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Nanotechnology: Development, Risk and Regulation

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Abstract

'Over the past few years, a little word with big potential has been rapidly insinuating itself into the world's consciousness. That word is "nano". It has conjured up speculation about a seismic shift in almost every aspect of science and engineering'[1]. This "nano" revolution has now officially begun. While products are being introduced in the marketplace, its proponents are forecasting incredible possibilities especially for the poor, from abundant food to clean energy. Although it is true that there is much more to be understood about nano-scale research and manipulation, it must be recognized that nanotechnology is no longer a part of the distant future. It is a technology that is already an important part of the commercial marketplace, even if not yet widely acknowledged and recognized. 'As nanotechnology steps onto centre stage and the bounty it promises begins to become reality, it will raise several issues of ethics, public policy, law and social responsibility. Most of the questions are not new, but nanotechnology increases the urgency and importance of addressing them'[2].

This paper explores this new technology by analyzing its potential impact on development, its socio-ethical implications, the risks involved and finally confronting legal regulation.

I. Introduction: Nanoscience & nanotechnologies

Nanotechnology is a new approach to industrial production, based on the manipulation of things so small that they are invisible to the naked eye and even to most microscopes. Nanotech is named for the nanometer, a unit of measure, a billionth of a meter, one-thousandth of a micrometer. The *Oxford English Dictionary* defines Nanotechnology as -'the branch of technology that deals with dimensions and tolerances of less than 100 nanometers, especially the manipulation of individual atoms and molecules'. Nanotech deals in the realm where a typical grain of sand is huge (a million nanometers in diameter). A human hair is 200,000 nanometers thick. A red blood cell spans 10,000 nanometers. A virus measures 100 nanometers across, and the smallest atom (hydrogen) spans 0.1 nanometers. Nanotechnology encompasses many different concepts but it is more generally associated with the "manipulation of matter on an atom-by-atom or molecule-by-molecule basis" to construct or build a certain atomic or molecular configuration.[3]

Most industrial manufacturing processes are based on top-down technologies i.e. they take larger objects and materials and make them smaller. Blocks or chunks of raw material are cast, sawed, or machined into precisely formed products by removing unwanted matter. In Nanotech rather than being produced from large chunks of material that have to be normally sawed, planed, and

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1 Mark Ratner and David Ratner (2003), *Nanotechnology: A gentle introduction to the next big idea*, Prentice Hall p. 2.
2 Ibid at p.158.
3 Frederick Fiedler & Glenn Reynolds (1994), 'Legal Problems of Nanotechnology: An Overview', *3 S. Cal. Interdisc. L.J.* pp. 593- 595.

ground to form, most products are constructed by tiny molecular machines, such as cells and organelles, working from the bottom up. "This approach can produce results that would seem impossible if judged by the standards of conventional top-down production technology, but that are taken for granted in their proper context."[4] The scale and complexity of this effort will likely remove boundaries that have long existed between various scientific and engineering disciplines and between various technological fields, for example, 'solid-state devices and biochemistry'.[5] The confluence of the sciences under nanotechnology is considered what makes it such an immensely powerful field. The convergence of nanotechnology with other new technologies like biotechnology, information and cognitive sciences are collectively treated as 'convergent technologies' or with the acronym NBIC (nano, bio, info, cogno). The resultant synergy would tremendously increase the transformative potential of new technologies as a whole.

Nanotechnology as a scientific field is only a few decades old. In 1959 Richard P. Feynman—the great American physicist and Nobel laureate—gave what may have been the premier talk on nanotechnology. *There's Plenty of Room at the Bottom* anticipated the nano-revolution to follow. Looking around at the "most primitive, halting steps" of miniaturization in his day, Feynman considered the possibilities of manipulating matter on the smallest scale, asking "Why cannot we write the entire 24 volumes of the *Encyclopedia Britannica* on the head of a pin?" Feynman set out what has now become the standard research agenda for the entire field of nanotechnology. His vision included the possibilities of manipulating matter atom-by-atom, of "a billion tiny factories, models of each other" that would assemble parts and manufacture materials at the atomic level, and in the future "arrange atoms the way we want, the very *atoms*, all the way down" [6]

The other most important development in the short history of nanotechnology is the discovery of nanostructures. In 1985 the discovery of a new form of carbon named buckminsterfullerene was the Nobel Prize winning achievement and a foundation for the hopes for nanotechnology.[7] A quarter of a century after Feynman's talk came K. Eric Drexler, dubbed as the 'messiah' of nanotechnology, who popularized Feynman vision. His book, *Engines of Creation*, was met with intense interest as well as criticism. It also kindled hype and accelerated the rush in government and corporate funding for nanotechnologies.

Nanotechnologists foresee a second industrial revolution sweeping the world. From nano wires, nano carbons to nano medicines the prospects are endless. For developing countries, nanotechnology has potentials in the form of improved water purification, energy systems, health care, food production and communications. Some Nanotechnologists have gone to the extent of stating that nanotech holds the key to eradicate hunger and thirst in poor countries.[8] The trouble, of course, is that these machines might go awry. "Like Frankenstein's monster, they might display a "mind of their own," to draw on a frequent motif of science fiction and Hollywood. Nanomachines might wreak havoc on our bodies and environment".[9] Terrorists might even

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[4] Ibid. at p. 596. See also, Glenn Fishbine (2002), *The Investors Guide to Nanotechnology and Micro machines*, John Wiley & Sons, pp. 7- 8.

