Biotech to Nanotech Inventions – Effective Patenting Strategies

a report by
Claudio Germinario

European Patent Attorney, Società Italiana Brevetti

The biotech revolution carried with it the need to redefine the limits of patentability. The rise of nanotechnology is again challenging the criteria and practice applied by patent offices to inventions in ground-breaking sectors of technology. By examining European Patent Office case law, this article discusses how the patentability requirements of novelty, inventive step, industrial applicability, clarity and sufficiency of disclosure apply to inventions in the nanotechnology area, and how the experience of biotech patents can teach a lesson on effective patenting strategies for nano-technology inventions.

Scope of Protection – Pioneer Inventions and Broad Claims

Article 69 of the European Patent Convention (EPC) provides that the protection conferred is defined by the terms of the claims. Concerning broadness of claims and of protection conferred, nanotechnology may learn from biotechnology. At the beginning of the 1980s the European Patent Office (EPO) considered the biotechnological field as a pioneer field deserving broadest possible protection. Many patents conferring huge protection were granted, assuming that a pioneer invention was 'inventive 'by definition. As a result the national courts had to deal with a very high number of extremely long and complicated litigations with unpredictable or contradictory outcomes. The same situation should be avoided in the nanotechnological field, in spite of its being considered a pioneer area.

Novelty

An invention is considered novel if, prior to the filing date of the patent, it has not been made available to the public by any means. An invention that has been the object of a written publication or an oral presentation does not fulfil the requirement of novelty. In practice, if a product, for example a red fluorescent protein (RFP), was previously published in a scientific journal, with its amino acid sequence and some characterising parameters, then this product will be excluded from subsequent patent protection. However, what happens when we move from the macro scale to the nano scale? For instance, if the invention consists of 'nanocrystals' or 'nanoparticles' of the same RFP protein having the same disclosed amino acid sequence, can the 'nanoprotein' be considered novel? The case law of the Board of Appeal of the EPO offers an indirect answer. In the following two cases, the novelty of a composite material comprising a particulate phase of a given chemical compound over a similar composite material comprising a particulate phase of the same chemical compound was recognised on the basis of the size of the particle phase, i.e. nano size in the invention versus micro/macro size in the prior art. In the first decision (nanocrystalline metals) the Board implicitly acknowledged the novelty of a material comprising a layer of nanocrystalline nickel obtained by electrodeposition, on the basis of the size of the nanocrystals (less than 11nm). Prior art documents disclosed essentially identical materials, yet comprising a layer of crystalline nickel, obtained by electrodeposition, having micro/macro size crystals. In this case the novelty issue was not even discussed, so implicitly recognising the novelty of the invention. In a second decision, concerning photodegradable cellulose ester taw, the Board had to evaluate the novelty of a cigarette filter consisting of a cellulose acetate tissue comprising nanoparticles of TiO2 of size less than 100nm as photodegrading agent. A prior art document disclosed essentially identical cigarette filters, but comprising Ti O2 particles of a much larger size, about 500 nm (pigment grade).The Board recognised the novelty of the invention. These decisions are not surprising since they simply extend to nano scale the principle generally accepted by EPO that a substance claimed in a well-defined crystalline form is considered novel over the same substance in a different crystalline form or in an amorphous form.

Inherency

Nanotechnology is not simply the technology of the infinitesimally small, but the technology of the infinitesimally small accompanied by at least one new

technical effect directly resulting from nano size. In the macro world it is a generally accepted rule that the discovery of a known substance's novel property is unable to restore that substance's novelty. It is considered that the novel property was inherent in the substance itself. This cannot happen to material at the nano scale, since the novel properties characterising the material in the form of a nanoparticle or a quantum dot result directly from the size of the matter and cannot usually be detected in the same material on macro scale, even if it is purposely looked for. Accordingly, the inherency approach and its impact on the novelty of macro materials simply no longer applies when we move from the macro to the nano scale.

Inventive Activity

The claimed subject matter implies 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. If, for example, the invention is an electronic element comprising modified double-stranded DNA used as a semiconductor, the questions are: Which is the relevant technical field? Who is the skilled person? Case law in the biotechnological field already offers some answers. The Boards have often recognised that in the biotech field the skilled person is represented by a team of persons, each an expert on a different aspect of the same technical field. This is all the more true in the nanotech platform. A multidisciplinary approach may increase the stringency of the requirement of inventiveness, since what may be inventive for one expert may prove obvious when evaluated by the combined knowledge of two or more experts.

A further question is whether the miniaturisation of an object in itself can endow the object with an inventive merit. In the macro domain the answer is in the negative. However, moving into nano size can be regarded as an obvious matter 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. For instance, it is reported in scientific literature that the photolithography technique for preparing integrated circuits has the limit of about 100nm. Overtaking this limit by an alternative top-down method or by novel bottom-up methods means overtaking the limits of available technology, which could never *a priori* be regarded as obvious.

