Intellectual property issues in nanotechnology

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Abstract

Emerging nanotechnologies have the potential to impact a wide range of commercially important bioscience and medical applications. For example, researchers are developing nanoscale materials as diagnostic probes and targeted therapeutic delivery vehicles. By filing patents, companies can protect their intellectual property and leverage their developments over the marketplace in a way that is consistent with antitrust laws. Policies and doctrines of the US Patent and Trademark Office pertaining to nanotechnology continue to develop. Companies must be aware of challenges and strategies particular to nanotechnology in seeking patents in order to maximise the value of their innovations.
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INTRODUCTION

Nanotechnology is a disruptive technology that will 'displace older technologies and enable radically new generations of products and processes'.[1] The term refers to products and processes in which the arrangement of matter is controlled at dimensions of less than 100 nanometres (nm), or less than one ten-millionth of a meter.[2] Although the average consumer may not realise it, nanotechnology is quickly becoming a part of our everyday lives and is changing the way products from cosmetics to automobile tyres are manufactured. Likewise, nanotechnology innovators are changing intellectual property practices. In 2005, the US Patent and Trademark Office (PTO) cumulative class for nanotechnology contained 3,162 issued patent and published applications. Of these, about 23 per cent were classified as chemical inventions.[3]

Nanotechnology innovators, corporate and academic alike, should be aware of the risks and opportunities presented by intellectual property rights, including patents belonging to other organisations that may block their ability to use a desired technology, and the

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ways in which patents and trade secrets can be managed to exclude others from using a company's innovations. Intellectual property-driven enterprises engaged in nanotechnology research must recognise the importance of protecting their innovations. Generally, two avenues are available to companies: trade secrets and patent protection.

TRADE SECRETS

In theory, a trade secret can be maintained indefinitely, but the security measures required to maintain that protection impose an ongoing and onerous burden. Once disclosed without confidentiality, or published by someone else, the innovation is no longer subject to trade secret protection. Moreover, once a product is sold or is in public use, the product and methods of making it become unpatentable in many countries. In the United States, products and processes enjoy a one-year grace period after entering the market.

Because it may be easy to reverse engineer their composition and shape, nanomaterials themselves may be difficult or impossible to protect as trade secrets. Other aspects of nanotechnology such as the starting materials that are converted into nanoparticles or other nanomaterials, methods of making nanomaterials, and methods of fabricating nanomaterials into composites can, however, be protected as trade secrets because these fabrication methods may not be as susceptible to reverse engineering.

THE ADVANTAGES OF PATENTS

Obtaining patent protection is generally a more robust method of protecting an innovation than protection by trade secret. By obtaining patents on nanotechnological innovations, a company can exclude others from making, using, selling or importing the patented invention for a period, generally 20 years, from the filing of an application in the PTO. Unlike trade secrets, someone who owns a patent can exclude someone who independently developed the same innovation, and may be able to prevent reverse engineering and other research using the patented invention. The patent owner can block someone who was trying to protect an invention as a trade secret in many countries. This right to cut off second movers (and even prior innovators) is of great importance in an intensely researched, emerging field such as nanotechnology.

Although an innovator must disclose the invention when applying for a patent, the innovator can thereafter, without compromising protection, present the information openly to investors, customers, and technical talent, in order to bring new nanotechnology to market.

Those acquiring strategically useful patent portfolios in nanotechnology face particular challenges. They should seek patent protection as soon as possible. Although the US has a first to invent system, many rights accrue to the first to file for a patent. Because a patent provides the right to exclude others, and not necessarily the right to practise an invention, early innovators can obtain 'blocking patents' on essential technologies during the 'IP gold rush', typical of emerging technologies. These 'blocking patents' may prevent later patentees from practising their invention and allow the owner of the blocking patent to obtain royalties, cross-licenses from those whose later inventions depend on the essential nanotechnologies, or exclude new technologies from the marketplace. Through selective licensing, the holder of the blocking patent can leverage an initial research investment across a broad range of products and processes developed by competitors. Likewise, companies who delay seeking patent protection risk having profits drained through obligatory license fees to holders of blocking patents or being shut out of a market entirely.

PATENT PRACTICE FOR NANOTECHNOLOGY

In prosecuting a nanotechnology patent application, the patent attorney must establish novelty[4] and obviousness.[5] A patent examiner may assert that a nanostructured product lacks novelty because the relevant nanostructure was present in an existing product, even though the nanostructure was not recognised. For example, a material may have been recognised as having a desirable technical characteristic, although the mechanism underlying the characteristic was not understood. Under the doctrine of inherency, the PTO will not grant a patent simply for later identifying the mechanism underlying the characteristic of a known material.[6] The patent examiner, however, bears the burden of demonstrating that the characteristics of a material sought to be patented actually arise from structures already present in a known material.