[5] Barry Newberger (2003), 'Intellectual Property and Nanotechnology', 11 *Tex. Intell. Prop. L.J*. pp. 649 – 650.

[6] Feynman, R. (1960), *There's plenty of room at the bottom*. Presented in 1959 and first published in the February 1960 issue of California Institute of Technology's Engineering and Science, which owns the copyright. www.its.caltech.edu/~feynman/plenty.html accessed on 14 Dec 2006.

[7] Buckminsterfullerene was discovered by Sir Harold Kroto in the UK and Richard E. Smalley and Robert F. Curl, Jr in the US. These three researchers shared the 1996 Nobel Prize in chemistry for their discovery. Named after the architect R Buckminster Fuller (Bucky) whose geodesic dome design is similar to the molecular structure of C_{60}.

[8] Nanotechnology could also provide solutions integrating several of the abovementioned domains. Examples of this integrated approach could include 'healthy housing' that targets energy, water, and health needs, as well as social and economic needs, through superior materials and design. Other streams might include new food production technologies, or potable water management and delivery.

[9] G. Pascal Zachary, *Ethics for a Very Small World*, Global Newsstand, Vol. 14, No.3, March 2003, p. 108.

harness this technology to nefarious ends. In addition to legal and regulatory concerns, there are several socio-political issues that will likely arise from the development of nanotechnology. "In a peaceful and stable world, the benefits of new medical treatments or better consumer goods are likely to be welcomed; in a world in conflict, nanotechnology is likely to find military applications with potentially grave consequences".[10] Few deny that new products may entail new hazards especially health hazards - but most Nanotechnologists say existing regulations are adequate for controlling any hazards that may arise. This however may not be true considering the newness of the technology. Most products on sale are not being labeled as nano products and consumers are unaware of the possibility that they are using or consuming such products.

No one denies that Nanotech will produce real benefits, but, based on experiences of nuclear power, biotechnology and the chemical industry, skeptics are calling for a precautionary approach. The Precautionary Principle is sometimes called the foresight principle. It is important to foresee the implications of this new technology, which will be a major test of the Precautionary Principle as a new way of managing innovation. "In the clash between activists and scientists in Europe and North America over GM (genetically modified) products, developing countries were largely excluded, and pressure from industrialized countries discouraged developing countries from applying GM advances toward development and managing associated risks themselves"[11]. It is felt that the same will happen with nanotechnology. Unless nanotechnology is shared generously, it may create a "nano divide" similar to the "digital divide" and "genetic divide" that exists now between many developed and developing countries. Inequalities within and between nations may be exacerbated if individuals and corporations gain monopoly control of nanotech by patenting the building blocks of the universe.

Mihail Roco, chief advisor on nanotechnology at the National Science Foundation, predicts that within ten years, the entire semiconductor industry and half of the pharmaceutical industry will rely on nanotechnology. [12] The U.S. House of Representatives passed HR 766, the Nanotechnology Research and Development Act of 2003. This bill authorizes more than $2 billion of federal research money over the next three years. [13] Regardless of whether or not nanotechnology will become an accepted and viable economic and scientific force in the future, this has not stopped economic forecasters from estimating that the nanotechnology market will be worth over $1 trillion by 2015[14].

II. Societal and ethical implications of nanotechnologies

Societal and ethical implications of nanotechnology have become a hot topic of public debates in many countries because both revolutionary changes and strong public concerns are expected from its development.[15]

Impacts of nanomaterials on the environment and human health are uncertain. Nanoparticles can enter the blood stream through the lungs and possibly through the skin, and seem to enter the

[10] Francisco Castro (2004), 'Legal and Regulatory concerns facing Nanotechnology', 4 *Chicago-Kent Journal of Intellectual Property* p. 143.
[11] Michael Ruse & David Castle (2002), *Genetically Modified Foods*, Prometheus Books NY, p.249- 250
[12] M C. Roco and W S. Bainbridge (2001), *Societal Implications of Nanoscience and Nanotechnology,* Kluwer Academic Publishers, Boston, at p.4.
[13] Funding Fuels Nanotechnology Research (2003) *Nano-frontier*, Vol.1, Issue 2, available at < http://www.nanobuildings.com/news/PreviousIssues/Vol1Issue2/default.asp> accessed on 12 Jan 2007.
[14] The National Science Foundation forecasts that $1 trillion worth of nanotechnology- enabled products will be on the market by 2015. Available at: www.nsf.gov/crssprgm/nano/reports/nni031210roco@euronanoforum.pdf Accessed on 4 January 2007.
[15] Rosalyn W. Berne and Joachim Schummer (2005), 'Teaching Societal and Ethical Implications of Nanotechnology to Engineering Students through Science Fiction', *Bulletin of Science Technology Society*; 25; p. 459.

brain.[16] Few studies are available on the affects nanoparticles will have if inhaled by humans. Other human health concerns include largely unknown effects of using nanotechnology in pharmaceuticals. These nanoparticles will also enter the food chain affecting plants and animals. It is also not known if these particles are biodegradable.

