2. Statistical presence and sub-ranges

A further novelty issue related to materials containing nanotechnological inventions is related to the possibility of invalidation of a patent due to the existence in the prior art of materials containing pure accidental, unplanned and small amounts of the substance claimed as the invention. An example illustrating this situation is found in patents for new steel compositions that claim the presence of nanostructures or nanoprecipitates, like grains or carbides of particular size and distribution that confers the material particular and improved properties over the prior art by the modification of mechanisms of deformation and the control of movement of dislocations.[98] Due to the nature of the manufacturing process, these same structures and carbides can be found in some steels produced in the past, not because the producer intentionally looked for this structure, but because it was impossible to avoid the presence of an small amount of such elements. These products are part of the prior art, even if the presence of such phases were unknown to the manufactures or other parties. As we will see, it is still unclear if such information is relevant to attack the novelty of a patent.

The evaluation of each case will depend largely on the way the applicant drafts the claims of the patent application, and in some cases the presence of traces of these phases containing the nanostructure may clearly anticipate the invention. If the claims are drafted to protect any presence of the phase in the steel, from zero to some value, the invention may not be new. Nevertheless, if the claims are limited to a content far from the small amount found in the prior art, the invention should be considered novel. Even so, the presence of the innovative phases in the prior used steels is usually unknown and it is not always clear how to define the limits of the claims scope to keep the claims of the patent away from this kind of prior art. An alternative solution to the applicants would be to avoid product claims and to assure patentability by claiming the process of manufacturing of the new steel. Even when the scope of protection is much more limited, process claims would give the patent owner more certainty on validity issues. In spite of the validity risks mentioned, in some cases prior art with the mentioned characteristics may not constitute an anticipation of the invention. Such is the case if the prior art doesn't provide enough information to the person skilled in the art to reproduce the invention, where the presence of a phase in a previous manufactured steel may not be considered as a disclosure complete enough to replicate the invention.

98 *See,* for example patent EP0826782B1, *High strength and high toughness steel wires and method for making the same*, filed in 1997.

A second point that should be of concern for applicants in the nanotechnology field is the protection of materials by defining particle sizes ranges.[99] If the prior art discloses nanoparticles used as fillers for composites in a range that may overlap with the invention, usually in the range from zero to micrometers, a patent claim intended to protect particles in the range of nanometers could be considered as anticipated by the prior art.[100] For example, patent EP1457509 claims a "Polymeric composition, which contains: a) at least one epoxy resin, b) at least a copolymer also opposite Epoxiden reactive groups and a glass transition temperature Tg of -20 DEG C or less, c) Nano-particles with one by means of neutron small-angle scattering (SANS) of measured average particle size from 5 to 150 Nm." Composite materials made of epoxy resins, a copolymer and reinforcement particles, in the range of micrometers, are well known in the prior art. Usually, patents protecting these concepts disclose particle diameters smaller than micrometers, range that includes nanoparticles even if the invention was originally not intended to cover this kind of reinforcing components. Nonetheless, the referred patent proposes to use particles in the range of 5 to 150 nanometers, features that could make the invention new. EPO has granted the patent, considering that this claim fulfills the novelty and inventive step requirements. The grant was made based on the improved properties obtained by the inclusion of nanoparticles, the criteria usually used in cases of inventions on improvements. Provided that reduction in size of reinforcing particles has been presented in the past as a technique to improve the properties of the matrix, the question arises on how different the result obtained with particles in this range of size should be, compared to microsized particles, to be considered novel.

One possible response to this question can be found in EPO decisions related to "sub-range" inventions. On this matter the TBA indicated that the "selection of a sub-range of numerical values from a broader range is possible when each of the following criteria is satisfied: (i) the selected sub-range should be narrow; (ii) the selected sub-range should be sufficiently far removed from the known range illustrated by means of examples; (iii) the selected area should not provide an arbitrary specimen from the prior art, i.e. not a mere embodiment of the prior description, but another invention (purposive selection)."[101] In claiming sizes in the range of nanometers, the requirements (i) and (ii) seem to be satisfied, as the values are orders of magnitude away from any range in the micro or macro size. The third requirement will be satisfied in case that the properties obtained in the claimed range are far different from what is expected by a person skilled in the art.[102]

99 *See,* Christian Kallinger and Others, *Patenting Nanotechnology: A European Patent Office Perspective*, Nanotechnology Law & Business, Spring 2008, p95-105.

100 *Id.*

101 T 198/84.

102 *See,* EPO Guidelines C-IV 9.8, Novelty: Selection Inventions.

In spite of the aforementioned secondary requirement generated by EPO case law, EPC provisions do not expect improvement of properties as a patentability requirement. The applicant does not need to demonstrate that the invention performs better than relevant prior art, but only to show that the invention is new, non obvious and to provide enough disclosure to allow others to reproduce the invention.[103] If there is no requirement to provide results showing properties of the invention, how can point (iii) of the referred decision can be assessed by the EPO? In this case, the burden of proof may be on the applicant side, and even when there is no requirement to provide such information, she may be obliged to do it to demonstrate patentability over a "sub-range invention". Thus, the applicant may be forced to include examples and to disclose supporting information on this respect that otherwise may be protected by secrecy. Again, we can see that the particularities of nanotechnology requires applicants to take into account practices that would not be needed in other fields, and to disclose information that otherwise would be kept secret, in order to obtain a valid patent.

