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REVIEW

Nanotechnology applications and intellectual property rights in agriculture

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Abstract Nanotechnology research uses specific properties of materials at the nanoscale to develop improved materials, devices, systems and therapeutics. There is a risk of overlapping patent claims and lack of distinction between nano-based and traditional patents due to the interdisciplinary nature of nanotechnology. There is an increasing trend of granted patents. The World Intellectual Property Organization and World Health Organization, regulatory and policy bodies, are working to make a comprehensive property right regulation for nanotechnology products. The USA, the leader of nanotechnology products, has made guidelines to make patent search easier for nano-based products. The European Patent Office has also created a new classification for nano-based inventions. Here we review the status of intellectual property rights protection of nanomaterial, environmental implications and application of nanotechnology in agriculture.

Keywords Environmental risk · Intellectual property rights · Nanotechnology · Patents · Regulations · World Intellectual Property Organization (WIPO)

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Introduction

Nanotechnology is an interdisciplinary science with manipulation of matter in near atomic scale to produce new structure, material and devices (CDC report). Nanotechnology research and development generally are directed towards understanding and creating improved materials, devices and systems (Raliya et al. 2013). Nanomaterials, in particular, are defined as materials that have a length scale between 1 and 100 nm. At this size, materials begin to exhibit unique properties that affect physical, chemical and biological behaviours (CDC 2016). These properties have found tremendous application in the field of medicine, agriculture, energy, materials and manufacturing. However, this advancement of translation of basic scientific research into the domain of commercialization has accelerated a complexity for intellectual property right protection. In recent years, there is a spur in nanotechnology-related patents (Fig. 1). Research activities in this field also have to deal with ethical and social issues, starting from health to environmental risk factors (Sweeney 2006). In this article, we have mentioned important applications of nanotechnology in agriculture sector and highlighted important issues concerning the regulation, risk of overlapping patents claim and environmental issues. This article is an abridged version of the chapter published by Chowdhury et al. (2016) in the series Sustainable Agriculture Reviews (http://www.springer.com/series/8380).

Nanotechnology applications

The nanotechnology application in agricultural offers various advantages as compared to conventional practices like applying fertilizers and pesticides to crops using

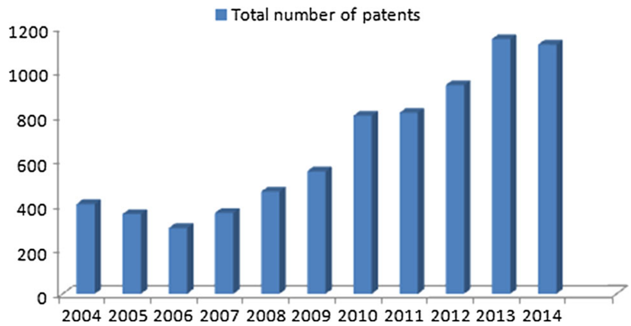

Fig. 1 Trend showing increase in the number of nanotechnology patents in the last 10 years as granted by United States Patent and Trademark Office and European Patent Office

nanocapsules and nanoemulsions as smart delivery system for the control of disease and pest in plants (Aouada and de Moura 2015). The nanoparticles as carriers increase the effectiveness of the active materials and reduce volatilization. Advantages of nanoparticles are the gradual and controlled release of agrochemicals which allow delivery of active ingredients for a desired period in the vicinity of the roots or the vegetative parts (Aouada and de Moura 2015). Other major application of nanotechnology in agriculture is the improvement of soil characteristics. The physical and chemical nature of soil largely has an impact on plant growth. Nanomaterial products produce zeolites and nanoclays which help in liquid agrochemicals or water retention in soil (Parisi et al. 2015). Clean potable water is one of the major global challenges particularly in the developing countries. Nanoscopic materials such as carbon nanotubes, nanofibres or sponges are used as nanofilters for water purification. To remove heavy metals like arsenic, magnetic nanofibres are used for nanofiltration (Bhati et al. 2015; Sekhon 2014). Nanotechnology can also play pivotal role in crop improvement by using nanoparticles as vectors for gene transfer including calcium phosphate, carbon, silica and gold. The genetically modified plants or microbes can also be used for the production of nanomaterials. The agricultural waste products can be processed to obtain nanomaterials, e.g. nanofibres from wheat and soy hulls bio-nanocomposite production (Parisi et al. 2015).