Recently in March 2006, the German and then the international press reported that people had become sick after using Magic-Nano products (Kleinmann GmbH; Sonnenbuehl, Germany): aerosols designed to coat glass and ceramic with a protective, dirt-repellent film. Within days, about 100 consumers became ill with symptoms such as coughing, headaches, sleep disruption and vomiting. A small number were hospitalized with pulmonary oedema, but most recovered in a matter of days. The health scare renewed fears of nanotech products in Germany, the only country where the product was marketed, and the press had a field day reporting on the first "nano-recall" as authorities pulled the product from the shelves. However, after investigation, the German government and Kleinmann's supplier, Nanopool GmbH (Schwalbach, Germany), concluded that the problem was not with the nano-components of the aerosol. So the first 'nano scare' did not actually involve any nanoparticles. But the incident did raise questions about the risks posed by these new products, and prompted calls for regulation.[17] “Thus it is clear that the current state of understanding of the risks to human health and the environment from nanomaterials is one of almost complete ignorance; there are reasons to think that there could be harmful impacts but the nature and extent of the hazards and risks are essentially unknown”.[18]

Advances in nanoscience and nanotechnology are rapidly furthering the unification of domains—a profound convergence of our understanding of, and ability to manipulate at the most fundamental levels, the material constituents, and processes of inert substances and living things. Expressed succinctly, “From the point of view of nanotechnology, what used to be separate domains of biomedicine, information technology, chemistry, photonics, electronics, robotics, and materials science come together in a single engineering paradigm”.[19]

“The convergence of nanotechnology with information technology linking complex networks of remote sensing devices could lead to covert surveillance that will be hard to detect. Tiny sensors and listening devices that cannot be detected by the eye are also seen possible”[20]. “The philosopher Jeremy Bentham imagined an architecture for a prison he called the Panopticon. In Bentham’s prison all the cells are open to surveillance by a single guard hidden in a tower at the center. The idea is that prisoners would behave themselves because they could never be sure they were not being watched”[21]. It does not take much imagination to see how nanotechnology could shrink video cameras and microphones while vastly expanding the ability to record and store information. In fact, this trend seems unavoidable in the long run. Possible future convergence of nanotechnologies with biotechnologies and other cognitive sciences could be used for radical human enhancements, thus raising ethical questions. Nanotechnology may also have military applications. It can be used to make smaller and more efficient weapons and bombs

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[16] The UK's Health and Safety Executive has published a review of nanoparticle exposure in the UK. Prepared by the Institute of Occupational Medicine, "Nanoparticles: An occupational hygiene review" concludes that all four main groups of nanoparticle production processes may result in exposure by inhalation, dermal or ingestion routes. Available at: UK reviews Nanoparticle exposure October 2004. < http://nanotechweb.org/articles/society/3/10/1/1> Accessed on 19 April 2006.

[17] See, Howard Wolinsky, ‘*Nanoregulation: A recent scare involving nanotech products reveals that the technology is not yet properly regulated*’**,** EMBO reports 7, 9, 858–861 (2006). Available at http://www.nature.com/embor/journal/v7/n9/full/7400799.html Accessed on 2 November 2006.

[18] Roland Clift, ‘*Risk management and regulation in an emerging technology*’, in Geoffrey Hunt & Michael Mehta (2006), *Nanotechnology: Risk, Ethics and Law*, Earthscan, UK pp. 144-146.

[19] Nordmann, A. (2004), *Converging technologies—Shaping the future of European societies*. Available at http://www.ntnu.no/2020/pdf/final_report_en.pdf

[20] Wei Zhou (2003), ‘Ethics of Nanobiotechnology’, 19 *Santa Clara Computer & High Tech. L. J*. pp. 481-483;

[21] Lyon D (1993), ‘An electronic Panopticon? A Sociological critique of surveillance theory’, *The Sociological Review*, 41:4, p. 655

by taking chemical and biological weaponry to another level. Massachusetts Institute of Technology's (MIT) Institute for Soldier Nanotechnologies has received US$50 million of research funding from the U.S. Army; and the U.S. Department of Defense is a key funder of nanoscience research and development for military purposes. Other countries have already followed suit.[22]

Many are calling for a review of ethical considerations pertaining to nanotechnology. However it cannot be denied that many of the social and ethical issues are the same as those that affect a wide range of other high technologies. That is, while the technology is new, the issues it raises have been faced before by researchers and society.[23] The ethical challenges of nanotechnologies are very similar to the ethical challenges of biotechnology and biology and this knowledge base may be a good starting point and foundation for a discussion of ethical reflections on nanotechnology.[24]

III. Nanotechnology and development

With calls for sustainable development – nanotechnology (NT) is being depicted as the answer to development without wastage and without harming the environment. "Its exploitation and utilization is predicted to transform developing countries and help reduce poverty. Billions of people around the world still suffer from inadequate access to clean water, energy, information, shelter, health care, and other basic needs".[25] Nanotechnologists say that all this will change with exploitation of this new technology.

Research and development of appropriate applications could increase the potential benefits from applying advanced NT. One of nanotechnology's most compelling promises is that of access to safe drinking water. Point-of-use water filtration could purify water for those who do not have clean and reliable water supplies. This will not only affect poverty and health goals but also children hauling water for their families all day may even be able to go to school instead. Nano filters can be used to remove bacteria, viruses and other contaminants. Natural arsenic in wells which is a problem in many countries can be solved using nanotechnology. Major sections of society in poor and developing countries do not have access to electricity. Having access to electricity has direct implications on pumping of water, saving firewood, powering of various appliances, lighting schools etc. Using nanotechnology cheap photovoltaic films can be produced. Integrated into roofing panels these could yield a safe and sustainable source of inexpensive energy. NT can also be used to increase the efficiency of energy storage devices.