A further problem identified with inventions that claim a sub-range in size or composition of an equivalent but broader known range, comes from the infringement perspective. The question to answer is whether the user of a nano-technological invention can be considered as an infringer of a prior patent claiming wider ranges; even when at the moment of the filing of the prior patent the nanotechnological invention was unknown and unforeseeable. This issue may have serious consequences for users and manufacturers of nanotechnology, as the universe to check for non-infringement purposes would not only consist of patents in the field of nanotechnological inventions, but also any other kind of patents with scope broad enough to cover a wide range of sizes or compositions. For example, in performing a freedom to operate analysis,[104] third parties would need to take into account patents specifically relevant to the field of the invention and also other patents that even if they were not filed with the intention to cover nanotechnological invention, may cover part or the totality of the technology under assessment. For example, the use of nanoparticles of Silicon Carbide (SiC) as reinforcement in metals may infringe a patent protecting the use of SiC as filler in general —with particles in the range of zero to microsizes— even when the use of these nanoparticles confers exceptional properties to the composite not anticipated by the first applicant. This is an important issue to be taken into account by applicants who many times erroneously confuse patentability with freedom to use. These two

103 *See,* for example T 588/93, Note however, that while improvement or better performance over prior art is not an EPC requirement *per se*, it may provide evidence of inventive step.

104 *Freedom to operate* or *freedom to use* analysis is the common terms used to identify the process of searching and assessing relevant patents in order to verify rights conferred to other patent owners on the technology of interest. The terms *patent clearance* or *non-Infringement* analysis are also used.

concepts are not necessarily related, and patentable technology may still infringe third party patents.

Before evaluating the infringement issue, the case of enforceability of a patent against a product that was not envisaged at the moment of the patent filing will be assessed. Article 83 of EPC requires a patent application to "disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".[105] This requirement may be a bar for enforcement of a patent against an embodiment unknown at the moment of filing if the disclosure doesn't provide the teaching on how to reproduce such particular embodiment; in this way the patent can be considered invalid to cover such particular feature. In a case that may be applied to this situation, the TBA decided that "[t]he disclosure need not include specific instructions as to how all possible component variants within the functional definition should be obtained."[106] In spite of this, the Board also stated that "[…] any non-availability of some particular variants of a functionally defined component feature of the invention is immaterial to sufficiency as long as there are suitable variants known to the skilled person through the disclosure or common general knowledge, which provides the same effect for the invention."[107] In this way the court affirmed that the invention needs to be disclosed properly, or reproducible by general knowledge by the person skilled in the art, to be enforceable. If the variant —in this case the unforeseeable embodiment— can be reproduced by the common general knowledge of the skilled person in the art, then the patent is valid and enforceable against the nanotechnological invention. However, if the new embodiment was not envisaged and the effect of such new embodiment, in our case the nanotechnological invention, provides a different effect, the patent may not be considered as valid according to article 83 of EPC, mostly if the disclosure doesn't provide enough information to reproduce the invention. As a result, to be enforceable and considered infringed, the description needs to be complete enough to allow the reproduction of the invention and even in cases where the new embodiment was not envisaged, the infringement is possible if the disclosure requirement is satisfied.

In trying to anticipate how a court may construct the scope of the claims of a patent on consideration of an embodiment not foreseeable at the moment of the patent filing, we should refer to decisions in the biotechnology field, where the TBA defined that EPC doesn't requires that "[…] the suggested features in the claims […] may cover an unlimited number of possibilities. It follows that the features may generically embrace the use of unknown or not yet envisaged possibilities, including specific variants which might be provided or invented in the future."[108] Although the

105 EPC, Article 83, Disclosure of the Invention.

106 T 0292/85.

107 *Id.*

108 *Id.*

EPO has no authority to rule on infringement issues, the exclusive responsibility of courts at member states, the decision provides insight on how the issue would be solved at a national level. As an example, in a case related to nanoparticles used as reinforcement in composite materials and in line with the thoughts of the EPO, the District Court of Frankfurt/Main ruled that: "It could be left undecided whether the defendant was right and the amorphous silicon (SiO2) used was not known to the average expert at the priority date of the patent in question due to dimensions of its particles within the range of a few (hundred) nanometers. Even fillers unknown at the time of the patent application are within the scope of the patent in question".[109]

It may be concluded that, in this situation, materials containing previously unknown and unforeseeable characteristics will be probably considered as infringing the referred existing patents, even if such characteristics are considered new and inventive and allowed to be protected by a patent on improvements.

3. Higher degree of purity

In correlation with the higher control of the manufacturing processes, nano-technology allows the production of materials in a more precise way, in some cases by the production of devices and materials by the manipulation of individual atoms. This permits obtaining materials of higher purity, by controlling the exact composition of what is produced, to give origin to new inventions. While the new manufacturing process can easily fulfill the patentability requirements, the product obtained by that process, the purified material, might lack of novelty. Clarification is necessary to differentiate between cases in which a product with higher purity is in the market and instances where a product, due to description in the written prior art, is the same material with a different content of impurities.

The presence of impurities is usually considered an undesirable effect generated by a technical limitation in the manufacturing processes under use. One must distinguish among impurities and additions of small amount of elements that may indeed cause an effect on the product, like for example the "doping" of silicon to produce solid-state diodes.[110] In some cases, it is the desire of the manufacturer to reduce the content of impurities in order to improve the properties of the material. In other cases, obtaining a material without any impurities may generate new properties

109 *See,* Thorsten Beyerlein, *The Need and Purposes of a "Nanotechnology Act" in Germany and Europe*, Nanotechnology Law & Business, December 2007, p 545, *supra* note 37.

110 For example patent EP1008157B1 *Thin Film Capacitor Using Diamond-Like Nano-composite Materials, filed in 1996.*