In food industry, nanoparticles and nanosensors ensure food safety, which has gained tremendous recognition at present (Echegoyen 2015; Ranjan et al. 2014; Dasgupta et al. 2015). The encapsulations of nutraceuticals, flavour enhancers within nanocapsules and nanoparticles that can selectively bind and remove chemicals from food are some of the recently used nanotechnological innovations (Özer et al. 2014). Fabrication of food-grade vitamin E nanoemulsion also showed considerable antioxidant and antimicrobial activity (Dasgupta et al. 2015). Development of improved tastes and textures through nanoscale processing of foodstuffs and maintaining hygiene during food processing through antibacterial nanocoatings on food preparations are also popular (Özer et al. 2014). Magnetic nanoparticles, nanowires, carbon nanomaterials and biological nanomaterials have been employed in the synthesis of biosensors (Sagadevan and Periasamy 2014). Biosensors have application in the removal of harmful contaminants from the soil and wastewater. Biosensors incorporated with nanomaterials can do real-time detection of pesticides, pathogens, toxic materials, odour-producing microbes in soil, air, water, etc. (Baruah and Dutta 2009).

International organization on nanotechnology management

World Intellectual Property Organization acts as a global forum for intellectual property services, policy, information and cooperation. The organization facilitates international patent protection under the Patent Cooperation Treaty system and complements intellectual property services at the national and/or regional level. An applicant filing a patent application under this treaty can seek protection for an invention in 148 countries throughout the world. The role of the treaty also stretches to help patent offices in granting patents and making the wealth of technical information accessible to the public (Havas 2014).

Food and Agriculture Organization (FAO) of the United Nations and World Health Organization proposed a tiered approach to prioritize the classes or types of material to be used for invention in nanotechnology for helping risk assessment strategies (FAO/WHO 2013). Another important body, Working Party on Manufactured Nanomaterials (WPN), established by the Organization for Economic Cooperation and Development under the Committee of Scientific and Technological Policy, works on international cooperation in health-related and environmental safety-related aspects of manufactured nanomaterials (Raimond 2008). The organization presently offers testing guidelines for global acceptance in hazard recognition and characterization of food chemicals, pesticides, veterinary drugs and other substances to which humans are exposed (FAO 1995).

In the European Union, nanoparticles are regulated under Registration, Evaluation, Authorisation and Restriction of Chemicals under which a registrant needs to upgrade his registration for a substance already registered in its macroform but introduced into the market in the nanoform. It must fulfil the conditions like changes in composition, quantities, uses and safety report to enable appropriate risk management (Bucheli 2014). In 2011, the European Food Safety Authority stated that the risk of an engineered nanomaterial in the food and feed category will be determined by its chemical composition, physicochemical properties, interactions with tissues and potential exposure levels (Rauscher 2014).

Agronanotechnology regulations in major countries

Recently, numerous agricultural applications have been discovered from nanotechnology products (Table 1). But, nanotechnology applications are at nascent stage in comparison with other industrial applications in commercial scale. Different regulations are evolved to assess the safety of the nanoproducts in agriculture due to the potential effect and commercialization. Safe manufacturing practices, product testing and assessing potential environmental risks hazard will play a crucial role to enable the acceptance of nanotechnology in the market (Watson et al. 2011). Different countries impose different regulations on the production and marketing of nano-based products.

The US agencies such as the United States Department of Agriculture, Environment Protection Agency, Food and Drug Administration, Consumer Product Safety Commission and the cabinet-level National Science and Technology Council confer regulations on various aspects of agronanotechnology. The Toxic Substances Control Act formed by the California Department of Toxic Substances Control has made it mandatory for the manufacturers to provide information on nanomaterials present in specific chemicals (Watson et al. 2011; Soliman 2012). Environmental Protection Agency, under the authority of Federal Insecticide, Fungicide and Rodenticide Act, registers pesticides and approves nanoscale versions of even conventional substances as newly registered. The Food and Drug Administration, under the authorization of the Federal Food, Drug and Cosmetic Act, approves food additives, food packaging, processed foods and dietary supplements (Watson et al. 2011).

