

### III. Novelty

EPC requests novelty for an invention to be patentable.<sup>73</sup> To assess this requirement, EPC defines the state of the art from which the invention needs to differentiate, as “[...] everything made available to the public by means of a written or oral description, by use, or in any other way [...]”.<sup>74</sup> This means that not only information disclosed in writing or orally may be considered as part of the prior art, but also any substance, material or product containing the invention if it is available to the public before the date of filing of the patent application or the respective priority.

In the following sub-sections we will explore issues related to novelty requirements in light of particularities of nanotechnological inventions.

#### *1. Patenting naturally existing structures*

Some of the objects of research in the nanotechnology field have been inspired by morphologies present in nature. Some examples of these structures can be found in the self-cleaning surfaces existing in some vegetables and animals. The wings of butterflies and the leaves of some plants are illustrations of these cases.<sup>75</sup> Maybe the most well-known example is the lotus plant.<sup>76</sup>

With many patents protecting different aspects of their morphology and composition, carbon nanotubes have been proposed as other examples of naturally occurring structures. Carbon nanotubes and multi-walled carbon nanotubes are structures of low energy, i.e. atoms organized in the thermodynamically lowest

73 EPC, Article 54.

74 *Id.*

75 *Emulating nature self-cleaning effects for textiles through nanotechnology*, Mincor TX TT from BASF keeps dirt and water at bay, M2 Presswire, May, 2007. Available at <http://www.basf.com> (last visited September, 2009). The outside of the seed of the lotus plant are coated by wax crystals around 200 nanometers in size. These crystals prevent the surface from being touched by water or other. This hydrophobic effect is also facilitated by a particular surface morphology, generating an effect of super-hydrophobicity and allowing the plant to keep pores free of dust. The same hydrophobic effect can be seen in other plants such as the nasturtium, reed or lady's mantle.

76 *Id.*

possible energy for that material.<sup>77</sup> Under the laws of thermodynamics, any system tends to its lowest state of energy, and for this reason some researchers have argued that it is possible that carbon nanotubes are present in nature as self generated structures.<sup>78</sup> Nevertheless, as other conditions need to be satisfied to make possible the occurrence of this phenomenon, for example suitable pressure and temperature to make the natural generation of carbon nanotubes not only thermodynamically possible but also kinetically feasible, the natural presence of these structures cannot be demonstrated by a pure theoretical analysis.<sup>79</sup> This does not mean that there is no foundation to say that carbon nanotubes are not present in nature but only that there is not yet factual evidence on the presence of naturally generated carbon nanotubes.<sup>80</sup>

Far from being a new issue, the problem of patentability of substances previously existing in nature appeared in the past in other countries and fields of technology, as biotechnology and pharmaceuticals.<sup>81</sup> However, the discussion in the field of biotechnology was mostly approached in terms of ethical and social aspects in allowing patents protecting forms of life generated by the nature but isolated by humans, raising a debate on why something that was not invented but discovered should be owned by a private entity instead of being part of the public domain. In line with European Directives<sup>82</sup> and decisions of the TBA and the Enlarged Board of Appeal of the EPO (EBA), the EPO solved such problem by modifying the EPC to allow patentability of these kinds of substances provided that the patent is drafted to protect the isolated form of the organism and not the subject matter as present in nature.<sup>83</sup> As a result, a microorganism already present in nature, if the other patentability requirements are fulfilled, is allowed to be patented if claimed in the right way, i.e. claimed as the isolated form of the living being.

The comparison with the case of pharmaceutical compounds may also provide insights capable of extrapolation to nanotechnological inventions. Particularly relevant may be the experience of companies in patenting active chemical

77 Oscar M. Dunens, et al, *Inconsistencies in the Carbon Nanotube Patent Space: A Scientific Perspective*, Nanotechnology Law & Business, Spring 2008, p25-40.

78 *Id.*

79 *Id.*

80 *Id.*

81 See, for example, K. D. Raju, *The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the Trips Agreement*, November 2007.

