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Patented Nanopharmaceuticals: A Hope for Patent Expired Formulations

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Abstract

A lot of medicines are on their way to patent expiration but emergence of nanotechnology in medicines has revolutionized the pharmaceutical industry. Actually, Nano medicine is an exciting multidisciplinary field which involves understanding & application of drugs at the Nano-level. Unique & novel phenomenon is observed when particles are reduced to Nano dimensions. Development of novel nanopharmaceuticals & application of innovative techniques in drug industry needs to be protected. Patents are exclusive rights given to an individual to protect novel creations as a result of one's intellect. A patentee is awarded certain exclusive rights by which conversion of intellectual creation to commercialization can be protected. As the companies gear up to go smaller in size to achieve better & much more effective Nano medicines, the PTO (Patents & Trademarks Office) strengthens its regulatory charter to tackle any contravention.

Keywords: Nanopharmaceutical; Patent expiration; Intellectual Property; Regulatory status

Nanotechnology offers great advancement to medicine. It is one of the fastest growing industries in the world. As per the reports of National Science Foundation, by 2015 it is estimated to be roughly around 1 trillion dollars industry [1]. A popular science magazine, 'Scientific American' in 2006, defined nanotechnology as the understanding and control of matter at dimensions of roughly 1-100 nm in size, where unique phenomenon enables novel applications. Several drugs have been already patented and further approved by the USPTO & USFDA respectively. Anticancer nanoformulations such as Doxorubicin (Doxil™), Daunorubicin (DaunoXome™) & Paclitaxel (Ambraxne™) have been developed and patented in the past & are approved by the FDA for commercialization [1]. Usually the nanoformulations are not bioequivalent to their parent version, therefore cannot apply for FDA approval via Abbreviated New Drug Application (ANDA) under section 505 (b) (j) of the Federal Food, Drug & Cosmetic Act. For such drugs, New Drug Application (NDA) under the section 505 (b) (1) is required to be filed at the FDA. But, if nanoformulations are found to be bioequivalent to their parent versions ANDA can be filed & FDA approves it to be a New Chemical Entity (NCE) [2].

A patent is generally a legal document granted to an individual by the government. The aim of patent is to protect the exclusive rights of the patentee in regard to his intellectual creation. Patent law, arguably one of the most obscure legal disciplines, is now at the forefront of drug development and nanopharmaceuticals.

In recent years, various methods have been employed successfully to tackle drugs with low aqueous solubility & bioavailability. Nanotechnology has encompassed all the previous solubility enhancement techniques & is more efficient in delivering drug to target site [3]. Several nanopharmaceuticals currently in the market have been approved by the FDA according to pre-existing laws.

A lot of medicines are on their way to patent expiration but emergence of nanotechnology in medicines has revolutionized the pharmaceutical industry. Table 1 enlists some hit commercial products whose patent is going to expire this year. Through nanotechnology, these molecules can be formulated as novel system for patenting them again.

With the advancement in the nanopharmaceutical industry, the number of patent filings has dramatically increased. Pharmaceutical companies have developed new strategies & techniques to re-patent drugs which are on the way to expiration by modifying them via nanotechnology. There is no such classified system in the Patent Office for nanomedicines. Due to broadly quoted definition of nanotechnology by the U.S National Nanotechnology Initiative, the PTO is unable to distinguish nanomedicines to structure special guidelines by which nanopharmaceutical products could be effective regulated [4]. Certain guidelines have been created which ensures that merely decreasing the size of the particles of a single active ingredient, or changing weight & size ratio in a known combination or scaling up of already known technique does not entitle it to be novel. But, these strategies are sufficiently not enough to manage the whole nanopharmaceutical industry. Therefore, reforms are urgently needed at the PTO to strengthen its framework & structure distinctive guidelines for nanomedicines.

Brand Name	Generic Name
Asacol®	Mesalamine delayed-release tablet
Avodart®	Dutasteride
Advicor®	Lovastatin/niacin
Viracept®	Nelfinavir
Namenda®	Memantine
Nexium®	Esomeprazole
Celebrex®	Celecoxib
Actonel®	Risedronate
Micardis®,	Telmisartan,
Micardis® HCT	Telmisartan HCl
Temodar®	Temozolomide
Maxalt®	Rizatriptan
Exelon®	Rivastigmine
Avelox®	Moxifloxacin
Copaxone®	Glatiramer injection

Table 1: List of some hit molecules whose patent is expiring this year (2014).

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A number of oral, parenteral & dermal nanoformulations have been patented and approved by the FDA for commercialization. Doxil®, Abraxane®, DaunoXome® are some potent nanotech derived formulations approved by FDA [5,6].

For a product to be patented it must be novel, an inventive step must be involved & it must be industrially applicable. So, to patent a Nano drug, it must involve some inventive & novel step in miniaturization.

The criteria laid down by the USPTO will surely affect the Nano medicine industry, but innovative technological advances may perhaps open new gateways to the approaching era of nanomedicines.

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