"Packaging of integrated systems applying advanced nanotechnology for diagnostic testing, custom formulation of medication, and targeted delivery of treatments, could help deliver medical care where doctors and hospitals are scarce. Nanoporous membranes may help with disease treatment in developing countries. They are a new way of slowly releasing a drug, important for people far away from a hospital".[26]

Continuing drastic reductions in the cost of information technologies, enabled by NT, would facilitate universal access to computing and communications. Thus NT may help make computers,

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[22] Langley, C., with Parkinson, S., & Webber, P. (Eds.). (2005), '*Soldiers in the laboratory: Military involvement in science and technology – and some alternatives*'. Available at: www.sgr.org.uk/ArmsControl/Soldiers_in_Lab_Report.pdf accessed on 10 Jan 2007.

[23] Joel Rothstein Wolfson (2003), 'Social and Ethical Issues in Nanotechnology: Lessons from Biotechnology and Other High Technologies', 22 *Biotechnology L. Rep*. p. 376,

[24] See, Mette Ebbesen, Svend Andersen and Flemming Besenbacher (2006), 'Ethics in Nanotechnology: Starting From Scratch?, *Bulletin of Science Technology Society*; 26; pp. 451- 462.

[25] Fiona Moore (2004), 'Implications of Nanotechnology', *Health law Review*, Vol. 10 (3), p. 10. See also, Barrett Hazeltine & Christopher Bull (1999), *Appropriate Technology*, Academic Press - London, p. 263- 265.

[26] See, Glenn Hanlan Reynolds (2003), 'Nanotechnology and Regulatory Policy: Three Futures' *Harvard Journal of Law and Technology*, Vol. 17(1), pp. 188 – 205.

cell phones and other related tools accessible to the poor. "Materials formulated with molecular precision could provide better shelter and tools. In agriculture and food processing, NT is predicted to make significant advances."[27] Its uses in food production could range from designing new and better food products to foods that do not rot. This could have implications on poor countries facing famines or droughts. Molecular manufacturing could enable clean production and new methods for environmental remediation, enabling global abundance to be both feasible and sustainable. Actual applications of NT will depend on a range of factors, including the evolution of related technologies such as biotechnology and information technology, economic systems, and institutions regulating intellectual property.[28]

However like all technologies there is another side. Many scholars and thinkers have predicted that even with continuing progress in poverty reduction, many people will probably still be poor when molecular manufacturing technologies become available – as NT could still be expensive for much of the developing world. The effect and challenge of bridging the NT divide also needs to be considered. This divide may work contrary to claim that NT will help developing countries. Only a few developing countries are presently involved in nanotechnology research like India, China and South Africa. Most poor and developing countries lack the ability to research and exploit these new technologies. They lack qualified personnel as well as infrastructure.

Patent rights are being extended around the World through the provisions of the World Trade Organization (WTO), Agreement on Trade Related Aspects of Intellectual Property (TRIPS).[29] Proponents of TRIPS argue that patents and other intellectual property Rights (IPRs) are essential for promoting research and development (R&D) as well as stimulating innovation. The Patent system is supposed to grant a limited monopoly for an invention so that the patent holder can extract benefit from it for a period of time. Patent and other intellectual property rights have a dual function: providing incentives for invention and facilitating prompt productive use of new technologies. "But, by its very nature, nanotechnology complicates the assumptions that underlie the principles of patenting inventions. Nanotechnology bridges the conceptual gaps between substance and information, hardware and software, and technology and science"[30]. It is however, essential that when applied in the sphere of new technologies like nanotechnology, it is important that besides encouraging inventiveness it must be ensured that the benefits of these trickle down to even the poorest. Most of the nanotech products are being patented in developed countries. This will prevent other developing countries from exploiting these technologies and create the same patent conflicts witnessed with the digital and biotech revolutions. Corporate interests will almost certainly control the lions share and will dominate ownership and access, putting poor countries at a severe disadvantage.[31]

In terms of public awareness and regulation, developing countries have shown themselves to be inadequately equipped to cope with these advanced technologies. Many developing countries tend to lack appropriate environmental, health and other safety regulations. They also lack monitoring and enforcement capabilities. A recent RAND report titled '*The Global Technology Revolution 2020*'[32] highlights the fact that in 2020, areas of particular importance for technology

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27 Charles Vordran (2004), 'The Many faces of Nanotechnology', 16 No. 7 *J. Proprietary Rts*. pp. 6- 8.

28 The Royal Society and the Royal Academy of Engineering. (2004), '*Nanoscience and Nanotechnologies: Opportunities and Uncertainties*', pp.20- 22. Available at: www.nanotec.org.uk/finalreport.htm accessed on 18 August 2006.
See Also, A. S. Bhalla (1996), *Facing the Technological Challenge*, Macmillan London, p.p. 126 – 132.

29 For the TRIPS Agreement *see*: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm Accessed on 10 January 2006.

30 Siva Vaidhyanathan, *Nanotechnologies and the law of patents: A collision course*, in Geoffrey Hunt & Michael Mehta (2006), *Nanotechnology: Risk, Ethics and Law*, Earthscan, UK pp. 225-226.

31 See, Barry Newberger (2003), 'Intellectual Property and Nanotechnology', 11 *Tex. Intell. Prop. L.J*. pp. 649 – 652.

32 RAND technical report (2006), '*The Global Technology Revolution 2020*'. Available at http://www.rand.org/pubs/technical_reports/TR303/ Accessed on 29 September 2006.

trends will include biotechnology, nanotechnology, materials technology, and information technology. It also reiterates that with respect to new technologies like biotechnology and nanotechnology, technologically advanced countries will dominate and the benefits of these new technologies will play out differently in different countries. Technologically lagging countries like much of Africa face challenges in institutional, human, and physical capacities that will severely handicap their ability to exploit these new technologies to the maximum.

