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Patent Profiling for Nano Enabled Drug Delivery

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Abstract

Nano Enabled Drug Delivery (NEDD) is widely researched and developed to improve the administration and efficacy of pharmaceutical compounds and molecules. To understand the research situation of NEDD from macro perspectives, we used patent data to analyze from three aspects and got some interesting results [1]: NEDD was developing steadily, but “safety problems” were becoming big challenges in recent years [2]. NEDD was a highly interdisciplinary emerging field, whose more attractive subsystems were “vector” and “cargo” [3]. One superpower, US, and several strong countries formed the global research pattern. Such “tech mining” offers a systematic perspective on the emerging science or technology under study that is not readily achievable within the individual knowledge of particular researchers.

Keywords: Nano Enabled Drug Delivery (NEDD); Patents; International Patent Classifications (IPCs); Tech mining

Introduction

Nano Enabled Drug Delivery (NEDD) systems are rapidly emerging as a key sub-area of nanotechnology’s application. Drug Delivery Systems (DDS) can improve the administration and efficacy of pharmaceutical compounds including antibodies, peptides, vaccines, drugs and enzymes [1]. As one subset of drug delivery innovation, NEDD, in which the small molecule delivery systems are at the sub-micron scale, is promising to both (a) enable targeted delivery to organs and tissues, individual cells and organelles and (b) release the drug at a controlled rate [2]. Recently, NEDD is getting more and more attention and being applied widely by combining with more multiple medical materials, such as herbal medicines [3] and RNAi [4]. Understanding the status and developmental prospects of this area around the world is important to determine research priorities, and to evaluate and direct progress. Global patent databases provide a reservoir of information that can be tapped to provide intelligence [5]. Therefore, we do patents profiling for NEDD here for such needs.

Data

The data we used in this study was driven from a search for NEDD-related abstract records in the Derwent Innovation Index (DII) database that covers most high-quality patents from the world’s leading patent authorities. Our previous research has focused on the search strategy for NEDD by analyzing its topical structure and sub-systems [2,6]. Here we used this search strategy and developed a dataset from 1999 to 2016 in November 11, 2016, getting 13,346 records. We did further cleaning by consulting part of Jing Ma’s, et al. method to clean our data [6]. Some irrelevant words and phrases, including soybean, insect resistance, transgenic plant, herbicide resistance/herbicide, plant, and seed, were adopted as filters to remove records on plant materials. Then, we got 12,850 records. The process for collecting and indexing patents from multiple patent authorities is time consuming, so we anticipated that the data for 2014, 2015, and 2016 would be incomplete, which should be noted here. And, we used basic patent data (the first time an invention is collected in the DII if the invention has been applied as a patent in different countries) in this research.

Results

Profiling of database search results can offer global-level insights to help identify research situation at the macro-level, key players, and a variety of promising “green shoots” of research. We used the number of basic patent to show the research activity trends; we employed International Patent Classifications (IPCs) to trace technology development as IPCs could reflect the distribution of research subsystems; we identified top countries in patents application as the key players in NEDD.

Research activity trend analysis

Figure 1 showed the patent research activity trend of NEDD. According to the trend of this curve, we divided the whole time into 2 stages, 1999~2002 and 2003~2013. It is noted that we didn’t consider the decline of recent three years because of the incompleteness of data.

The feature of these two stages were as follows:

Stage 1 (1999~2002): There were only a few of records before

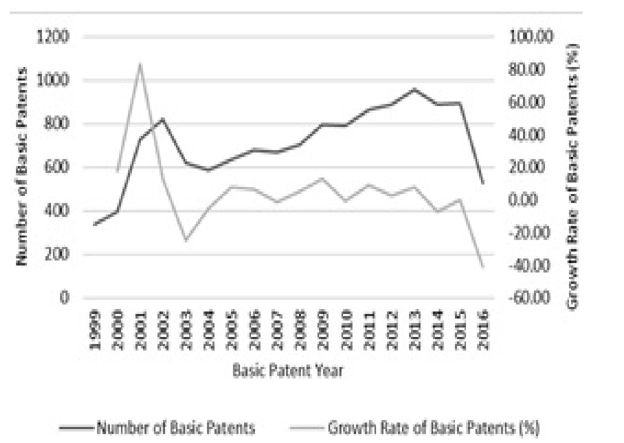

Figure 1: The patent research trend of NEDD.

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1999 but a rapid growth from 1999 to 2002. The emerging of NEDD brought multiple chances, which made the number of patents boom. Many corporations and research institutions perceived the chances and invested a lot of resource into R&D, which facilitated the production of innovation, as well as patents. During this stage, Human Genome Sciences Inc., Incyte Corporation and Millennium Pharmaceuticals, Inc. kept at the first level of R&D and applied the most patents.