European Union regulations on agronanotechnology comprise several horizontal and vertical legislations. The Food Law Regulation (European Commission) 178/2002 establishes principles and obligations comprising all the stages of food/feed production and distribution which help in assessing and managing the risks associated with the use of

Table 1 Various nanotechnological applications in agricultural sector

Field of application	Products description	References
Nanopesticide and nanofertilizer	1. Neem oil (*Azadirachta indica*) nanoemulsion as larvicidal agent 2. Macronutrient fertilizers coated with zinc oxide 3. Pesticides encapsulated in nanoparticles for controlled release 4. Ammonia from buckyballs used as fertilizer	Anjali et al. (2012), Milani et al. (2012), Sastry et al. (2009)
Soil improvement	Soil enhancer product, based on a nanoclay component, for water retention and release	http://www.geohumas.com/us/products.html
Water resource management	1. Filters coated with TiO_2 nanoparticles for the photocatalytic degradation of agrochemicals in contaminated waters 2. Carbon nanotube filters for toxin removal 3. Gold nanoparticles for pathogen detection 4. Nanoparticle for toxic metal detection and removal	Mc Murray et al. (2006), Bhati et al. (2015)
Crop improvement	1. Mesoporus silica nanoparticles transporting DNA to transform plant cells 2. Development of a purple-coloured rice variety ‘Khao Kam’ through the drilling of a nanosized hole in the cell wall and membrane of rice cell to insert a nitrogen atom 3. Transfection reagents 4.DNA loaded supported gold nanoparticles, process for the preparation and use thereof	Torney et al. (2007), Shrivastava and Dash (2009)
Food industry	1. Airtight plastic packaging with silicate nanoparticles 2. Nanoemulsion-based icecream 3. Frying oil extender (OilFresh) uses nanoproducts to keep frying oil fresh for a longer time 4. Polymer composites with nanoclay as improved materials for food packaging	Sastry et al. (2009), Momin and Joshi (2015)
Nanobiosensor	1. Pesticide detection with a liposome-based nanobiosensor 2. Contamination of packaged food 3. Pathogen detection 4. Nanosensors linked to a GPS tracking unit for real-time monitoring of soil conditions and crop growth	Vamvakaki and Chaniotakis (2007), Sastry et al. (2009)

nanomaterials in food. The Registration, Evaluation, Authorisation and Restriction of Chemicals is a horizontal legislation which encompasses both bulk and nanosized materials which need to be registered at the European Chemical Agency provided they are manufactured or imported in more than one ton per year and are not subjected to other exclusions. Regulation (European Commission) 258/97 is a vertical legislation on the novel foods and ingredients. This regulation makes the pre-market approval of nanoenabled foods mandatory and considers re-evaluation of any nanoscale additives for safety purpose. Directive 91/414/EEC is another vertical legislation regulating the evaluation, marketing and use of pesticides. This legislation is complemented with the Regulation (European Commission) 1107/2009 which follows strict criteria in the approval of substances to be used as pesticides (Watson et al. 2011).

In Japan, no specific nanotechnology product legislation is available till date, but research activities are ongoing in the field. Indeed according to the report of the Organization for Economic Co-operation and Development (2007), Japan is among the three key nanotechnology patent powerhouses along with United States Patent and Trademark Office (USPTO), and the European Patent Office (EPO). Japan releases a basic survey report on safety assessment on the use of nanotechnology in food sector (FSCJ 2010). The Republic of South Korea has established a "National Nano-safety strategic plan" (2012/2016). The Korean agency also published "Guidance on safety management of nano-based products" (Montovani et al. 2012; Park 2012). In India, during 2001, the government has launched a programme called Nano Science and Technology Initiative (NSTI) followed by the programme Nano-mission in 2007 under which major research funding on nanotechnology is being done and issued guidelines on safety handling of nanomaterials in the research laboratory (DST, Report 2016). In China, food safety is regulated by food safety law, which does not include any NM specification. The National Centre for Nanoscience and Technology (NCNST) and the Commission on Nanotechnology Standardization are responsible for developing national standards in the nanotechnology area. Application of nanomaterials in the food sector has so far been rejected by Chinese regulatory authorities (FAO/WHO 2013).