82 See, Directive 98/44/EC.

83 EPC, Rule 27(a), Patentable biotechnological inventions, "Biotechnological inventions shall also be patentable if they concern: biological material which is isolated from its natural environment or produced by means of a technical process even if previously occurred in nature".

compounds that were not developed by research efforts, but discovered in nature and processed as medicines to cure humans.<sup>84</sup> In many cases, the discovery of the substance is made as a result of cooperation with indigenous communities which have been using the plant containing the active compound to cure the same or different illness for centuries.<sup>85</sup> For similar cases, following the same criteria applied to biotechnological inventions, the TBA indicated that natural occurring substances and substances present in nature are patentable provided that the legal protection is limited to the isolated or purified substance.<sup>86</sup>

In the case of nanotechnological inventions two circumstances need to be differentiated. The first one is when the researcher discovers a structure originated in nature and patents such structure. The second is when an independently generated invention is patented and later declared unenforceable because the discovery of the same structure in the nature. In analyzing these cases, it should be noted that there is no requirement in patent law to disclose the origin or the creative process that gave result to the invention; because of this, examiners or courts are not allowed to distinguish between these two situations. However, in many jurisdictions patent law obliges the applicant to disclose each and every piece of prior art she is aware to the patent office.<sup>87</sup> If the applicant fails to disclose all the information to assess patentability of the invention, the patent may be declared invalid. In this way, the applicant is obliged to refer to the natural substance when describing the state of the art, if known by her, in a way to allow the examiner to perform a complete assessment of novelty taking into account the natural occurring substance.

Bearing in mind the definition of prior art, a substance present in nature should be considered relevant in assessing novelty and inventive step if it is available to the public. Public availability should be interpreted as the hypothetical possibility to have access to the information, without considerations of the reasons or interest of a person to access it or the knowledge of the person about the existence of such information.<sup>88</sup> In this way, even if the existence of the natural occurring substance was unknown to the public, after its discovery the piece of prior art can be used to

84 Jerry I.-H. Hsiao, *Patent Protection for Chinese Herbal Medicine Product Invention in Taiwan*, The Journal of World Intellectual Property, Vol. 10, no. 1, 2007.

85 The case of patents for Naga Jolokia pepper originally from the Naga tribal community used as a medicine or the patent for the energy drink Jeevani produced from a greed plant from Kerala are examples of patenting modified versions of products that have been present in nature.

86 See, for example, T 767/95.

87 For example, according to US law, failing to disclose all relevant prior art that is known by the applicant at the moment of filing and during the prosecution process of the patent application may be considered Inequitable Conduct and make the patent unenforceable according to 37 CFR 1.56.

88 T 444/88.

attack the novelty of the nanotechnological invention. It is important to note that microscopy techniques developed during recent years made the advance of nanotechnology possible by allowing researchers to see the structures by magnifying them up to 2 million times. Many inventions would not be possible without the existence of these techniques. If a court may consider that before the existence of these techniques the natural occurring substances and structures, even present in nature, were not accessible to the public because no possibility to observe the subject matter was possible due to the inexistence of that kind of microscope, is a point of uncertainty. If we bear in mind the fundamental reasons for the novelty requirement, we have to consider public availability only after the existence of techniques that made it possible to access the knowledge available in nature.

A second point in assessing patentability of a natural occurring substance is the possibility for the invention to be rejected by considering it not an invention but a discovery. On this matter the TBA clearly said: "To find a substance freely occurring is a mere discovery and therefore unpatentable."<sup>89</sup> Nevertheless, the Board opened the possibility to patent substances present in nature by indicating "Moreover, if the substance can be properly characterized either by its structure, by the process by which it is obtained or by other parameters and it is "new" in the absolute sense of having no previously recognized existence, then the substance per se may be patentable."<sup>90</sup> According to this statement, the extra requirement to patent this kind of substance is to characterize it by structure, generation process or any other parameter. The requirement of having no previously recognized existence appears as contrary to the definition of prior art, the existence of which does not need to be known, just available to the public irrespective of the knowledge, intention and actual desire of the public to access it. It is not clear whether the natural substance could not be patented if also its structure, generation process or other parameter used to characterize the invention were accessible to the public. Whatever the case may be, a natural occurring nanomaterial can be patented if the description contains a characterization of an unknown and not previously available to the public parameter or property.

In case it is impossible to find a manner to characterize the invention in a way to fulfill the requirement of the EPO, there is still an option to claim protection not over the substance or structure but over a practical use of it. The Manual for Examiners of the EPO establishes that "If a new property of a known material or article is found out, that is mere discovery and unpatentable because a discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). If, however, that property is put to practical use, then this constitutes an

89 V 0008/94, 1995, cited in Steven Hildebrand, *Patenting of Human Genes in Europe: Prerequisites and Consequences*, Diploma Paper, Zurich, 2001.