Stage 2 (2003~2013): After 2003, number of basic patents kept growing without fierce fluctuation because of the steady development of NEDD. When basic research on NEDD was maturing, more investors wanted to promote its commercialization and governments would push the development of such an important technology [7]. For example, The US Department of Health and Human Services increased the investment on research of NEDD, US announced the plan of Cancer Nanotechnology and founded the Association of Cancer Nanotechnology in 2004. Another possibility of the low growth rate of basic patent in this stage was "potential safety problems of nanomaterials". Drezek, et al. argued that nanomaterials should be considered the details of individual materials, applications and environments to avoid generalizations that might stifle the entire field [8]. Keck, et al. thought many developers of nano-biomaterials didn't know much about medicine so that it was hard for them to understand fully about the rule of extraneous materials in organism [9].

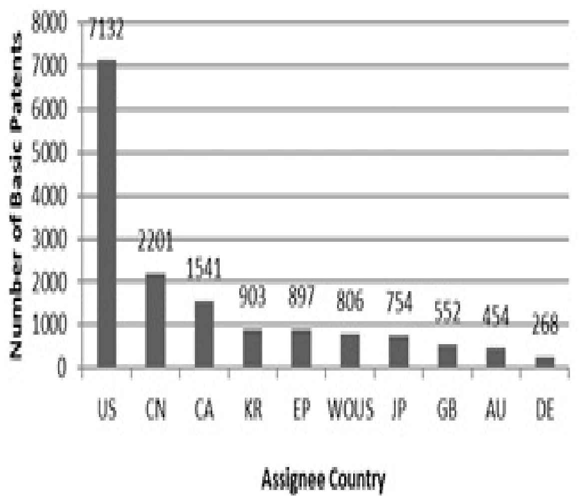

Figure 2: Number of basic patent for different assignee countries.

However, the proposal of new theories and the development of new materials in recent years are inspiring the R&D of NEDD, which is hopeful to overcome obstacles to be used for clinic.

Research scope

NEDD has drawn much attention from research and industry areas as a highly interdisciplinary emerging field. It requires knowledge of biomedicine, nanotechnology, gene therapy, and many related fields. There are six NEDD subsystems: cargo, vector, route, controlled release, targeting, and imaging [2].

Totally, 329 different 4-digit IPCs were involved, which could reflect the width of research scope. We listed the top IPCs with more than 2000 basic patents and corresponding subsystems in Table 1. A61K was the biggest subordinate research area of NEDD and a quarter of the patents relating to NEDD belonged to this area. These IPCs corresponding applications were still likely to be the most important sub-fields in the coming years according to the technological continuity [10].

By combing each 4-digit IPCs with corresponding subsystems, we could find that the hot subsystem of NEDD in research was "vector", followed by "cargo". More and more medical materials were adopted as vectors or cargos to improve the performance in route, controlled release, targeting, and imaging, that was why the vector and cargo were the most high-profile.

One superpower and several strong countries

Patent represents innovation activities and technical advancement [11]. A big amount of patents in a country means that this country has a good achievement in one technological field, which can be thought as technical advancement to some extent. Therefore, we can use the whole patent number of a country to represent this country's R&D ability roughly and to picture the research-leading countries. Figure 2 showed the basic patent number of different assignee countries.

US held the most patents, which meant US was the strongest country in NEDD R&D, followed by China, Canada, Korea and Europe. The "WOUS" meant the patent assignee applied to Patent Cooperation Treaty (PCT) for IP rights word wide. There were two reasons of US being the superpower. One was that US government had

4-digit IPCs	IPC explanations	Subsystem	Number of basic patents
A61K	preparations for medical, dental, or toilet purposes	vector	41894
A61P	specific therapeutic activity of chemical compounds or medicinal preparations	controlled release; targeting	31091
C12N	microorganisms or enzymes; compositions thereof; propagating, preserving, or maintaining microorganisms; mutation or genetic engineering; culture media	cargo; vector	27746
C07K	peptides	vector	11922
C07D	heterocyclic compounds	vector	6884
G01N	investigating or analysing materials by determining their chemical or physical properties	vector; controlled release; targeting,	6786
C12Q	measuring or testing processes involving enzymes or microorganisms; compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes	cargo; vector; controlled release; targeting	5131
C07H	sugars; derivatives thereof; nucleosides; nucleotides; nucleic acids	vector	4727
C12P	fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optical isomers from a racemic mixture	cargo; vector	3473

Table 1: Top 4-Digit IPCs of NEDD.

many investments and policies on NEDD which pushed the research process. And another was that US was the biggest medical market around the world so that many assignees applied patents in US to ask for Intellectual Right protecting during market expansion [5]. This phenomenon enlightened researchers and investors that US kept the leading level of both R&D and marketing.

Conclusion

According to this study, we could draw three conclusions. NEDD was developing smoothly. But the number of basic patents implied this tendency and the lower growth rate might have relationship with "potential safety problems of nanomaterials", which was hopeful to be resolved with the proposal of new theories and the development of new materials in recent years [1]. So NEDD was a promising field and more attention was needed to its safety problems. As a highly interdisciplinary emerging field, there were 329 different 4-digit IPCs and six subsystems being involved [2]. While the most attractive subsystems were "vector" and "cargo", researchers should also pay attention to other four subsystems, because not a single subsystem could be omitted in the effective utilization of NEDD. The R&D of NEDD around the world was unbalanced with US's superpower and other strong countries [3]. So researchers and investors should focus far more on US when beginning their study or making investing decisions.

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