NANOMATERIALS

For example, carbon black has been included in rubber to improve the durability of tyres for more than 90 years.[7] The structure of fullerenes, carbon molecules evocative of soccer balls and having a diameter of about 1 nm, was not determined until the 1980s. Fullerenes were subsequently found to be present in, for example, candle soot.[8] Nevertheless, in 1998, the PTO awarded US Patent Number 5,750,615 to Lukich *et al.*, which was assigned to The Goodyear Tire & Rubber Company, for the 'Use of Fullerene Carbon in Curable Rubber Compounds'. The examiner may have been unable to demonstrate that fullerene compounds in ordinary carbon black were present in a sufficient fraction to meet the criterion specified in the patentees' claim.

A patent claim that specifies a structure having a certain size may be found to be 'obvious' by a patent examiner if the structure was previously known, even though the size specified in the prior art was different.[9]

A known structure implemented at the nanoscale or a known material in which nanostructures are enhanced may still, however, be patentable. One can establish that the rescaling of what is known is not obvious if it can be argued that certain physical phenomena that are insubstantial at larger length scales dominate at the nanoscale. The functioning of the structure at such a small scale would, in fact, not have been obvious to another working in the field at the time of invention. Other strategies to avoid a determination of 'obviousness' include limiting the claimed structure to a specific material, claiming a new use for a known structure or making claims on the process of producing the structure, rather than the structure itself. One drawback to the last approach is that 'process claims' can be more difficult to enforce than 'apparatus claims' dealing with the structure itself.

Additionally, application of the doctrine that rescaling constitutes 'obviousness' has not been strictly applied by the PTO in the context of micro- and nanotechnological inventions. For example, the PTO has granted patents for a micromechanical electromagnetic motor,[10] a micromechanism with a floating pivot,[11] and a microstructure with bumps suspended above a substrate.[12]

Recently, the PTO awarded US Patent Number 5,750,615 to Zhang *et al.*,[13] which was assigned to 3M Innovative Properties Company, for 'Dental Materials with Nano-Sized Silica Particles'. The PTO found a claim to 'non-aggregated, non-fumed silica particles [of average diameter less than about 200 nm] having a silane treated surface' valid, even though 'silane treated precipitated silica' was discussed in an earlier patent.[14]

BIO-NANOTECHNOLOGY

Nanotechnology is inherently interdisciplinary, and therefore has the potential to impact a wide range of commercially important applications. For example, the intersection of nanotechnology with biological science and medical device engineering is an active area of research and development. Cells can be viewed as molecular machines, and the characteristic length of many cellular structures is less than 100 nm. Thus, nanotechnology can provide tools to probe the functioning of biological mechanisms and adjust the functioning of these mechanisms to effect medical treatment.

Quantum dots are semiconductor crystals with diameters that can range from about 1 to 100 nm, and can be made to fluoresce at a desired wavelength when illuminated by visible or ultraviolet light. They can be functionalised with a wide range of biomolecules to make them useful as diagnostic or imaging probes.

For example, patent protection can be pursued for quantum dots functionalised with antibodies capable of binding to antigens, either *in vitro* (as a test-tube assay) or *in vivo* (for medical diagnosis in identifying diseased tissue in a patient). Quantum dots can have higher quantum yield and lower toxicity than conventional fluorescing dyes, so that they can be used as sensitive probes that do not unduly perturb the biological system under study.[15] Researchers are investigating metallofullerenes as a vehicle for delivering radiotherapeutic atoms to targeted tumour cells, in order to attack and reduce the tumour while avoiding collateral damage to healthy tissue characteristic of conventional radiotherapy.[16] Carbon nanotubes can be wrapped with polymers functionalised with biomolecules, such as amino acids, sugars, DNA fragments, and steroids, providing a route for integration of nanoscale devices with biological systems.[17]

CONCLUSION

Because nanotechnology is still an immature technology, there is a tremendous opportunity for companies pursuing research in the field. In addition to the opportunity to file patents for innovations and strategic technologies and processes, early leaders have the opportunity to participate in the formation of particular standards set by industry groups or government agencies. These standards can make it possible for a patent holder to exert additional leverage over the marketplace in a way that is consistent with antitrust laws. The flip side of this proposition is that companies late to the game may find themselves blocked from producing materials that comply with such standards by companies who have already patented them. A diversified portfolio of patents should be a crucial component of a company's overall business strategy, especially in a fast-moving field like nanotechnology where many legal and standards issues remain unresolved.

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