90 *Id.*

invention which may be patentable.”<sup>91</sup> According to this rule, a nanomaterial or nanostructure can be patented if the unknown property of such material is used in a practical way. As we can see, the problem of the natural occurring structures can also be approached from the patentable subject matter requirements, but in any case, even if the discovery is considered an invention, it needs to pass the novelty requirement. In this regard, the ambiguity one finds in the foregoing position is that the property, even being unknown, should be considered as part of the prior art. If this is the case, and the property was available to the public, the substance or structure as such could be considered non-patentable.

Yet, the EPO considers that not only the new property of the substance can be patented, but even the substance itself <sup>92</sup>, in a way that the use of the property constitutes a patentable invention, and also the matter that has such property.<sup>93</sup> From this case one may infer that in order to keep good chances of patentability under the uncertainties that novelty and subject matter requirements may generate, applicants should seek to claim every aspect of the nanotechnological material, including the matter itself, supported by a description of its use and also the use of such matter in a particular function, taking care to disclose the technical effect produced by the invention. Since the requirement to disclose a technical effect needs to be included in the description of the invention but there is no need to incorporate such use or technical effect in the claims, the scope of protection can still cover the material in general and not its particular use.<sup>94</sup> Furthermore, these requirements may change from country to country, and applicants should take into consideration the differences that may exist with regard to the patentability of discoveries.<sup>95</sup>

91 *See, supra* note 46, Part C IV 2.3.1 Discoveries.

92 *Id.*

93 The EPO Guidelines indicate that “To find a previously unrecognized substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as a feature of the invention.”

94 Note that the only explicit reference in EPC to the disclosure of the industrial applicability in a particular technology is made in Rule 29(3), The human body and its elements requires that “The industrial application of a sequence of a gene must be disclosed in the patent application”.

95 Different approaches may be present in other countries. For example, the US courts established that “A new mineral discovered in the earth” cannot be patented because is not a human made product. This would bar patenting of any material or structure present in nature. US patent law has been criticized because the lack of consideration of non-written foreign disclosures as prior art to asses novelty or obviousness of patent applications. The law establishes that patents are entitled for a person unless, before the filing on an application, “

As we said, the EPO has introduced a modification to the EPC to explicitly allow patentability of subject matter already present in nature in the case of biotechnological inventions.<sup>96</sup> Strictly speaking, this provision doesn't apply to other fields outside of biotechnological inventions. Two interpretations can be given to this rule when applied to other fields. The first one may consider that the patentability of biological material occurring in nature is an exception to the general criteria of non-patentability of natural occurring substances. The second option may contemplate the view that this specific provision was limited to the field of biotechnological inventions because of the need to comply with the EC Directive on Biotechnological Inventions, and that the same principle may be applied to nanotechnological inventions. If there is some difference among the treatment that should be given to nanotechnological inventions compared with biotechnology, this should be based on both, the particularities of the nature of the technology and policy issues that may force lawmakers to provide further protection for this kind of industry. The implementation of particular patent rules in the biotechnology sector, particularly Directive 98/44/EC, allowed Europe to develop its own biotech industry and to compete with other developed countries in the field.<sup>97</sup> At the moment there is no evidence of a request from the nanotechnological industry for strengthening patent protection and no real evidence has been found on the necessity to increase the patentability requirement for inventions related with natural occurring structures.

[...] the invention [...] [is] patented or described in a printed publication in [...] a foreign country." Consequently, any knowledge that was not disclosed in writing or in a patent is not valid to be used as prior art. This provision impedes invalidating a patent taking into account non-written prior art, which includes materials and substances present in nature. Other example can be found in the law of some Latin-American countries, for example Argentina, where "live matter and substances preexisting in nature, even if had being isolated, purified and characterized, they continue as discoveries and therefore non patentable." These provisions have been criticized as contrary to TRIPS Agreement. For example, on patentability of nature pre-existing structures Strauss says "From the lack of a definition of the concept of invention under TRIPs Agreement it may not be generally concluded that WTO Members, no matter whether developed or developing countries could legitimately follow a definition of invention that broadly excludes material pre-existing in nature from patentability." In this way, Strauss considers that Art 6g of Argentine patent law under which "any kind of life material or substances already existing in nature," does not constitute an invention, cannot be viewed as being in conformity with Art. 27 of the TRIPs Agreement.

96 See, *supra* note 83.

97 European Commission, *European Life sciences and biotechnology: A strategy for Europe*, 2007.

## 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.<sup>98</sup> 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.