Despite the projections and benefits of NT's to developing countries and the poor, caution is required. This new field about which a lot more is yet to be known may just become the poor man's nightmare.

IV. Nanotechnology, Risk and the Precautionary Principle

Risk is central to debates on new technologies and their implications on society. Hence it is hardly surprising that the '*risk society'* perspective developed in writings by Beck and Giddens[33] has been drawn in to these debates.

Risk society analysis of contemporary life suggests that risk has become a central, generalized pre-occupation to the extent that it is configuring contemporary institutions and contemporary consciousness. Beck argues that the modernistic optimistic idea that science and rational government can deliver security, prosperity and general welfare has been replaced by a pessimistic awareness of the ills brought about by the scientific-rational endeavour to deliver a planned, safe, opportunity-rich society. Earlier generations in society would think of 'industry' as employment, security, earnings, improvements in living standards; today's generation is likely to think of pollution, environmental degradation, unemployment etc. In other words, we now think of the negatives – the risks- associated with the possibilities of modernity, rather than the benefits.[34] In Beck's[35] terms, our individual consciousness and social organization are dominated by the distribution of ills rather than the distribution of goods. The social production of wealth was once the main goal of development - the "new paradigm of the risk society" is how risks can be "prevented, made harmless, dramatized and directed and channeled away".

Beck's point is that the externalization of risk is no longer possible because it is increasingly apparent that many hazards are a by-product of the same techno-scientific rationality that initially promised progress, development, and safety. Risk society also expects security and safety from these risks that cannot be satisfied, thus resulting in growing distrust of expert knowledge. Distrust of experts and knowledge systems means that the context of science and technology has changed, and there is now greater scrutiny, skepticism and a sense of risk associated with it. It seems likely that government and public demands for greater accountability are set to strengthen in publicly funded and also commercially-driven science and technology. Such demands are linked to broad shifts in modern society commonly identified with a loss of trust in public institutions and the weakening of collective sources of meanings and certainty. A related conceptualization is that of '*reflexive modernization*', where increasingly opportunities, threats and ambivalences fall to the individual to resolve or make sense of.[36] Ultimately, whether at the micro or macro level, risk is understood as being somehow un-detachable from any type of innovation processes, not only it is associated with the transition to modernity and globalization at the individual and institutional level but affects also the choices of individuals and institutions themselves.

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[33] Giddens. A (1990), *The consequences of modernity*, Cambridge, Polity Press.
[34] Barbara Hudson (2003), *Justice in the Risk Society*, Sage publications, London, pp.43-45.
[35] Ulrich Beck (1992), *On the logic of Wealth Distribution and Risk Distribution- Risk Society*, Sage London pp. 19- 50. See also, Beck, Ulrich 1992b. 'From Industrial Society to the Risk Society: Questions of Survival, Social Structure and Ecological Enlightenment', *Theory, Culture & Society* 9: pp. 97- 123.
[36] Supra at 32.

"The precautionary principle is often invoked when dealing with situations that may be dangerous or hazardous. It is a principle for guiding human activities, to prevent harm to the environment and to human health. It is not a new principle, but is one based on common sense aphorisms such as "*An ounce of prevention is worth a pound of cure*," "*Better safe than sorry*," and "*Look before you leap*."[37] However there is no standard or accepted version of the precautionary principle. Without any consensus as to what the precautionary principle actually entails, it does not provide a meaningful foundation for regulation. The precautionary principle does not answer the key risk management questions, such as what level of risk is acceptable and what early indications of potential hazard should trigger precaution. Even more crucial, the precautionary principle freezes us in place. No technology at its inception can satisfy the precautionary principle in a strict form, so the principle becomes a formula for doing nothing.[38]

The precautionary principle has been accepted to have two forms – a *strict form* and an *active form*. The *strict form* requires inaction when something poses a risk. Like in relation with nanotechnology, following the strict form would mean a complete stop to it to prevent any environmental or health risks. The *active form* calls for choosing less risky alternatives when they are available, and for taking responsibility for the potential risks. For e.g. Article 15 of the Rio Declaration on Environment and Development, states: "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost effective measures to prevent environmental degradation."[39]
The problem with the strict form is that almost any scientific action amounts to certain level of risk. Strict adherence to this form will bring all scientific work to a standstill. So also inaction may actually prevent action with risks from mitigating greater risks.

The active form does not automatically forbid risky activities; instead it calls for an appropriate effort to mitigate the risk.
The disadvantages of the strict interpretation of the precautionary principle to nanotechnology are:[40]

a) No other solution may be found for certain pressing problems.
b) Inaction on the part of responsible people could simply lead to the development and use of MNT [molecular nanotechnology] by less responsible people.
c) Lack of understanding of the technology will leave the world ill-equipped to deal with irresponsible use.