In a case regarding a method of treating or coating a substrate, the invention was a coating composition comprising a dispersion of copolymer particles having size of 70nm or less. The miniaturisation of the particles to 70nm or less, although achieved by 'normal' methods, was able to endow the claimed coating with an unpredictable special effect. The Board recognised the inventive step of the invention over the coating described in the prior art, which comprised larger particles (100–500nm).

Another important factor in evaluating the inventive activity is the 'reasonable expectation of success'. This principle may have a strong impact on the evaluation of inventive step in any pioneer field. In fact, the prejudicial effect of an alleged suggestion of the invention given in the prior art depends on the circumstances. In a traditional technical field the procedures are normally known, standardised, reproducible, and the results easily predictable. Under these circumstances the realisation of a suggestion is often accompanied by a high expectation of success, and therefore not by inventive merit. On the contrary, in an emerging field, the result of an action is hardly predictable. In this situation, the realisation of a 'suggestion' is not always accompanied by a 'reasonable expectation of success'. Thus, achieving the desired result may prove inventive although theoretically suggested. For instance, in one of the above mentioned cases, as many as eight prior documents apparently suggested the process of the invention for electrodepositing nanocrystalline nickel. 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 magnitudes, if not with the benefit of hindsight."

Sufficiency of Disclosure

The patent application shall describe the invention in a manner sufficiently clear and complete for it to be carried out by the skilled person. According to EPO case law, this requirement implies that the skilled person should be able to realise the invention essentially over the whole ambit of the claim. Moreover, the realisation of the invention, therefore the achievement of the declared effects, may not depend on chance. Yet, since as a matter of practice in all technical fields, the claimed subject-matter is normally a 'reasonable' generalisation of the 'real invention', these two requirements play a decisive role in the patent protection of nanotech inventions. In fact, when the technical effect characterising the invention depends on the size of the material, any arbitrary generalisation of the 'real invention' may prevent the declared technical effect from being achieved – in other words, the invention from being carried out. In the above-mentioned case concerning anti-reflecting coating for photolithography, the effect characterising the invention was the percentage

of reflected versus incident radiation of less than 5%. This effect was achieved by an anti-reflective TiN layer having a thickness between 15 and 35nm. Outside this very limited range, the amount of reflected radiation immediately strongly increased. Therefore, any arbitrary generalisation of this range would make the realisation of the invention impossible. The same applies to the concept of 'equivalents', and strongly suggests that in the nanotech platform 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 nanotech patents need a reasonable number of examples, describing as many embodiments of the invention as possible.

A further aspect of the requirement of sufficiency of disclosure is metrology, namely the availability of the analytical methods and tools. The skilled person, in the attempt to carry out the invention, must be able to monitor the parameters of the invention and to check the results. While in a 'ripe' technical field analytical methods, means and assays are usually available this may not be the case in a pioneer field. Accordingly, all the methods and tools necessary to check parameters and results should be properly disclosed in the application.

Clarity

Claims shall define the object of the protection and shall be clear, concise and based on the description. Which is the most suitable claim format for a nanotech invention being able to meet the requirement of clarity without unduly reducing the scope of protection? No specific claim forms exist for nano-invention, but some are certainly more suitable than others.

Product-by-process claim

At nano scale it may prove difficult to properly define an invention by way of its structural features. It may be easier and safer to identify the invention by way of its disclosed preparation process. The product-by-process claim is therefore extensively used to define nanotech inventions. The meaning recognised by the Board of appeal of this type of claim seems to be a little different when the invention is on macro scale or in the nano-field. At macro scale, there is a generally recognised principle according to which a new process for preparing a known product is unable to restore the novelty of the obtained product. At the nano scale it is difficult to prove that even minor modifications in the process parameters are neutral as regard to the structural features of the obtained product. This is the position taken by the Board of Appeal in more than one decision, for instance in a case in which Nickel nanocrystals of 11nm size were obtained by electrodeposition by passing in an ion solution a direct current (DC) at pulse intervals. These nanocrystals have been considered novel over nickel nanocrystals of the same size obtained by electrodeposition by passing in the ion solution a DC 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. The Board, in a further case, acknowledged the novelty of a nanocrystalline product obtained by sputtering versus electrodeposition. Finally, a device having a specific surface topography was defined by means of its preparing process involving epitomical growth. The Board recognised the novelty of the device, accepting that the process gave rise to peculiar characteristics. Another frequently used claim-type for the characterisation of nanotech inventions is the functional claim, which defines the claimed compound by way of its functional properties. As seen, the miniaturisation to nano scale is normally accompanied by some novel properties or activities. It is often easier and more reliable and repeatable to describe and to monitor the novel property caused by the nano size than to describe or to monitor the structural features actually causing the novel property. For this reason the functional definition of the invention is extensively used in this field. A final aspect of clarity is the clarity of the novel terminology used to describe the invention. In a pioneer multidisciplinary area the technical meanings of the terms are not necessarily standardised and equally recognised by the experts of the different overlapping fields. This circumstance can make the interpretation of both the claim and the scope of protection subjective and unpredictable. Therefore, all technical terms used in a claim should be properly explained in the specification. ■