily

predictable. Under these circumstances, putting to practice the suggested teaching of a prior art document is always accompanied by a high expectation of success, and does not involve any inventive merit.

In reverse, in an emerging field in which the technology is not necessarily available and the procedures are not always standardized or reproducible, the result of an action is hardly predictable. In this situation, the realization of a "suggestion" is not always accompanied by a "reasonable expectation of success". Thus, achieving the desired result may prove inventive even though it is theoretically suggested.

For example, the above discussed decision [6] related to a composite material comprising a layer of nanocrystalline nickel of less than 11 nm, obtained by electrodeposition. As many as eight prior documents apparently suggested the same process of the invention, but in the context of microcrystalline structures (i.e., in the order of 100- to 1000-fold larger). Under these circumstances, the Board found that "...the skilled person had no obvious reason to foresee that the prior teaching could still be successfully extrapolated to structures smaller by at least two orders of magnitude, if not with the benefit of hindsight". In other words, the skilled person could not have any expectation of success when putting to practice the prior art teaching on nano-size level.

7. Sufficiency of Disclosure

The patent application describes the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. This requirement means that the skilled person should be able to repeat the invention, essentially over the whole ambit of the claim, based on the technical teaching given by the application (corroborated by the common general knowledge), and the realization of the invention, with the achievement of the declared effects of the invention, may not depend on chance. These conditions are essential in the patent protection of nanotech inventions.

In fact, when the technical effect achieved by, and characterizing, the invention strongly depends e.g., on the (nano) size of the claimed material or on the delicate conditions necessary to obtain said material and to realize the invention, the requirement of sufficiency of disclosure plays a decisive role and leaves no room for practices broadly shared in other technical fields, such as arbitrary generalization of the real invention or the extension of the protection to non-investigated equivalents.

Coming back to the antireflective coating for use in photolithography of decision T 453/97 (Note [14] and Figure 1) the effect characterizing the invention was the percentage of reflected versus incident radiation of less than 5%. This effect was quickly lost outside the very limited thickness range of 25 to 40 nm. Therefore, any arbitrary generalization of this range would make the realization of the invention and the achievement of the characterizing effect impossible.

The same applies to the concept of "equivalents", and strongly suggests that in the nanotech field there appears to be no room for any form of speculation or arbitrary extension of the scope of protection to cover embodiments theoretically "equivalent" to the real invention, but not yet investigated. This means that the need for a sufficient number of examples and experimental results substantiating all described embodiments of the invention is felt in the nanotech field more than in any other technical field.

For instance, in a case relating to an electro-magnetic transducer [17], one element of the invention was a semiconductor layer produced by molecular beam epitaxy using, as a doping element, atomic (N°) nitrogen radicals.

A similar method was described in a prior art document which illustrated with all experimental data an embodiment making use of molecular (N2°) nitrogen radicals, but which also cited as an alternative the use of atomic (N°) radicals, though without any support of examples or experimental results. Lacking any experimental confirmation, the Board considered that the use of atomic (N°) radicals in the prior art document was a merely a speculative attempt to disclose not yet investigated subject matter and accordingly disregarded this prior art teaching.

8. Metrology

A specific aspect of the requirement of "sufficiency of disclosure" is metrology. For the scientist, the definition of metrology is "the science of weights and measures" [18], thus including procedures, techniques, instruments, sensors, or any other tool for measuring.

On the contrary, for the patent attorney, "metrology" refers to an important aspect of patentability, namely the requirement of "sufficiency of disclosure" which enables the "repeatability" of the invention by the skilled person. Thus, metrology is indeed a condition for patentability.

To meet this requirement, the expert, supported by the technical teaching in the patent specification, optionally integrated by common general knowledge, should be able to put to practice the invention, in addition to achieving the technical effects the invention is said to produce. It goes without saying that the skilled person must be aware of all necessary instructions for monitoring the parameters characterizing the invention and for measuring the results obtained, in order to understand whether or not he/she has actually achieved the declared effect of the invention.

In a traditional technical field all analytical procedures, tools, and techniques are usually a part of the common general knowledge, and thus they need not be exhaustively described in the patent specification. However, this is not always the case in a pioneer field, such as nanotechnology.

In fact, nanotechnological inventions, like all inventions in any emerging fields, are often characterized by non-conventional features and effects: by unusual

parameters, e.g., nano-size, monoatomic layers; by unusual processes, e.g., epytaxis, spattering, mono-atomic deposition; by unusual effects, e.g., detection of a single analyte molecule or detection of fluctuation of a specific index. Under these circumstances, the patentability of an invention strongly depends on the detailed description in the patent text of all technical aspects falling within the concept of "metrology".

This requirement has been clarified in many decisions of the Board of Appeal of the EPO. In a very recent case [19], the patent claimed: (i) "A silica glass for EUV lithography containing TiO, characterized in that the fluctuation of the refractive index (Δn) is at most 2 $\times$ 10-4 within an area of 30 mm $\times$ 30 mm in each of two orthogonal planes".

