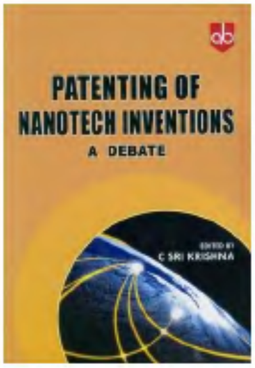

Patenting of Nanotech Inventions: A Debate. C. Sri Krishna (ed.). The ICFAI University Press, 52, Nagarjuna Hills, Punjagutta, Hyderabad 500 082. 193 pp. Price: US $16.

As an ardent user of 'systems thinking' in intellectual property management, it was easy to divide this book into the following: what in nanoscience and technology is being patented (input), the process (throughput) and the statistics (output). The book throws light on patent issues in the fascinating arena of nanoscience and technology. Contributions from eight authors are as follows: Nikolas J. Uhlir (Finnegan Henderson Farabow Garrett and Dunner LLP) has written an interesting chapter titled 'Throwing a wrench in the system: Size-dependent properties, inherency, and nanotech patent applications'. Mark A. Lemley (Standford Law School) has written about 'Patenting nanotechnology'. Siva Vaidhyanathan (New York University) has written a thought-provoking article on 'Nanotechnology and the law of patents: A collision course'. Birgit R. Burgi (Swiss Federal Institute of Technology) and T. Pradeep (DST Unit on Nanoscience at IIT Madras) have covered an important area of 'Societal implications of nanoscience and nanotechnology in developing countries'. Mary C. Till, Michele M. Simkin and Stephen Maebius (Foley and Lardner LLP) have contributed on 'Nanotech meets the FDA: A success story about the first nanoparticulate drugs approved by FDA'. Lawrence Letham (Letham Law Firm LLC) covers 'Thinking about issues associated with nanotechnology', which in fact is best as the first chapter of the book. Raj Bawa (Bawa Biotechnology Consulting, LLC) writes on 'Nanotechnology patenting in the US'. Kshitij Aditeya Singh (Institute of Nanotechnology, UK) has dealt with 'Intellectual property in the nanotechnology economy'.

Addressing what is being patented in nanoscience and technology, Lemley suggests that the basic building blocks (basic research) are currently being patented. Vaidhyanathan describes an analogy of patenting bricks used for construction. Lemley draws from the history of basic science in computer hardware, software, internet and biotechnology. These technologies were not patented (by error), or were left unpatented because universities worked on them. Universities did not bother to patent them, or if patented, the Government forced inventors to license the patents at reasonable non-exclusive rates. The rush to patent an area that is a fledging in its technology life cycle, implies that building blocks like carbon nanotubes, semiconducting nanocrystals, light emitting nanocrystals, metal oxide nanorods, atomic force microscopes, methods of making self-assembling nanolayers, and methods to produce nanotubes through chemical vapour deposition are being patented. Thankfully, the buckminsterfullerene was left out of the patent system. Vaidhyanathan mentions that the term patents in nanotechnology is not clearly defined as it also consists of rods of carbon, or nanotubes and bucky balls (already a contradiction to Lemley), all of which have been patented 250 times in different forms. According to Singh, the areas of patenting include composition of matter, devices, apparatus, systems and control of nanomaterial and devices, and methods. Letham describes terminologies such as nanotechnology, dividing them into nanomaterials and nanodevices. Uhlir points out that nanotechnology is said to be any technology on a nanometre scale. He accelerates a healthy confusion, by mentioning that it is the minute size that is novel. Reductions in the sizes of previously known materials or objects do not seem to meet the novelty and non obviousness criteria. However, in the case of nanotechnology changing the size of magnetic nanoparticles by only a few nanometres the magnetic characteristic may change from ferromagnetic to diamagnetic to super paramagnetic. Properties of nanoparticles are strongly size-dependent.

Lemley brings out the cross-industry and multidisciplinary nature of nanopatents. As stated by Lemley:

> *'Unlike other new industries in which the patentees are largely actual or at least potential participants in the market, a significant number of corporate nanotechnology patentees will own rights not just in the industry in which they participate, but in other industries as well.'*

The patent examiner's competence, how claims in the patent document are addressed, litigation, prior art processing capabilities of the patent office and the obvious consequences of errors in judgment at the patent office are relevant in understanding the throughput. According to Singh, the patent office's competency in terms of qualified patent examiners is a challenge.

Bawa, Ulhir and Singh emphasize the lack of prior art. This causes the examiner to make errors in judgment. Prior art is a crucial part of an examiner's decision on novelty and non obviousness. According to Ulhir, since scale is an important agenda in nanotechnology, chances are high that the same structure has been already patented but at say micrometres (larger scale/size). This throws up the doctrine of inherency when understanding prior art. The doctrine of inherency common in USA, clearly directs a patent examiner to consider whether the earlier patent at a larger metre scale (say micrometre) was put in use/practised. Only if it is not, is novelty valid for the nano patent. This comes from the view that the older patent on a larger scale, say micro scale, has inherent in it the nanoscale and anticipates the nanoscale patent in advance. The doctrine of inherency confounds the situation further for the patent examiner. Patent practice data are unavailable. Uhlir brings out an interesting caution in favour of nano-patents. Quoting Ulhir:

> *'Mere similarity in scale between the claimed invention and the prior art is insufficient evidence to reasonably support an argument that the claimed invention and the prior art are the same.'*

Ulhir brings out the relevance of claims. The patent examiner must assess whether the claims in the patent application overlaps with claims in other patent documents. As Ulhir mentions, the 'name of the game is in the claim'. During infringement litigations the patentee and infringer must pay attention to the claims and understand their scope. The court (during litigation) must also interpret claims to decide who is guilty. Often claims are either drawn towards the physical structure or physical properties of the nanomaterial or object. Additional to the structural claims are claims on particle size, in combination with other structural elements, like presence of coating on the particles, etc. Claims related to properties are not as strong to support, as claims drawn to structures. Physical structural claims must be broad enough to cover the physical properties too. Thus the claims on structure must not be too narrow.