Environmental implications and management

Nanotechnology has transformed the scenario of global industry, but certain risks are associated with the environment and human health. Its regulation is still evolving, and the main problem for the decision- and policy makers is the vagueness associated with the risks of nanotechnology which limits the development of international synchronization.

The nanomaterials can be formed either by natural or synthetic processes. The physicochemical nature of nanomaterials can have huge impact on the fate of environment. Insufficient knowledge of nanomaterial toxicity and risks may hinder the pace of industrial application of nano-enabled technologies. The potential activities of these materials must be studied comprehensively. In the absence of definitive data, nanomaterial research and regulations could be supported by an efficient characterization of factors leading to toxicity and risks (Linkov et al. 2009a). Studies clustered the nanomaterials into ordered risk categories using multicriteria decision analysis by taking into account the variables associated with the toxicity and risk of nanoparticles. Their research finding does not quantify the environmental risks, but attempts were made for recommendations on precise measurements of nanoparticles (Linkov et al. 2009b).

Nanotechnology offers significant benefits to mankind but have detrimental health effects too. Nanoparticles having small size can disperse into anatomical barriers to reach the liver, lungs, kidneys, etc., and damage the cells which can cause lesions, granulomas, cancers, Parkinson's disease, Alzheimer's disease, etc. (Chaudhry et al. 2008; Miller and Senjen 2008; Chau et al. 2007; Oberdorster et al. 2005). As a consequence, there is a potential threat to the millions of people working in vast expanses of agricultural lands by using of nanofertilizers and pesticides which can enter into the food chain (Rico et al. 2011). Detailed understanding of the biological mechanism of nanoparticles is required before field application to formulate regulatory rules and help risk management (Sastry et al. 2010; Sastry and Rao 2013).

Development must be made to have skilled manpower to carry out new research experiments to incorporate and implement the theory and techniques of nanotechnology. This will also led to standard operating protocol for the nanotechnology industry to adhere to the engineering controls for effective risk management. Many countries have recommended various precautionary measures to manage the risk associated with nanoparticles. The Health and Environment Alliance, Belgium, recommends a list of measures to manage the risks associated with nanomaterials (HEA 2011). There is a need of a comprehensive policy by uniform international body to alleviate the risk involved with nanotechnology applications.

Limitations of nanotechnology for the protection of intellectual property rights

Nanotechnology-related inventions are upsurging across all research and development and industry sectors. Millions of patents on nanotechnology can be retrieved in the worldwide database. To search prior art on nanotechnology, the patent offices worldwide have classified nanotechnology under the International Patent Classification (WPN 2015). The United States Patent and Trademark Office received around 618330 patent applications in the fiscal year 2014, with a sum total of 24,090 patents related to nanotechnology granted in 2014, which is a growth of more than 12.68% in the number of nanotechnology patents in comparison with 2013 (USPTO 2014). To manage increasing number of patents and scrutinize a nanoinvention poses serious concerns among the patent grantees to review the new patent in terms of novelty and utility over earlier inventions. An additional difficulty in such searches is that all nanotechnology-related inventions may not necessarily contain the word "nano" in its claim. In order to overcome such problems, the United States Patent and Trademark Office in October 2004 established an index to the United States Patent Classification System for Nanotechnology called "Class 977", specifically for nanotechnology related products (Shand and Wetter 2007). This would easily distinguish between different patent categories (Fig. 2) and further serve as a cross-reference to help examiners and the public to search prior art including issued US patents and published patent applications. Similarly, European Union has also created a new classification for the nano-based inventions, called Y01N, for ease in retrieving nanotechnology-related prior art. While nanotechnology opens opportunities for new inventions and discoveries, new challenges are confronted at the patent office as the grantees may lack expertise or adequate domain knowledge to assess nanotechnology patent applications leading to disregard the previous inventions (Paradise 2012). The patent owners can exercise their right by excluding others to undergo research work on its invention, which can seriously restrict future research on nanoinventions. Premature disclosure of trade secrets by pressure from the academic circles to publish or report in government funding projects can reduce the ability to secure patents. Shortcuts in drafting a provisional application also increase the possibility of falling short of minimum disclosure requirements causing limitations in scope of claims that can be supported by the final specification (Tullis 2012). The recent euphoria for patenting and the inability of patent offices to handle a large number of patent applications have resulted in the rejection of valid claims (Miller et al. 2004).