With nanotechnology though there are proponents of the strict application of the precautionary principle, it is widely felt that the active form be applied with proper regulation. This active precautionary approach should firstly be proportionate to the risk involved. If substantial risk is involved there must be adequate and proportionate precaution. Secondly, a comparison must be made between the most likely positive or negative consequences of the envisaged action and those of inaction in terms of overall cost, both in the long- and short-term. Thirdly, the measures adopted must be consistent with measures already adopted in similar circumstances. Finally, the measures should be maintained as long as the scientific data are inadequate, imprecise or inconclusive. Such measures should be alterable in the light of new scientific findings. Hence,

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37 Michael Mehta (2004), 'From Biotechnology to Nanotechnology', *Science, Technology & Society*, Vol. 24, No. 1, pp. 34-39.

38 Robin Fretwell Wilson (2006), 'Nanotechnology: The challenge of regulating known unknowns', *The Journal of Law, Medicine & Ethics*, Volume 34, Issue 4: 704-713.

39 Chris Phoenix & Mike Treder (2003), '*Applying the Precautionary principle to Nanotechnology*', Centre for Responsible Nanotechnology. Available at:
< http://www.crnano.org/precautionary.htm> Accessed on 12 June 2006.
See Also, John Applegate (2002- 2003), 'The Taming of the Precautionary Principle', *WM & Mary Envtl. L & Pol'y Review*, Vol. 27, pp. 13 – 18.

40 Neil Jacobstein and Glenn Harlan Reynolds, '*Self Assessment Scorecards for Safer Development of Nanotechnology*', October, 2004, Foresight Institute. Available at :
http://www.foresight.org/guidelines/current.html Accessed on 12 May 2006.

developments in nanotechnology will require new approaches for addressing uncertainty and heightened understanding of how risks and benefits should be balanced.

V. Nanotechnology and intellectual property rights (IPRs)

'As with the emergence of any pioneering technology, nanotechnology creates issues and opportunities in perfecting intellectual property rights. Laws covering products and technology since the Industrial Revolution may not apply to nanotechnology. Can you patent an atomic or molecular structure? How do you protect an atom or molecule-sized device from being illegally copied? How will patent policies evolve and affect the scope of nanotechnology patents? These and other intellectual property questions require resolution in order to make effective and efficient use of nanotechnology innovation.'[41]

The field of nanotechnology is currently one of the most active on an international basis, with respect to number of patent applications. By February 2004, the number of issued U.S. patents incorporating the term "nano" reached 1,348 patent titles and 82,740 patent descriptions.[42] 'In addition, participants in the nascent nanotechnology industries employ the law of trade secrets to supplement their control over key technology and expertise. Although less directly involved in the nanotechnology industry, copyright law and trademark law also affect participants in nanotechnology markets. For example, computer software plays an important role in nanotechnology research and commercialization, and copyright law is a major factor in the management of such software products. As nanotechnology companies grow, they will become increasingly active in the filed of trademark law, as they build and manage the names and other forms of commercial identification that brand their products and services. Another valuable form of intellectual property is the design of the products or product packaging. The distinctive look of a product or its packaging often serves effectively to help consumers identify the product and distinguish it from its competitors. Protection for designs afforded by intellectual property law could be useful for some nanotechnology applications. Design patents could provide legal protection for nanotechnology advances that do not meet the requirements of other forms of intellectual property rights such as novelty or non- obviousness. For example it could be argued that though merely reducing the size of an invention is not novel, it creates a distinctive design, thus qualifying it for design protection. Another form of intellectual property that can be protected is trade secrets. Trade secrets consist of information or knowledge that is not widely known and provides competitive advantage to its owner'.[43] Trade secret protection offers the advantage of avoiding the effort and expense of patent applications and has a potentially indefinite duration; subject, of course, to reverse engineering. With lengthy commercialization timelines for some nanotechnologies and the 20-year limit on the patent term, it may be advisable to opt for trade secret protection as long as the product is not easy to reverse engineer in the near future. However, trade secret protection requires continuous diligence, and once a trade secret is revealed, it has no further protective value.

Biotechnology and pharmaceuticals are two segments of industry that stand to gain a great deal from nanotechnology because treatment or even cures for many of the world's most virulent illnesses may be possible through nanotechnology. Under current laws in many countries, developers and research companies can patent drugs as well as genetic patterns and synthesis techniques. Researchers are afforded this patent protection for the same reasons that other firms in other industries are awarded patents – to encourage them to innovate and to allow them to recover the costs of research, development and testing of their products. The patenting of essential medicines and biotech products are already highly controversial issues and as

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[41] Terry K. Tullis, 'Current intellectual property issues in nanotechnology', 2004 *UCLA J.L & Tech*. Notes 12. Available at: < http://www.lawtechjournal.com/notes/2004/12_040809_tullis.php> accessed on 20 March 2007.
[42] Ibid.
[43] See, Jeffrey Matsuura (2006), *Nanotechnology regulation and policy worldwide*, Artech House, pp. 37-57.

nanotechnology starts to deliver its promises in these areas, questions relating to nano-patents will become paramount.