Ulhir also highlights lexicographic issues during litigation and examination leading to lengthy 'Markman hearings' (common practice in the US courts to understand each other's terminology and interpretations). Additionally, with the patent examiner's inability to make proper inherency calls, double patenting that is invidious (to some extent fraudulent) and innocent occurs. Yet another issue is that of definition and clarity, failing which each patent office will classify nano-patents in various patent classes and this will lead to a patent thicket (a forest-like entanglement of similar patents) characterized by a limited oligopoly. According to Singh, the nano-patent classes (assumed to be taken from the international patent classification) in which patents are filed are many and wide in range, namely electricity, human necessities, chemistry and metallurgy, performing operations and transporting, mechanical engineering, physics, fixed construction, textiles and paper.

Switching gears to pharmaceuticals and nano-patents, Till *et al.* describe the FDA approval process for drugs. They ask a question:

> *'Dose conversion of an existing drug into a nanoparticulate form result in a "new chemical entity" subject to an entirely new regulatory review process that starts from square one?'*

They feel that the nanoparticulate cannot have the typical approval process as, nanoparticulate drugs show a lack of bioequivalence. On the other hand, if bioequivalence can be shown, then it is possible to use the typical approval process as in a reformulated drug. Benefits of a nanoparticulate in pharma are worthy of quoting:

> *'Increased bioavailability, faster onset of action, dose uniformity, reduction in fasted and fed variability, decreased toxicity, smaller dosage form and stable dosage forms of the drug which could not previously be formulated conventionally.'*

Two examples of nano-drug products are briefly described by Till *et al.* One is a 'new chemical entity' Emend®, known as aprepitant that is a nanoparticulate (patent awarded in 2003). Safety and toxicity tests could not be easily done on the active agent. Another example is the TriCor® in nanoparticulate form. It showed less variability between fasted and fed patients when consumed. Nanoparticulate drugs appear to have different pharmacokinetic profiles than their larger particle originals, and thus need new testing. Hence these drugs come under a 3 or 5 year non-patent exclusivity (independent of patent rights) and under the Hatch–Waxman Act, they can also extend the period of their patent.

From the outcomes viewed in terms of statistics, it is seen that the type of organizations that focus on nanotechnology are universities, national laboratories, Government agencies, large companies with significant R&D, start-ups and spin-offs, mainly by researchers of universities. Singh shows that universities hold about 70% of the world's nano-patents and Indian national laboratories have filed about 38 patents. According to Lemley, university patents tend to be upstream (building blocks from the basic R&D side), and thus not downstream (applied R&D and implementation side). This basic research side of nanotechnology is critical for innovation. Universities tend to be drivers of early-stage inventions, which they normally would have published, until the Bayh Dole Act changed this behaviour. The concern is whether the spate of patenting will result in patent thickets and whether litigation will impede downstream implementations for industry? With patent thickets, royalties will be collected from many claimants and patent trolls will buy up patents to sell again. Patents in pharmaceutical and chemical fields have highest counts, followed by semiconductors. Japan leads in nanoelectronics, followed by USA. Bawa describes popular graphs showing the growth of nanotechnology. Singh briefly mentions the application areas namely, energy, especially hydrogen storage, polymer membranes for fuel cells and semiconductors for solar cells. In personal healthcare, products in cosmeceuticals and nutraceuticals are emerging. Bawa and Singh bring out some interesting managerial challenges, with the patent battle moving from boardrooms to that of university laboratories.

Burgi and Pradeep and also Letham, focus on an important area in nano-patents, namely the implications on society. It is well known that patent examiners are not expected to permit patents on intellectual efforts that harm society. The chapter by Burgi and Pradeep is well written. The authors bring out the importance of cybernetic systems, and mention that social systems often tend to alter more slowly than the faster changing technological system. Hence society may react to nano science and technology much more slowly. However, in the mean time, it is unclear whether the release of atomic and molecularly engineered matter will cause problems to human health. Accumulation of such unknown novel materials whose behaviours are just being discovered can even pose a risk to some of the organs in the human body. The authors bring out the urgent need for organizations such as the Environmental Impact Assessment, to assess reliability, safety, risks and policies. Nano-weapons, nano-robots leaving their bonds and flying into the environment as grey goo, malicious undetected sensors, delivery of nerve agents with nano-devices unseen with human eyes, infecting people with deadly viruses and undetected weapons using artificial intelligence need standards and quality control. Further, while many developing countries have not quite gained from industrialization, R&D and new technology, it is important that nanotechnology addresses the needs of developing countries for sustainable development, including biodiversity, safe drinking water, improving food nutrient efficiency, health diagnosis, pollution, energy management and global partnership.

The book is a rich and exciting read, with few overlaps that occur in edited books. However, there are parts not connected to nano-patents that could have been avoided.

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