Patent protection is effective only within the issuing country. But increased administrative effort is required for securing international patents. Strong patent protection may spur research and invention but may lead to monopoly. Though a patent is granted to a nanotechnological invention, it becomes invalid due to the operation of a previously granted patent for a similar type of invention leading to expensive litigation. Innovators lacking the resources to litigate patent validity may be forced to license these patents rather than contest them (Barpujari 2010). Delay in commercialization of nanotechnology products will give rise to problems such as unintentional infringement of patents, creating business uncertainty and concerns over patents with some nanotechnology inventions ending up in courts rather than in the patent office (Clarkson and DeKorte 2006). The nanotechnology IPR landscape is still somewhat chaotic, and limitations can be observed when most of the patents do not result in active commercialization.

The future of intellectual property rights in nanotechnology

Nanotechnology may prove to be the next revolution "in standing" to flourish the agriculture sector. Although patents were granted to nanotechnological applications and

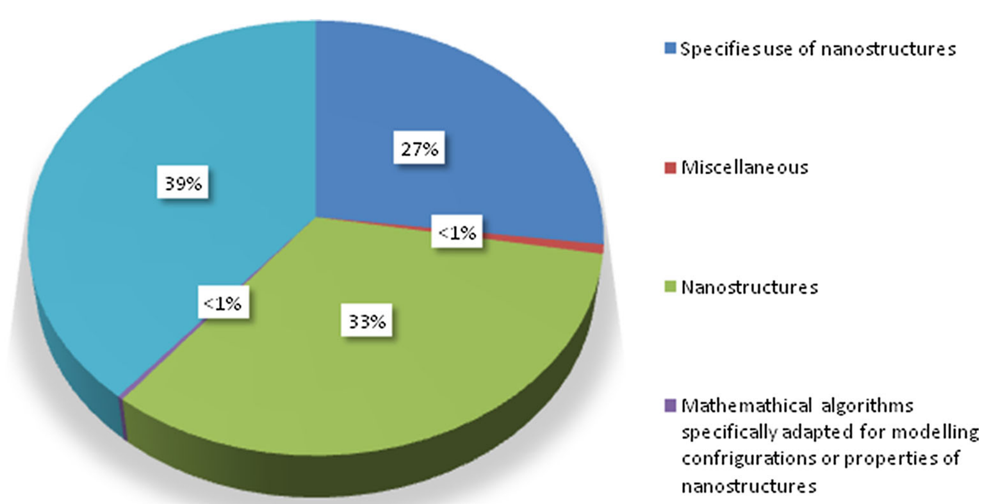

Fig. 2 Diagrammatic representation of the percentage of nanotechnology patents obtained by the various sub-classes of Class 977 as of July 2010

processes, more cohesive and clearer policy between different countries is necessary. Nanotechnology is a multidisciplinary field with application in diverse arena. Therefore, patent granters and examiners need to be trained both in international, national and regional level about its multidimensional aspect. WIPO can play a pivotal role by networking collaboration between different agencies like WHO and World Trade Organization (WTO) where each has distinct, but complementary mandates to work on issues relating to nanotechnology patent issues, public health aspect and trade policy, respectively. Most of the developed countries have included the "nanotechnology" term in their existing patent classification system and assigned a separate class. But developing countries like India are yet to assign a separate class and lacking peer policies on nanotechnology. This can be revamped in line of Drug and Cosmetic Amendment Bill 2015, where the words "Drug, Medical technology, Clinical trials", etc., are included and regulations are clearly mentioned.

Another way of promoting nanotechnology research and smoothening patent grants is "stronger public–private partnership". One way to achieve this is cohesive licensing model where incentive to research and development driven companies may be given to promote nanotechnology products (Chowdhury et al. 2014). It will help to control price in future which is one of the major hurdles in other fields like drug industry. Continuous discussions are being made in different platforms, and policies are being amended, but concentrating solely on intellectual property rights will not help for success stories. Different international and national regulatory agencies on social, health and economics should come under same platform to help on policies formulation for promoting innovation on nanotechnology. Countries should increase their gross domestic product investment in nanotechnology research to promote innovation, especially in agriculture sector, where nanotechnology holds a potential for "Agriculture Revolution".

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