Some of the current issues and challenges encountered in nanotechnology intellectual property are briefly described below:

a. **Patent Applicability**: It is generally accepted that the properties of matter and other fundamental scientific discoveries are not patentable. An initial challenge for patent strategists is to determine how to obtain patent coverage that is based on the discovery of inherent properties of materials. Simply submitting a smaller version of a known structure would not be considered patentable without additional utility or novelty.
b. **Patenting Abstract ideas** - Nanotechnology is a new field and so most of its patents will be for basic inventions, not for fully developed final products, creating problems because patents on basic inventions are inclined to cover larger areas than final products but one is not allowed to patent purely abstract ideas with the exception of developing them in the future to more specific inventions. For emerging technologies like nanotechnology, its patents are early in the research process and perhaps not fully covered by the traditional understanding and meaning of developed inventions.[44]
c. **Overlapping ideas** – Since nanotechnology is a broad discipline encompassing several others, the granting of such patents could be problematic. Broad patents granted to inventors can lock up or impede crucial improvements needed to take a new field from interesting lab results to commercial viability.
d. **Balancing Innovation and Restrictive Intellectual Property**: Granting exclusive patent rights can be restrictive to future research and could stifle the potential of more researchers getting involved. It is essential that a proper balance be maintained between granting exclusive patent rights to inventors on one hand and allowing access to others to continue research on the other.
e. **Technology Transfer**: Considering the potential of nanotechnology and its ability to converge with other technologies, it is essential that the granting of patents does not stifle the potential of this technology to be transferred between researchers, universities and even countries. It is essential that this immensely useful technology be transferred to poorer countries to enable them to utilize and benefit from some of the ground breaking research and products.
f. **Infringement** – Nanotechnology patents may be problematical to enforce because it is hard to discover infringement.
g. **Intellectual Property Litigation**: Nanotechnology intellectual property litigation has already emerged around trade secret issues. Given the breadth of the field and opportunity for broad patent coverage, intellectual property litigation over patents is likely to emerge in the near future. Long lead times for the commercialization of some nanotechnologies will delay challenges to patents, creating business uncertainty and concerns over patents which may become invalidated years in the future. Considering the expense of litigation, innovators lacking the resources to litigate patent validity may be forced to license these patents rather than contest them.

Hence, in the long term, nanotechnology is likely to increase the relative importance of intellectual property for society. Some day, when nanotechnology assemblers can manufacture nearly any object on-site using inexpensive materials, intellectual property may become the only valuable property right. The blueprints for constructing such objects will also likely be of considerable value. Nanotechnology is an emerging technology with exciting prospects for intellectual property, in both the near term and for many years to come.

VI. Regulating Nanotechnology

[44] Georgios Zekos, 'Patenting abstract ideas in nanotechnology', *The Journal of World Intellectual Property* (2006), Vol. 9, no.1, p. 126.

“Regulatory appraisal and control of new technologies and development involves balancing the costs of being too restrictive on innovation with the hazards and costs of being too permissive, in situations of scientific uncertainty and ignorance. …….we have many examples where regulatory inaction led to costly consequences that were not — and sometimes could not have been — foreseen” [45]

As with any new and powerful technology, appropriate controls, in the form of regulations and legislation, must be tailored to fit the risk/benefit ratio. Sometimes these controls come about by trial and error. “In the case of nanotechnology, passively waiting for regulations to develop may allow unnecessary harm to society, either in the form of technology unregulated, or technology undeveloped”[46]. As a result, the need for standards for regulation and risk assessment becomes significant to the future growth of the industry. Effective regulation establishes a climate of regulatory certainty. Regulatory certainty exists when the rules to be applied are clear and well understood. Certainty requires clarity as to which authorities will be responsible for enforcement and regulation. Research and technology are essential for economic growth and improvements in the quality of life. Regulatory initiatives must be able to protect research and technology infrastructure and avoid placing restraints on the freedom of scientific enquiry; but after carefully evaluating risks and potential conflicts.

One way to positively control nanotechnology is to contemplate the likely directions new technologies will take and to prepare flexible legislation providing for appropriate regulatory schemes even before the products arrive in the marketplace – but this again would be speculative. Nanotechnology research and development, and related discussions about how to best regulate and utilize new technological capabilities will engage with larger societal debates about technology and social values. “Some of this debate will focus on the relevance of and various interpretations of “precautionary principles,” how to make decisions before solid scientific confirmation is available, who should bear the burden of showing that new technologies are safe or dangerous, and an appropriate balance between anticipatory planning and resilient learning responses.”[47] In the absence of consensus on underlying principles, specific arguments about nanotechnology issues are likely to be entangled with these more fundamental philosophical disputes.

“The development of new technology tends to outpace the development of methods to ensure a more egalitarian sharing of its benefits or even the analysis of its associated risks. This has been seen in the case of biotechnology”[48].

In order to be able to regulate nanotechnologies the following measures have to be considered and initiated:

1. **Funding for Risk & Ethics research**: Currently much of the research and funding is focused on the technology, its application and commercialization, thus neglecting social and ethical research. A percentage of the budget must be devoted for study of ethical, legal, and social implications. ‘In the Human Genome Project, James Watson

[45] Harremoës P, D Gee, M MacGarvin, A Stirling, J Keys, B Wynne, S G Vaz (2001), ‘*Late lessons from early warnings: the precautionary principle*’, European Environment Agency, Environmental issue report No 22.

[46] Frederick A. Fielder and Glen H. Reynolds, ‘Legal problems of Nanotechnology: An overview’, 3 *Southern California Interdisc. L. J.* (1993- 1994) p. 629.

[47] Bryan Bruns (2003), ‘*Participation in Nanotechnology*’ International association for public participation, Ottawa, Canada, p. 8. Available at: < http://www.sts.utexas.edu/nano/pp_nano.html Accessed on 19 June 2006.

[48] Meridian Institute (2005), ‘*Nanotechnology and the poor: Opportunities and Risks*” p. 17. Available at www.nanoandthepoor.org. Accessed on 19 August 2006.

recommended that 3–5% of the budget be devoted for study of ethical, legal, and social implications. This massive infusion of research funds energized the ethics community'[49].