The validity of the patent was contested in an opposition procedure based on the following opponent's arguments: " ... that the patent did not provide sufficient information on the measurement of the parameters appearing in the claims: i.e., 'the fluctuation of the refractive index (Δn) ... '". Therefore, the skilled person repeating the invention did not know for sure whether the obtained glass fell within the scope of protection of the claims.

Another decision [20] related to a patent protecting "A silica gel, characterized, inter alia, by the feature represented by the silanol-group density of 6–20 ... " in combination with other parameters.

Yet, the patent specification taught an incomplete and erroneous method for determining and measuring the silanol-group density cited in the claim. Nor could the skilled person find any more reliable teaching in the prior art documents. For this reason, the Board revoked the patent, affirming that: " ... an erroneous method of measurement or determination of an essential parameter of the claimed product unavoidably results in a lack of sufficiency of disclosure of the claimed product ... ".

The same principles were recently confirmed by still another decision [21] relating to an adsorbent article, whose absorbent capability was defined in the patent claims by totally inconsistent values produced by an arbitrary test method.

The Board revoked the patent, arguing that: " ... the purpose of a parameter contained in a claim is to define an essential technical feature of the invention. ...The method specified for determining that parameter should therefore be such as to produce consistent values, so that the skilled person will know, when he carries out the invention, whether what he produces will fall within the scope of the invention".

9. Clarity

This requirement ensures that the claims define the object of the protection and are clear, concise, and based on the description.

A simple question arises here: which is the most suitable claim format, for a nanotech invention, that is able to meet the requirement of clarity without unduly reducing the scope of protection?

In fact, there exists no claim form specific to nano-invention, but there are claim forms which are certainly more suitable than others, as illustrated below.

10. Product-by-Process Claim

At the nano scale, it may prove difficult to properly define an invention, product, substance, or material by way of its structural features. It may be easier and safer to identify the invention by way of its preparation process, using wording such as: "product obtainable by the following preparation process comprising . . . ". For this reason, the product-by-process claim is extensively used to define inventions in the nanotech platform.

For example, the "nanocrystal metallic material" object of decision T0915/00 [6] was defined as being " . . . obtainable by a process comprising the electrodeposition of the material on a substrate in a solution containing ions of the metal characterized . . . by passing a D.C. current . . . at pulse intervals . . . ".

The meaning recognized by the Board of Appeal of this type of claim is quite different when the invention is on the macro scale or in the nano field. At the macro scale, there is a generally recognized principle according to which a new process for preparing a known product is unable to restore the novelty of the obtained product.

Yet, at the nano scale, it is difficult to prove that even minor modifications in the process parameters are neutral as regards the structural features of the obtained product. This has been the position taken by the Board of Appeal in more than one decision.

In the aforementioned decision [6], Nickel nanocrystals with the size of 11 nm were obtained by electrodeposition by passing in an ion solution a D.C. current at pulse intervals. These nanocrystals have been considered different from Nickel nanocrystals of nearly the same size obtained by electrodeposition by passing in the ion solution a D.C. current having the same characteristics, but applied continuously. The Board accepted the appellant's argument that the different process resulted in a different crystalline structure, though having the same size.

By applying the same criteria, the Board acknowledged in a subsequent decision [22] the novelty of a nanocrystalline product obtained by sputtering versus the same nanocrystalline product obtained by electrodeposition.

In an earlier case [23], a device having a specific surface topography was defined by means of its preparation process involving epitaxial growth. The Board recognized the novelty of the device, accepting that the process gave rise to peculiar characteristics.

11. Functional Definitions

Another frequently used claim type for the characterization of nanotech inventions is the functional claim, which defines the claimed compound by way of its functional properties. As seen above, the miniaturization to the nano scale is frequently accompanied by a novel specific property. Accordingly, it is sometime easier and clearer to characterize the miniaturized material by way of its novel property caused by the nano-size rather than to characterize the material by way of its structural features, which eventually produce the novel property. For this reason, the functional definition of the invention is extensively used in this field.

12. Terminology

A final aspect of clarity is the clarity of the terminology used to describe the invention. In a pioneer multidisciplinary area, the technical meanings of the terms are not necessarily standardized and equally recognized by the experts of the different overlapping fields. This circumstance may render the interpretation of the claim, and accordingly the interpretation of the scope of protection, subjective and unpredictable. Therefore, all nanotech patent applications should contain a self-standing "glossary" clearly explaining the meaning, for the purpose of the invention, of all technical terms used in the claims. This glossary should be intended not only to facilitate the examination of the application, but, with a view to the future, to enable the national courts to make reliable decisions on the question of patent infringement.

Conflicts of Interest: The author declares no conflict of interest.

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