2. **Risk management strategies**: Appropriate measures have to be initiated to access and manage risks involved in the development and propagation of nanotechnologies. This will ensure that the adaptation of existing regulation is strongly evidence based and confirmed by research data.
3. **Review of existing legislations**: A review of existing (national and international) legislations is essential in order to identify specific regulatory gaps, prioritize fields of action and suggest appropriate measures if needed.
4. **Code as a regulatory tool**: Code and software used to programme and develop nano-machines/ nanobots can become part of the regulatory mechanism.
5. **Cooperation**: In order to be able to regulate nanotechnology all the actors/ stakeholders involved will have to come together. Business houses and Governments will have to engage with academicians, NGO's and funding societies. Such engagement would mean discussion about the direction of development and the research to evaluate risks and deliver benefits.
6. **Public Dialogue**: Public involvement is also considered essential. The lack of dialogue between research institutes, granting bodies, and the public on the implications and directions of nanotechnology may have devastating consequences, including public fear and rejection of nanotechnologies.
7. **Best practices and code of conduct**: The development of best practices and a code of conduct particularly relating to the manufacturing and commercialization of nanotechnology can lead to enhanced safety and responsible development.
8. **Transnational initiatives:** In an interdependent world, the risks faced by any individual, company, region or country depends not only on their own choices but also on those of others. [50] Hence, transnational regulatory initiatives are essential to regulate nanotechnology whose application and adaptation is increasingly transnational in nature.

VII. Conclusion

The regulation of nanotechnology is likely to occur within a post-normal science era where uncertainty is high, values in dispute, stakes significant and public concern elevated. [51] Nanotechnology promises to be a profoundly disruptive technology that, especially in conjunction with other technologies like information technology and biotechnology, will usher in social and economic transformations. The rapid commercialization of nanotechnology, coupled with the potential risks from at least certain nano-materials as demonstrated in initial studies, lend urgency to the need for government and industry to direct more of their investments in nanotechnology development towards identifying the potential risks and addressing them. This can ensure that nanotechnology will deliver on its promise without delivering unintended adverse consequences.

At the Johannesburg summit, the main issues were poverty reduction, energy, water, health, and biodiversity.[52] Nanotechnology has the potential to make a positive impact on all of these if its

[49] Anisa Mnyusiwalla, Abdallah S Daar and Peter A Singer, 'Mind the gap: science and ethics in nanotechnology', *Nanotechnology* 14 (2003) pp. 9–13.

[50] IRGC (2006), '*Nanotechnology: Risk Governance*', International Risk Governance Council (IRGC), Geneva, p.62.

[51] Michael D. Mehta (2002), *Regulating Biotechnology and Nanotechnology in Canada: A Post-Normal Science Approach for Inclusion of the Fourth Helix*, available at: < http://www.nanoandsociety.com/ourlibrary/documents/mehta-nus-paper2002.pdf> accessed on 24 Feb 2007.

[52] Johannesburg Summit 2002 – the World Summit on Sustainable Development – brought together tens of thousands of participants, including heads of State and Government, national delegates and leaders from non-governmental organizations (NGOs), businesses and other major groups to focus the world's attention and direct action toward meeting difficult challenges, including improving people's lives and conserving our natural resources in a world that is growing in population, with ever-increasing demands

risks either do not materialize or are appropriately managed. A global view must consider the effects of nanotechnology on developing countries. Unevenness in the exploitation of nanotechnology can further widen the divide between developed and poor countries. “Nanotechnology is not a panacea, and will certainly not bring an end to all problems. Instead, it offers further challenges, both transitional ones of how to expand access to benefits and reduce risks, and more fundamental choices about how people want to live their lives, pursuing their interests and visions”[53].

A multi-stakeholder dialogue appreciating the potential benefits and addressing the risks at the same time is needed. Industry, governmental bodies, scientists and civil society have to negotiate passable solutions. Since the benefits and risks of new products are not limited on single countries, such an approach has to be global.

“Whether that future is one plagued by roving nanoswarms devouring the environment, or a utopia of endless abundance and freedom from disease, or merely a much better standard of living than we experience now depends on prudent planning and risk management as nanotechnology unfolds”[54]. Instead of shrinking from scientific and technological endeavour for fear of the uncertainty that accompanies it, we should embrace the challenge of creating the conditions for science and technology to thrive. But the simultaneous challenge is to generate new approaches to the governance of technology that can learn from past mistakes, cope more readily with complexity and uncertainty, and harness the drivers of technological change for the common good.[55]

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for food, water, shelter, sanitation, energy, health services and economic security. See, http://www.un.org/jsummit/index.html accessed on 15 March 2007.

53 Bryan Bruns, "*Applying Nanotechnology to the Challenges of Global Poverty*," 1st Conference on Advanced Nanotechnology: Research, Applications, and Policy, October, 2004. Available at http://www.foresight.org/Conferences/AdvNano2004/Abstracts/Bruns/ Accessed on 2 November 2006. p. 11.

54 Jason Wejnert (2004), ‘Regulatory Mechanisms for Molecular Nanotechnology’, 44 *Jurimetrics J*. p. 29.

55 Rebecca Willis and James Wilsdon (2003), *From Bio to Nano and Beyond: A progressive agenda for technology, risk and the environment,* Green Alliance. Available at: <http://www.green-alliance.org.uk/uploadedFiles/Publications/FromBioToNanoAndBeyond.pdf> accessed on 23 Feb 2007.